

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

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

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436 (3) and upon a final determination by the probable cause panel
437 of the appropriate board that any physician associated with that
438 controlled-substance medical clinic knew or should have known of
439 any violations of the factors described in subsection (3).

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

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

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

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

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

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

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

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

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

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

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

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494 section, ~~or~~

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

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

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

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

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523 ~~patient's record the reason for prescribing or dispensing that~~
524 ~~quantity.~~

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

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

543 (3) INSPECTION.—

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

551 (b) During an onsite inspection, the department shall make

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552 a reasonable attempt to discuss each violation with the owner or
553 designated physician of the controlled-substance medical ~~pain-~~
554 ~~management~~ clinic before issuing a formal written notification.

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

559 (4) RULEMAKING.—

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

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

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

579 (c) ~~(d)~~ The Board of Medicine shall adopt rules setting
580 forth standards of practice for physicians practicing in

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

- 585 1. Facility operations;
- 586 2. Physical operations;
- 587 3. Infection control requirements;
- 588 4. Health and safety requirements;
- 589 5. Quality assurance requirements;
- 590 6. Patient records;
- 591 ~~7. Training requirements for all facility health care~~
 592 ~~practitioners who are not regulated by another board;~~
- 593 7.8. Inspections; and
- 594 8.9. Data collection and reporting requirements.

595

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

604 (5) PENALTIES; ENFORCEMENT.—

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

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610 Abuse Prevention and Control Act; chapter 893, the Florida
611 Comprehensive Drug Abuse Prevention and Control Act; or the
612 rules of the department. In determining whether a penalty is to
613 be imposed, and in fixing the amount of the fine, the department
614 shall consider the following factors:

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

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

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

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

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

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

638 (d) An owner or designated physician of a controlled-

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

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

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

651 458.327 Penalty for violations.—

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

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

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

661 (2) Each of the following acts constitutes a misdemeanor of
662 the first degree, punishable as provided in s. 775.082 or s.
663 775.083:

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

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668 Health pursuant to s. 458.3265(1).

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

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

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

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

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

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

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

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

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

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697 ~~of this chapter;~~

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

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

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

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

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

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

721 459.0137 Controlled-substance medical pain-management
 722 clinics.—

723 (1) REGISTRATION.—

724 (a) A All privately owned controlled-substance medical
 725 clinic, facility, or office pain-management clinics, facilities,

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

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

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755 (c) As a part of registration, a clinic must designate an
756 osteopathic, dispensing physician who is responsible for
757 complying with all requirements related to registration and
758 operation of the clinic in compliance with this section. Within
759 10 days after termination of a designated osteopathic physician,
760 the clinic must notify the department of the identity of another
761 designated physician for that clinic. The designated physician
762 shall have a full, active, and unencumbered license under
763 chapter 458 or this chapter and shall practice at the clinic
764 location for which the physician has assumed responsibility.
765 Failing to have a licensed designated osteopathic physician
766 practicing at the location of the registered clinic may be the
767 basis for a summary suspension of the clinic registration
768 certificate as described in s. 456.073(8) for a license or s.
769 120.60(6).

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

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

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

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

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

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

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

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813 (h)1. If the registration of a controlled-substance medical
814 ~~pain-management~~ clinic is revoked or suspended, the designated
815 physician of the controlled-substance medical ~~pain-management~~
816 clinic, the owner or lessor of the controlled-substance medical
817 ~~pain-management~~ clinic property, the manager, and the proprietor
818 shall cease to operate the facility as a controlled-substance
819 medical ~~pain-management~~ clinic as of the effective date of the
820 suspension or revocation.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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900 ~~reason for prescribing or dispensing that quantity.~~

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

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

919 (3) INSPECTION.—

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

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

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

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

935 (4) RULEMAKING.—

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

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

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

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

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958 ~~management~~ clinics that primarily engage in the treatment of
 959 pain by prescribing or dispensing controlled substance
 960 medications. Such rules shall address, but need not be limited
 961 to:

- 962 1. Facility operations;
- 963 2. Physical operations;
- 964 3. Infection control requirements;
- 965 4. Health and safety requirements;
- 966 5. Quality assurance requirements;
- 967 6. Patient records;
- 968 ~~7. Training requirements for all facility health care~~
 969 ~~practitioners who are not regulated by another board;~~
- 970 7.8. Inspections; and
- 971 8.9. Data collection and reporting requirements.

972

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

981 (5) PENALTIES; ENFORCEMENT.—

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

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987 Abuse Prevention and Control Act; chapter 893, the Florida
988 Comprehensive Drug Abuse Prevention and Control Act; or the
989 rules of the department. In determining whether a penalty is to
990 be imposed, and in fixing the amount of the fine, the department
991 shall consider the following factors:

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

999 2. What actions, if any, the owner or designated
1000 osteopathic physician took to correct the violations.

1001 3. Whether there were any previous violations at the
1002 controlled-substance medical ~~pain-management~~ clinic.

1003 4. The financial benefits that the controlled-substance
1004 medical ~~pain-management~~ clinic derived from committing or
1005 continuing to commit the violation.

1006 (b) Each day a violation continues after the date fixed for
1007 termination of the violation as ordered by the department
1008 constitutes an additional, separate, and distinct violation.

1009 (c) The department may impose a fine and, in the case of an
1010 owner-operated controlled-substance medical ~~pain-management~~
1011 clinic, revoke or deny a controlled-substance medical ~~pain-~~
1012 ~~management~~ clinic's registration, if the clinic's designated
1013 osteopathic physician knowingly and intentionally misrepresents
1014 actions taken to correct a violation.

1015 (d) An owner or designated osteopathic physician of a

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1016 controlled-substance medical ~~pain-management~~ clinic who
1017 concurrently operates an unregistered controlled-substance
1018 medical ~~pain-management~~ clinic is subject to an administrative
1019 fine of \$5,000 per day.

1020 (e) If the owner of a controlled-substance medical ~~pain-~~
1021 ~~management~~ clinic that requires registration fails to apply to
1022 register the clinic upon a change of ownership and operates the
1023 clinic under the new ownership, the owner is subject to a fine
1024 of \$5,000.

1025 Section 8. Paragraphs (qq) and (rr) of subsection (1) of
1026 section 459.015, Florida Statutes, are amended to read:

1027 459.015 Grounds for disciplinary action; action by the
1028 board and department.—

1029 (1) The following acts constitute grounds for denial of a
1030 license or disciplinary action, as specified in s. 456.072(2):

1031 (qq) Applicable to a licensee who serves as the designated
1032 physician of a controlled-substance medical ~~pain-management~~
1033 clinic as defined in s. 458.3265 or s. 459.0137:

1034 1. Registering a controlled-substance medical ~~pain-~~
1035 ~~management~~ clinic through misrepresentation or fraud;

1036 2. Procuring, or attempting to procure, the registration of
1037 a pain-management clinic for any other person by making or
1038 causing to be made, any false representation;

1039 3. Failing to comply with any requirement of chapter 499,
1040 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
1041 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
1042 the Drug Abuse Prevention and Control Act; or chapter 893, the
1043 Florida Comprehensive Drug Abuse Prevention and Control Act;

1044 4. Being convicted or found guilty of, regardless of

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1045 adjudication to, a felony or any other crime involving ~~moral~~
1046 ~~turpitude~~, fraud, dishonesty, or deceit in any jurisdiction of
1047 the courts of this state, of any other state, or of the United
1048 States;

1049 ~~5. Being convicted of, or disciplined by a regulatory~~
1050 ~~agency of the Federal Government or a regulatory agency of~~
1051 ~~another state for, any offense that would constitute a violation~~
1052 ~~of this chapter;~~

1053 ~~5.6.~~ Being convicted of, or entering a plea of guilty or
1054 nolo contendere to, regardless of adjudication, a crime in any
1055 jurisdiction of the courts of this state, of any other state, or
1056 of the United States which relates to the practice of, or the
1057 ability to practice, a licensed health care profession;

1058 ~~6.7.~~ Being convicted of, or entering a plea of guilty or
1059 nolo contendere to, regardless of adjudication, a crime in any
1060 jurisdiction of the courts of this state, of any other state, or
1061 of the United States which relates to health care fraud;

1062 ~~7.8.~~ Dispensing any medicinal drug based upon a
1063 communication that purports to be a prescription as defined in
1064 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
1065 or has reason to believe that the purported prescription is not
1066 based upon a valid practitioner-patient relationship; or

1067 ~~8.9.~~ Failing to timely notify the board of the date of his
1068 or her termination from a controlled-substance medical pain-
1069 ~~management~~ clinic as required by s. 459.0137(2).

1070 (rr) Failing to timely notify the department of the theft
1071 of prescription blanks from a controlled-substance medical pain-
1072 ~~management~~ clinic or a breach of other methods for prescribing
1073 within 24 hours as required by s. 459.0137(2).

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1074 Section 9. Subsection (1) of section 465.0276, Florida
1075 Statutes, is amended to read:

1076 465.0276 Dispensing practitioner.—

1077 ~~(1)(a)~~ A person may not dispense medicinal drugs unless
1078 licensed as a pharmacist or otherwise authorized under this
1079 chapter to do so, except that a practitioner authorized by law
1080 to prescribe drugs may dispense such drugs to her or his
1081 patients in the regular course of her or his practice in
1082 compliance with this section.

1083 ~~(b) A practitioner registered under this section may not~~
1084 ~~dispense more than a 72-hour supply of a controlled substance~~
1085 ~~listed in Schedule II, Schedule III, Schedule IV, or Schedule V~~
1086 ~~of s. 893.03 for any patient who pays for the medication by~~
1087 ~~cash, check, or credit card in a clinic registered under s.~~
1088 ~~458.3265 or s. 459.0137. A practitioner who violates this~~
1089 ~~paragraph commits a felony of the third degree, punishable as~~
1090 ~~provided in s. 775.082, s. 775.083, or s. 775.084. This~~
1091 ~~paragraph does not apply to:~~

1092 1. ~~A practitioner who dispenses medication to a workers'~~
1093 ~~compensation patient pursuant to chapter 440.~~

1094 2. ~~A practitioner who dispenses medication to an insured~~
1095 ~~patient who pays by cash, check, or credit card to cover any~~
1096 ~~applicable copayment or deductible.~~

1097 3. ~~The dispensing of complimentary packages of medicinal~~
1098 ~~drugs to the practitioner's own patients in the regular course~~
1099 ~~of her or his practice without the payment of a fee or~~
1100 ~~remuneration of any kind, whether direct or indirect, as~~
1101 ~~provided in subsection (5).~~

1102 Section 10. Section 893.055, Florida Statutes, is amended

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1103 to read:

1104 893.055 Prescription drug monitoring program.—

1105 (1) As used in this section, the term:

1106 (a) "Patient advisory report" or "advisory report" means
1107 information provided by the department in writing, via
1108 electronic delivery, or as determined by the department, to a
1109 controlled-substance medical clinic and its employed physicians,
1110 an advanced registered nurse practitioner, a physician
1111 assistant, a prescriber, dispenser, pharmacy, or a patient
1112 concerning the dispensing of controlled substances. A
1113 controlled-substance medical clinic and its employed physicians,
1114 an advanced registered nurse practitioner, a physician
1115 assistant, or a pharmacy shall review each patient advisory
1116 report before any controlled substance is dispensed to a
1117 patient. All advisory reports are for informational purposes
1118 ~~only and impose no obligations of any nature or any legal duty~~
1119 ~~on a prescriber, dispenser, pharmacy, or patient.~~ The patient
1120 advisory report shall be provided in accordance with s.
1121 893.13(7)(a)8. The advisory reports issued by the department are
1122 not subject to discovery or introduction into evidence in any
1123 civil or administrative action against a prescriber, dispenser,
1124 pharmacy, or patient arising out of matters that are the subject
1125 of the report; and a person who participates in preparing,
1126 reviewing, issuing, or any other activity related to an advisory
1127 report may not be permitted or required to testify in any such
1128 civil action as to any findings, recommendations, evaluations,
1129 opinions, or other actions taken in connection with preparing,
1130 reviewing, or issuing such a report.

1131 (b) "Controlled substance" means a controlled substance

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1132 listed in Schedule II, Schedule III, or Schedule IV in s.
1133 893.03.

1134 (c) "Controlled-substance medical clinic" means a facility
1135 that employs a physician or osteopathic physician who prescribes
1136 on any given day more than 25 prescriptions of Schedule II or
1137 Schedule III controlled substance medications, or a combination
1138 thereof, or employs a physician or an osteopathic physician who
1139 is engaged in dispensing controlled substance medications.

1140 (d)~~(e)~~ "Dispenser" means a pharmacy, dispensing pharmacist,
1141 or dispensing health care practitioner.

1142 (e)~~(d)~~ "Health care practitioner" or "practitioner" means
1143 any practitioner who is subject to licensure or regulation by
1144 the department under chapter 458, chapter 459, chapter 461,
1145 chapter 462, chapter 464, chapter 465, or chapter 466.

1146 (f)~~(e)~~ "Health care regulatory board" means any board for a
1147 practitioner or health care practitioner who is licensed or
1148 regulated by the department.

1149 (g)~~(f)~~ "Pharmacy" means any pharmacy that is subject to
1150 licensure or regulation by the department under chapter 465 and
1151 that dispenses or delivers a controlled substance to an
1152 individual or address in this state.

1153 (h)~~(g)~~ "Prescriber" means a prescribing physician,
1154 prescribing practitioner, or other prescribing health care
1155 practitioner.

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

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1161 arrest or prosecution in the foreseeable future.

1162 (j)~~(i)~~ "Law enforcement agency" means the Department of Law
1163 Enforcement, a Florida sheriff's department, a Florida police
1164 department, or a law enforcement agency of the Federal
1165 Government which enforces the laws of this state or the United
1166 States relating to controlled substances, and which its agents
1167 and officers are empowered by law to conduct criminal
1168 investigations and make arrests.

1169 (k)~~(j)~~ "Program manager" means an employee of or a person
1170 contracted by the Department of Health who is designated to
1171 ensure the integrity of the prescription drug monitoring program
1172 in accordance with the requirements established in paragraphs
1173 (2) (a) and (b).

1174 (2) (a) By December 1, 2012 ~~2010~~, the department shall
1175 design and establish a comprehensive electronic database system
1176 that has controlled substance prescriptions provided to it and
1177 that provides prescription information to a patient's health
1178 care practitioner and pharmacist who inform the department that
1179 they wish the patient advisory report provided to them.

1180 Otherwise, the patient advisory report will not be sent to the
1181 practitioner, pharmacy, or pharmacist. The system shall be
1182 designed to provide information regarding dispensed
1183 prescriptions of controlled substances and shall not infringe
1184 upon the legitimate prescribing or dispensing of a controlled
1185 substance by a prescriber or dispenser acting in good faith and
1186 in the course of professional practice. The dispenser and the
1187 practitioners employed at or practicing at a controlled-
1188 substance medical clinic shall review the comprehensive
1189 electronic database system before prescribing or dispensing any

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1190 controlled substances to a patient. If the dispenser identifies
1191 or has any issues or concerns regarding the dispensing of the
1192 controlled substance medications, the dispenser shall
1193 immediately contact the prescriber before dispensing the
1194 controlled substance medication. The system shall be consistent
1195 with standards of the American Society for Automation in
1196 Pharmacy (ASAP). The electronic system shall also comply with
1197 the Health Insurance Portability and Accountability Act (HIPAA)
1198 as it pertains to protected health information (PHI), electronic
1199 protected health information (EPHI), and all other relevant
1200 state and federal privacy and security laws and regulations. The
1201 department shall establish policies and procedures as
1202 appropriate regarding the reporting, accessing the database,
1203 evaluation, management, development, implementation, operation,
1204 storage, and security of information within the system. The
1205 reporting of prescribed controlled substances shall include a
1206 dispensing transaction with a dispenser pursuant to chapter 465
1207 or through a dispensing transaction to an individual or address
1208 in this state with a pharmacy that is not located in this state
1209 but that is otherwise subject to the jurisdiction of this state
1210 as to that dispensing transaction. The reporting of patient
1211 advisory reports refers only to reports to patients, pharmacies,
1212 and practitioners. Separate reports that contain patient
1213 prescription history information and that are not patient
1214 advisory reports are provided to persons and entities as
1215 authorized in paragraphs (7) (b) and (c) and s. 893.0551.

1216 (b) The department, ~~when the direct support organization~~
1217 ~~receives at least \$20,000 in nonstate moneys or the state~~
1218 ~~receives at least \$20,000 in federal grants for the prescription~~

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1219 ~~drug monitoring program, and in consultation with the Office of~~
1220 ~~Drug Control,~~ shall adopt rules as necessary concerning the
1221 reporting, accessing the database, evaluation, management,
1222 development, implementation, operation, security, and storage of
1223 information within the system, including rules for when patient
1224 advisory reports are provided to pharmacies and prescribers, if:

1225 1. The direct-support organization receives at least
1226 \$20,000 in nonstate moneys for the prescription drug monitoring
1227 program;

1228 2. The state receives at least \$20,000 in federal grants
1229 for the prescription drug monitoring program; or

1230 3. The department collects at least \$20,000 through
1231 registration fees required by the state to dispense controlled
1232 substances.

1233

1234 The patient advisory report shall be provided in accordance with
1235 s. 893.13(7)(a)8. The department shall work with the
1236 professional health care licensure boards, such as the Board of
1237 Medicine, the Board of Osteopathic Medicine, and the Board of
1238 Pharmacy; other appropriate organizations, such as the Florida
1239 Pharmacy Association, ~~the Office of Drug Control,~~ the Florida
1240 Medical Association, the Florida Retail Federation, and the
1241 Florida Osteopathic Medical Association, including those
1242 relating to pain management; and the Attorney General, the
1243 Department of Law Enforcement, and the Agency for Health Care
1244 Administration to develop rules appropriate for the prescription
1245 drug monitoring program.

1246 (c) All dispensers and prescribers subject to these
1247 reporting requirements shall be notified by the department of

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1248 the implementation date for such reporting requirements.

1249 (d) The program manager shall work with professional health
1250 care licensure boards and the stakeholders listed in paragraph
1251 (b) to develop rules appropriate for identifying indicators of
1252 controlled substance abuse and diversion.

1253 (3) The pharmacy dispensing the controlled substance and
1254 each prescriber who directly dispenses a controlled substance
1255 shall submit to the electronic system, by a procedure and in a
1256 format established by the department and consistent with an
1257 ASAP-approved format, the following information for inclusion in
1258 the database:

1259 (a) The name of the prescribing practitioner, the
1260 practitioner's federal Drug Enforcement Administration
1261 registration number, the practitioner's National Provider
1262 Identification (NPI) or other appropriate identifier, and the
1263 date of the prescription.

1264 (b) The date the prescription was filled and the method of
1265 payment, such as cash by an individual, insurance coverage
1266 through a third party, or Medicaid payment. This paragraph does
1267 not authorize the department to include individual credit card
1268 numbers or other account numbers in the database.

1269 (c) The full name, address, and date of birth of the person
1270 for whom the prescription was written.

1271 (d) The name, national drug code, quantity, and strength of
1272 the controlled substance dispensed.

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

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1277 than a pharmacist, the practitioner's full name, federal Drug
1278 Enforcement Administration registration number, and address.

1279 (f) The name of the pharmacy or practitioner, other than a
1280 pharmacist, dispensing the controlled substance and the
1281 practitioner's National Provider Identification (NPI).

1282 (g) Other appropriate identifying information as determined
1283 by department rule.

1284 (4) Each time a controlled substance is dispensed to an
1285 individual, the controlled substance shall be reported to the
1286 department through the system ~~as soon thereafter as possible,~~
1287 but not more than 24 hours ~~15 days~~ after ~~the date~~ the controlled
1288 substance is dispensed ~~unless an extension is approved by the~~
1289 ~~department for cause as determined by rule.~~ A dispenser must
1290 meet the reporting requirements of this section by providing the
1291 required information concerning each controlled substance that
1292 it dispensed in a department-approved, secure methodology and
1293 format. Such approved formats may include, but are not limited
1294 to, submission via the Internet, on a disc, or by use of regular
1295 mail.

1296 (5) When the following acts of dispensing or administering
1297 occur, the following are exempt from reporting under this
1298 section for that specific act of dispensing or administration:

1299 (a) A health care practitioner when administering a
1300 controlled substance directly to a patient if the amount of the
1301 controlled substance is adequate to treat the patient during
1302 that particular treatment session.

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

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1306 ambulatory surgical center, hospice, or intermediate care
1307 facility for the developmentally disabled which is licensed in
1308 this state.

1309 (c) A practitioner when administering or dispensing a
1310 controlled substance in the health care system of the Department
1311 of Corrections.

1312 (d) A practitioner when administering a controlled
1313 substance in the emergency room of a licensed hospital.

1314 (e) A health care practitioner when administering or
1315 dispensing a controlled substance to a person under the age of
1316 16.

1317 (f) A pharmacist or a dispensing practitioner when
1318 dispensing a one-time, 72-hour emergency resupply of a
1319 controlled substance to a patient.

1320 (6) The department may establish when to suspend and when
1321 to resume reporting information during a state-declared or
1322 nationally declared disaster.

1323 (7) (a) A practitioner or pharmacist who dispenses a
1324 controlled substance must submit the information required by
1325 this section in an electronic or other method in an ASAP format
1326 approved by rule of the department unless otherwise provided in
1327 this section. The cost to the dispenser in submitting the
1328 information required by this section may not be material or
1329 extraordinary. Costs not considered to be material or
1330 extraordinary include, but are not limited to, regular postage,
1331 electronic media, regular electronic mail, and facsimile
1332 charges.

1333 (b) A pharmacy, prescriber, or dispenser shall have access
1334 to information in the prescription drug monitoring program's

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1335 database which relates to a patient of that pharmacy,
1336 prescriber, or dispenser in a manner established by the
1337 department as needed for the purpose of reviewing the patient's
1338 controlled substance prescription history. Other access to the
1339 program's database shall be limited to the program's manager and
1340 to the designated program and support staff, who may act only at
1341 the direction of the program manager or, in the absence of the
1342 program manager, as authorized. Access by the program manager or
1343 such designated staff is for prescription drug program
1344 management only or for management of the program's database and
1345 its system in support of the requirements of this section and in
1346 furtherance of the prescription drug monitoring program.
1347 Confidential and exempt information in the database shall be
1348 released only as provided in paragraph (c) and s. 893.0551.

1349 (c) The following entities shall not be allowed direct
1350 access to information in the prescription drug monitoring
1351 program database but may request from the program manager and,
1352 when authorized by the program manager, the program manager's
1353 program and support staff, information that is confidential and
1354 exempt under s. 893.0551. Prior to release, the request shall be
1355 verified as authentic and authorized with the requesting
1356 organization by the program manager, the program manager's
1357 program and support staff, or as determined in rules by the
1358 department as being authentic and as having been authorized by
1359 the requesting entity:

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

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1364 substances and who are involved in a specific controlled
1365 substance investigation involving a designated person for one or
1366 more prescribed controlled substances.

1367 2. The Attorney General for Medicaid fraud cases involving
1368 prescribed controlled substances.

1369 3. A law enforcement agency upon determination that
1370 probable cause exists that a crime is being committed and
1371 issuance of a search warrant regarding the ~~during active~~
1372 ~~investigations regarding~~ potential criminal activity, fraud, or
1373 theft regarding prescribed controlled substances.

1374 4. A patient or the legal guardian or designated health
1375 care surrogate of an incapacitated patient as described in s.
1376 893.0551 who, for the purpose of verifying the accuracy of the
1377 database information, submits a written and notarized request
1378 that includes the patient's full name, address, and date of
1379 birth, and includes the same information if the legal guardian
1380 or health care surrogate submits the request. The request shall
1381 be validated by the department to verify the identity of the
1382 patient and the legal guardian or health care surrogate, if the
1383 patient's legal guardian or health care surrogate is the
1384 requestor. Such verification is also required for any request to
1385 change a patient's prescription history or other information
1386 related to his or her information in the electronic database.

1387
1388 Information in the database for the electronic prescription drug
1389 monitoring system is not discoverable or admissible in any civil
1390 or administrative action, except in an investigation and
1391 disciplinary proceeding by the department or the appropriate
1392 regulatory board.

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1393 (d) The following entities shall not be allowed direct
1394 access to information in the prescription drug monitoring
1395 program database but may request from the program manager and,
1396 when authorized by the program manager, the program manager's
1397 program and support staff, information that contains no
1398 identifying information of any patient, physician, health care
1399 practitioner, prescriber, or dispenser and that is not
1400 confidential and exempt:

1401 1. Department staff for the purpose of calculating
1402 performance measures pursuant to subsection (8).

1403 2. The Program Implementation and Oversight Task Force for
1404 its reporting to the Governor, the President of the Senate, and
1405 the Speaker of the House of Representatives regarding the
1406 prescription drug monitoring program. This subparagraph expires
1407 July 1, 2012.

1408 (e) All transmissions of data required by this section must
1409 comply with relevant state and federal privacy and security laws
1410 and regulations. However, any authorized agency or person under
1411 s. 893.0551 receiving such information as allowed by s. 893.0551
1412 may maintain the information received for up to 24 months before
1413 purging it from his or her records or maintain it for longer
1414 than 24 months if the information is pertinent to ongoing health
1415 care or an active law enforcement investigation or prosecution.

1416 (f) The program manager, upon determining a pattern
1417 consistent with the rules established under paragraph (2) (d) and
1418 having cause to believe a violation of s. 893.13(7) (a)8.,
1419 (8) (a), or (8) (b) has occurred, may provide relevant information
1420 to the applicable law enforcement agency.

1421 (8) To assist in fulfilling program responsibilities,

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1422 performance measures shall be reported annually to the Governor,
1423 the President of the Senate, and the Speaker of the House of
1424 Representatives by the department each December 1, beginning in
1425 2011. Data that does not contain patient, physician, health care
1426 practitioner, prescriber, or dispenser identifying information
1427 may be requested during the year by department employees so that
1428 the department may undertake public health care and safety
1429 initiatives that take advantage of observed trends. Performance
1430 measures may include, but are not limited to, efforts to achieve
1431 the following outcomes:

1432 (a) Reduction of the rate of inappropriate use of
1433 prescription drugs through department education and safety
1434 efforts.

1435 (b) Reduction of the quantity of pharmaceutical controlled
1436 substances obtained by individuals attempting to engage in fraud
1437 and deceit.

1438 (c) Increased coordination among partners participating in
1439 the prescription drug monitoring program.

1440 (d) Involvement of stakeholders in achieving improved
1441 patient health care and safety and reduction of prescription
1442 drug abuse and prescription drug diversion.

1443 (9) Any person who willfully and knowingly fails to report
1444 the dispensing of a controlled substance as required by this
1445 section commits a misdemeanor of the first degree, punishable as
1446 provided in s. 775.082 or s. 775.083.

1447 (10) All costs incurred by the department in administering
1448 the prescription drug monitoring program shall be funded through
1449 federal grants, registration fees for controlled-substance
1450 medical clinics, or private funding applied for or received by

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1451 the state. The department may not commit funds for the
1452 monitoring program without ensuring funding is available. The
1453 prescription drug monitoring program and the implementation
1454 thereof are contingent upon receipt of the ~~nonstate~~ funding
1455 provided in this subsection. The department and state government
1456 shall cooperate with the direct-support organization established
1457 pursuant to subsection (11) in seeking federal grant funds,
1458 other nonstate grant funds, gifts, donations, or other private
1459 moneys for the department so long as the costs of doing so are
1460 not considered material. Nonmaterial costs for this purpose
1461 include, but are not limited to, the costs of mailing and
1462 personnel assigned to research or apply for a grant.
1463 Notwithstanding the exemptions to competitive-solicitation
1464 requirements under s. 287.057(3)(f), the department shall comply
1465 with the competitive-solicitation requirements under s. 287.057
1466 for the procurement of any goods or services required by this
1467 section.

1468 ~~(11) The Office of Drug Control, in coordination with the~~
1469 ~~department,~~ may establish a direct-support organization that has
1470 a board consisting of at least five members to provide
1471 assistance, funding, and promotional support for the activities
1472 authorized for the prescription drug monitoring program.

1473 (a) As used in this subsection, the term "direct-support
1474 organization" means an organization that is:

1475 1. A Florida corporation not for profit incorporated under
1476 chapter 617, exempted from filing fees, and approved by the
1477 Department of State.

1478 2. Organized and operated to conduct programs and
1479 activities; raise funds; request and receive grants, gifts, and

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1480 bequests of money; acquire, receive, hold, and invest, in its
1481 own name, securities, funds, objects of value, or other
1482 property, either real or personal; and make expenditures or
1483 provide funding to or for the direct or indirect benefit of the
1484 department in the furtherance of the prescription drug
1485 monitoring program.

1486 (b) The direct-support organization is not considered a
1487 lobbying firm within the meaning of s. 11.045.

1488 (c) The State Surgeon General ~~director of the Office of~~
1489 ~~Drug Control~~ shall appoint a board of directors for the direct-
1490 support organization. The State Surgeon General ~~director~~ may
1491 designate ~~employees of the Office of Drug Control~~, state
1492 employees other than state employees from the department, and
1493 any other nonstate employees as appropriate, to serve on the
1494 board. ~~Members of the board shall serve at the pleasure of the~~
1495 ~~director of the Office of Drug Control~~. The State Surgeon
1496 General ~~director~~ shall provide guidance to members of the board
1497 to ensure that moneys received by the direct-support
1498 organization are not received from inappropriate sources.
1499 Inappropriate sources include, but are not limited to, donors,
1500 grantors, persons, or organizations that may monetarily or
1501 substantively benefit from the purchase of goods or services by
1502 the department in furtherance of the prescription drug
1503 monitoring program.

1504 (d) The direct-support organization shall operate under
1505 written contract with the department ~~Office of Drug Control~~. The
1506 contract must, at a minimum, provide for:

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

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1509 ~~Control.~~

1510 2. Submission of an annual budget for the approval of the
1511 department ~~Office of Drug Control.~~

1512 3. Certification by the Office of Drug Control in
1513 consultation with the department that the direct-support
1514 organization is complying with the terms of the contract in a
1515 manner consistent with and in furtherance of the goals and
1516 purposes of the prescription drug monitoring program and in the
1517 best interests of the state. Such certification must be made
1518 annually and reported in the official minutes of a meeting of
1519 the direct-support organization.

1520 4. The reversion, without penalty, ~~to the Office of Drug~~
1521 ~~Control, or to the state if the Office of Drug Control ceases to~~
1522 ~~exist,~~ of all moneys and property held in trust by the direct-
1523 support organization for the benefit of the prescription drug
1524 monitoring program if the direct-support organization ceases to
1525 exist or if the contract is terminated.

1526 5. The fiscal year of the direct-support organization,
1527 which must begin July 1 of each year and end June 30 of the
1528 following year.

1529 6. The disclosure of the material provisions of the
1530 contract to donors of gifts, contributions, or bequests,
1531 including such disclosure on all promotional and fundraising
1532 publications, and an explanation to such donors of the
1533 distinction between the department ~~Office of Drug Control~~ and
1534 the direct-support organization.

1535 7. The direct-support organization's collecting, expending,
1536 and providing of funds to the department for the development,
1537 implementation, and operation of the prescription drug

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1538 monitoring program as described in this section and s. 2,
1539 chapter 2009-198, Laws of Florida, as long as the task force is
1540 authorized. The direct-support organization may collect and
1541 expend funds to be used for the functions of the direct-support
1542 organization's board of directors, as necessary and approved by
1543 the State Surgeon General ~~director of the Office of Drug~~
1544 ~~Control~~. In addition, the direct-support organization may
1545 collect and provide funding to the department in furtherance of
1546 the prescription drug monitoring program by:

1547 a. Establishing and administering the prescription drug
1548 monitoring program's electronic database, including hardware and
1549 software.

1550 b. Conducting studies on the efficiency and effectiveness
1551 of the program to include feasibility studies as described in
1552 subsection (13).

1553 c. Providing funds for future enhancements of the program
1554 within the intent of this section.

1555 d. Providing user training of the prescription drug
1556 monitoring program, including distribution of materials to
1557 promote public awareness and education and conducting workshops
1558 or other meetings, for health care practitioners, pharmacists,
1559 and others as appropriate.

1560 e. Providing funds for travel expenses.

1561 f. Providing funds for administrative costs, including
1562 personnel, audits, facilities, and equipment.

1563 g. Fulfilling all other requirements necessary to implement
1564 and operate the program as outlined in this section.

1565 (e) The activities of the direct-support organization must
1566 be consistent with the goals and mission of the department

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1567 ~~Office of Drug Control, as determined by the office in~~
1568 ~~consultation with the department,~~ and in the best interests of
1569 the state. The direct-support organization must obtain a written
1570 approval from the director of the Office of Drug Control for any
1571 activities in support of the prescription drug monitoring
1572 program before undertaking those activities.

1573 (f) ~~The Office of Drug Control, in consultation with the~~
1574 ~~department,~~ may permit, without charge, appropriate use of
1575 administrative services, property, and facilities of the ~~Office~~
1576 ~~of Drug Control and the~~ department by the direct-support
1577 organization, subject to this section. The use must be directly
1578 in keeping with the approved purposes of the direct-support
1579 organization and may not be made at times or places that would
1580 unreasonably interfere with opportunities for the public to use
1581 such facilities for established purposes. Any moneys received
1582 from rentals of facilities and properties managed by the ~~Office~~
1583 ~~of Drug Control and the~~ department may be held ~~by the Office of~~
1584 ~~Drug Control or~~ in a separate depository account in the name of
1585 the direct-support organization ~~and subject to the provisions of~~
1586 ~~the letter of agreement with the Office of Drug Control. The~~
1587 ~~letter of agreement must provide that any funds held in the~~
1588 ~~separate depository account in the name of the direct support~~
1589 ~~organization must revert to the Office of Drug Control if the~~
1590 ~~direct support organization is no longer approved by the Office~~
1591 ~~of Drug Control to operate in the best interests of the state.~~

1592 (g) ~~The Office of Drug Control, in consultation with the~~
1593 ~~department,~~ may adopt rules under s. 120.54 to govern the use of
1594 administrative services, property, or facilities of the
1595 department or office by the direct support organization.

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1596 (g)~~(h)~~ The department ~~Office of Drug Control~~ may not permit
1597 the use of any administrative services, property, or facilities
1598 of the state by a direct-support organization if that
1599 organization does not provide equal membership and employment
1600 opportunities to all persons regardless of race, color,
1601 religion, gender, age, or national origin.

1602 (h)~~(i)~~ The direct-support organization shall provide for an
1603 independent annual financial audit in accordance with s.
1604 215.981. Copies of the audit shall be provided to the Office of
1605 Drug Control and the Office of Policy and Budget in the
1606 Executive Office of the Governor.

1607 (i)~~(j)~~ The direct-support organization may not exercise any
1608 power under s. 617.0302(12) or (16).

1609 (12) A prescriber or dispenser may have access to the
1610 information under this section which relates to a patient of
1611 that prescriber or dispenser as needed for the purpose of
1612 reviewing the patient's controlled drug prescription history. A
1613 prescriber or dispenser acting in good faith is immune from any
1614 civil, criminal, or administrative liability that might
1615 otherwise be incurred or imposed for receiving or using
1616 information from the prescription drug monitoring program. This
1617 subsection does not create a private cause of action, and a
1618 person may not recover damages against a prescriber or dispenser
1619 authorized to access information under this subsection for
1620 accessing or failing to access such information.

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

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1625 enhancing the prescription drug monitoring program for the
1626 purposes of public health initiatives and statistical reporting
1627 that respects the privacy of the patient, the prescriber, and
1628 the dispenser. Such a study shall be conducted in order to
1629 further improve the quality of health care services and safety
1630 by improving the prescribing and dispensing practices for
1631 prescription drugs, taking advantage of advances in technology,
1632 reducing duplicative prescriptions and the overprescribing of
1633 prescription drugs, and reducing drug abuse. The requirements of
1634 the National All Schedules Prescription Electronic Reporting
1635 (NASPER) Act are authorized in order to apply for federal NASPER
1636 funding. In addition, the direct-support organization shall
1637 provide funding for the department, ~~in collaboration with the~~
1638 ~~Office of Drug Control,~~ to conduct training for health care
1639 practitioners and other appropriate persons in using the
1640 monitoring program to support the program enhancements.

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

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1654 care facility, including, but not limited to, an assisted living
 1655 facility or a hospital to which patients are admitted. As used
 1656 in this subsection, the term "proper identification" means an
 1657 identification that is issued by a state or the Federal
 1658 Government containing the person's photograph, printed name, and
 1659 signature or a document considered acceptable under 8 C.F.R. s.
 1660 274a.2(b)(1)(v)(A) and (B).

1661 (15) The Agency for Health Care Administration shall
 1662 continue the promotion of electronic prescribing by health care
 1663 practitioners, health care facilities, and pharmacies under s.
 1664 408.0611.

1665 (16) By December 1, 2011 ~~October 1, 2010~~, the department
 1666 shall adopt rules pursuant to ss. 120.536(1) and 120.54 to
 1667 administer the provisions of this section, which shall include
 1668 as necessary the reporting, accessing, evaluation, management,
 1669 development, implementation, operation, and storage of
 1670 information within the monitoring program's system.

1671 Section 11. Subsection (4) of section 893.0551, Florida
 1672 Statutes, is amended to read:

1673 893.0551 Public records exemption for the prescription drug
 1674 monitoring program.—

1675 (4) The department shall disclose such confidential and
 1676 exempt information to the applicable law enforcement agency in
 1677 accordance with s. 893.055(7)(f). The law enforcement agency may
 1678 disclose the confidential and exempt information received from
 1679 the department to a criminal justice agency as defined in s.
 1680 119.011 pursuant to a search warrant ~~as part of an active~~
 1681 ~~investigation~~ that is specific to a violation of s.
 1682 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

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