

By the Committees on Appropriations; Community Affairs; and Health Policy; and Senator Grimsley

576-04972-13

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1                   A bill to be entitled  
2           An act relating to the provision of health care with  
3           controlled substances; amending s. 456.44, F.S.;  
4           limiting the application of requirements for  
5           prescribing controlled substances; requiring a  
6           physician to consult the prescription drug monitoring  
7           program database before prescribing certain controlled  
8           substances; authorizing the Board of Medicine and the  
9           Board of Osteopathic Medicine to adopt a penalty for  
10          failure to consult the database; exempting nursing  
11          home residents and certain physicians from  
12          requirements regarding prescriptions of controlled  
13          substances; amending s. 465.003, F.S.; defining a  
14          term; conforming a cross-reference; creating s.  
15          465.0065, F.S.; providing notice requirements for  
16          inspection of a pharmacy; amending s. 465.016, F.S.;  
17          providing additional grounds for disciplinary action;  
18          conforming a cross-reference; amending s. 465.022,  
19          F.S.; conforming a cross-reference; requiring a  
20          pharmacy permittee to commence operations within 180  
21          days after permit issuance or show good cause why  
22          operations were not commenced; requiring the Board of  
23          Pharmacy to establish rules; requiring a pharmacy  
24          permittee to be supervised by a prescription  
25          department manager or consultant pharmacist of record;  
26          amending s. 465.023, F.S.; providing additional  
27          grounds for disciplinary action; conforming a cross-  
28          reference; creating s. 465.1902, F.S.; providing that  
29          the regulation of pharmacies and pharmacists is

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30 preempted to the state; providing that a local  
31 ordinance, rule, or regulation may not be enacted or  
32 remain in effect which regulates or attempts to  
33 regulate pharmacies or pharmacists in subject matters  
34 regulated under ch. 465, F.S.; amending s. 893.055,  
35 F.S.; deleting obsolete provisions; requiring a  
36 designated agent under the supervision of a health  
37 care practitioner to have access to information in the  
38 prescription drug monitoring program's database;  
39 deleting a provision that prohibits funds from  
40 prescription drug manufacturers to be used to  
41 implement the prescription drug monitoring program;  
42 authorizing the prescription drug monitoring program  
43 to be funded by state funds; revising the sources of  
44 money which are inappropriate for the direct-support  
45 organization of the prescription drug monitoring  
46 program to receive; amending s. 893.0551, F.S.;  
47 requiring the Department of Health to disclose certain  
48 confidential and exempt information to a designated  
49 agent of a health care practitioner or pharmacist  
50 under certain circumstances; creating s. 893.0552,  
51 F.S.; providing that regulation of the licensure,  
52 activity, and operation of pain-management clinics is  
53 preempted to the state under certain circumstances;  
54 authorizing a local government or political  
55 subdivision of the state to enact certain ordinances  
56 regarding local business taxes and land development;  
57 amending ss. 409.9201, 458.331, 459.015, 465.014,  
58 465.015, 465.0156, 465.0197, 465.1901, 499.003, and

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59 893.02, F.S.; conforming cross-references; providing  
60 an effective date.

61  
62 Be It Enacted by the Legislature of the State of Florida:

63  
64 Section 1. Section 456.44, Florida Statutes, is amended to  
65 read:

66 456.44 Controlled substance prescribing.—

67 (1) DEFINITIONS.—

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

76 (b) "Adverse incident" means any incident set forth in s.  
77 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

78 (c) "Board-certified pain management physician" means a  
79 physician who possesses board certification in pain medicine by  
80 the American Board of Pain Medicine, board certification by the  
81 American Board of Interventional Pain Physicians, or board  
82 certification or subcertification in pain management or pain  
83 medicine by a specialty board recognized by the American  
84 Association of Physician Specialists or the American Board of  
85 Medical Specialties or an osteopathic physician who holds a  
86 certificate in Pain Management by the American Osteopathic  
87 Association.

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88 (d) "Board eligible" means successful completion of an  
89 anesthesia, physical medicine and rehabilitation, rheumatology,  
90 or neurology residency program approved by the Accreditation  
91 Council for Graduate Medical Education or the American  
92 Osteopathic Association for a period of 6 years from successful  
93 completion of such residency program.

94 (e) "Chronic nonmalignant pain" means pain unrelated to  
95 cancer which persists beyond the usual course of disease or the  
96 injury that is the cause of the pain or more than 90 days after  
97 surgery.

98 (f) "Mental health addiction facility" means a facility  
99 licensed under chapter 394 or chapter 397.

100 (2) REGISTRATION. ~~Effective January 1, 2012,~~ A physician  
101 licensed under chapter 458, chapter 459, chapter 461, or chapter  
102 466 who prescribes more than a 30-day supply of any controlled  
103 substance, listed in Schedule II, Schedule III, or Schedule IV  
104 as defined in s. 893.03, over a 6-month period to any one  
105 patient for the treatment of chronic nonmalignant pain, must:

106 (a) Designate himself or herself as a controlled substance  
107 prescribing practitioner on the physician's practitioner  
108 profile.

109 (b) Comply with the requirements of this section and  
110 applicable board rules.

111 (3) STANDARDS OF PRACTICE.—The standards of practice in  
112 this section do not supersede the level of care, skill, and  
113 treatment recognized in general law related to health care  
114 licensure.

115 (a) A complete medical history and a physical examination  
116 must be conducted before beginning any treatment and must be

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117 documented in the medical record. The exact components of the  
118 physical examination shall be left to the judgment of the  
119 clinician who is expected to perform a physical examination  
120 proportionate to the diagnosis that justifies a treatment. The  
121 medical record must, at a minimum, document the nature and  
122 intensity of the pain, current and past treatments for pain,  
123 underlying or coexisting diseases or conditions, the effect of  
124 the pain on physical and psychological function, a review of  
125 previous medical records, previous diagnostic studies, and  
126 history of alcohol and substance abuse. The medical record shall  
127 also document the presence of one or more recognized medical  
128 indications for the use of a controlled substance. Each  
129 registrant must develop a written plan for assessing each  
130 patient's risk of aberrant drug-related behavior, which may  
131 include patient drug testing. Registrants must assess each  
132 patient's risk for aberrant drug-related behavior and monitor  
133 that risk on an ongoing basis in accordance with the plan.

134 (b) Before or during a new patient's visit for services for  
135 the treatment of pain at a pain-management clinic registered  
136 under s. 458.3265 or s. 459.0137, a physician shall consult the  
137 prescription drug monitoring program database provided under s.  
138 893.055(2) (a) before prescribing a controlled substance listed  
139 in Schedule II or Schedule III in s. 893.03. The physician may  
140 designate an agent under his or her supervision to consult the  
141 database. The Board of Medicine under chapter 458 and the Board  
142 of Osteopathic Medicine under chapter 459 shall adopt rules to  
143 establish a penalty for a physician who does not comply with  
144 this subsection.

145 (c) ~~(b)~~ Each registrant must develop a written

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146 individualized treatment plan for each patient. The treatment  
147 plan shall state objectives that will be used to determine  
148 treatment success, such as pain relief and improved physical and  
149 psychosocial function, and shall indicate if any further  
150 diagnostic evaluations or other treatments are planned. After  
151 treatment begins, the physician shall adjust drug therapy to the  
152 individual medical needs of each patient. Other treatment  
153 modalities, including a rehabilitation program, shall be  
154 considered depending on the etiology of the pain and the extent  
155 to which the pain is associated with physical and psychosocial  
156 impairment. The interdisciplinary nature of the treatment plan  
157 shall be documented.

158 (d)~~(e)~~ The physician shall discuss the risks and benefits  
159 of the use of controlled substances, including the risks of  
160 abuse and addiction, as well as physical dependence and its  
161 consequences, with the patient, persons designated by the  
162 patient, or the patient's surrogate or guardian if the patient  
163 is incompetent. The physician shall use a written controlled  
164 substance agreement between the physician and the patient  
165 outlining the patient's responsibilities, including, but not  
166 limited to:

167 1. Number and frequency of controlled substance  
168 prescriptions and refills.

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

171 3. An agreement that controlled substances for the  
172 treatment of chronic nonmalignant pain shall be prescribed by a  
173 single treating physician unless otherwise authorized by the  
174 treating physician and documented in the medical record.

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175        (e)~~(d)~~ The patient shall be seen by the physician at  
176 regular intervals, not to exceed 3 months, to assess the  
177 efficacy of treatment, ensure that controlled substance therapy  
178 remains indicated, evaluate the patient's progress toward  
179 treatment objectives, consider adverse drug effects, and review  
180 the etiology of the pain. Continuation or modification of  
181 therapy shall depend on the physician's evaluation of the  
182 patient's progress. If treatment goals are not being achieved,  
183 despite medication adjustments, the physician shall reevaluate  
184 the appropriateness of continued treatment. The physician shall  
185 monitor patient compliance in medication usage, related  
186 treatment plans, controlled substance agreements, and  
187 indications of substance abuse or diversion at a minimum of 3-  
188 month intervals.

189        (f)~~(e)~~ The physician shall refer the patient as necessary  
190 for additional evaluation and treatment in order to achieve  
191 treatment objectives. Special attention shall be given to those  
192 patients who are at risk for misusing their medications and  
193 those whose living arrangements pose a risk for medication  
194 misuse or diversion. The management of pain in patients with a  
195 history of substance abuse or with a comorbid psychiatric  
196 disorder requires extra care, monitoring, and documentation and  
197 requires consultation with or referral to an addiction medicine  
198 specialist or psychiatrist.

199        (g)~~(f)~~ A physician registered under this section must  
200 maintain accurate, current, and complete records that are  
201 accessible and readily available for review and comply with the  
202 requirements of this section, the applicable practice act, and  
203 applicable board rules. The medical records must include, but

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204 are not limited to:

205 1. The complete medical history and a physical examination,  
206 including history of drug abuse or dependence.

207 2. Diagnostic, therapeutic, and laboratory results.

208 3. Evaluations and consultations.

209 4. Treatment objectives.

210 5. Discussion of risks and benefits.

211 6. Treatments.

212 7. Medications, including date, type, dosage, and quantity  
213 prescribed.

214 8. Instructions and agreements.

215 9. Periodic reviews.

216 10. Results of any drug testing.

217 11. A photocopy of the patient's government-issued photo  
218 identification.

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

221 13. The physician's full name presented in a legible  
222 manner.

223 (h) ~~(g)~~ Patients with signs or symptoms of substance abuse  
224 shall be immediately referred to a board-certified pain  
225 management physician, an addiction medicine specialist, or a  
226 mental health addiction facility as it pertains to drug abuse or  
227 addiction unless the physician is board-certified or board-  
228 eligible in pain management. Throughout the period of time  
229 before receiving the consultant's report, a prescribing  
230 physician shall clearly and completely document medical  
231 justification for continued treatment with controlled substances  
232 and those steps taken to ensure medically appropriate use of



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233 controlled substances by the patient. Upon receipt of the  
234 consultant's written report, the prescribing physician shall  
235 incorporate the consultant's recommendations for continuing,  
236 modifying, or discontinuing controlled substance therapy. The  
237 resulting changes in treatment shall be specifically documented  
238 in the patient's medical record. Evidence or behavioral  
239 indications of diversion shall be followed by discontinuation of  
240 controlled substance therapy, and the patient shall be  
241 discharged, and all results of testing and actions taken by the  
242 physician shall be documented in the patient's medical record.

243  
244 This section ~~subsection~~ does not apply to a board-eligible or  
245 board-certified anesthesiologist, physiatrist, rheumatologist,  
246 or neurologist, or to a board-certified physician who has  
247 surgical privileges at a hospital or ambulatory surgery center  
248 and primarily provides surgical services. This section  
249 ~~subsection~~ does not apply to a board-eligible or board-certified  
250 medical specialist who has also completed a fellowship in pain  
251 medicine approved by the Accreditation Council for Graduate  
252 Medical Education or the American Osteopathic Association, or  
253 who is board eligible or board certified in pain medicine by the  
254 American Board of Pain Medicine or a board approved by the  
255 American Board of Medical Specialties or the American  
256 Osteopathic Association and performs interventional pain  
257 procedures of the type routinely billed using surgical codes.  
258 This section ~~subsection~~ does not apply to a physician who  
259 prescribes medically necessary controlled substances for a  
260 patient during an inpatient stay in a hospital licensed under  
261 chapter 395 or to a resident in a facility licensed under part

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262 II of chapter 400. This section does not apply to a physician  
263 licensed under chapter 458 or chapter 459 who writes fewer than  
264 50 prescriptions for a controlled substance for all of his or  
265 her patients during a 1-year period.

266 Section 2. Present subsections (1) through (17) of section  
267 465.003, Florida Statutes, are renumbered as subsections (2)  
268 through (18), respectively, paragraph (a) of present subsection  
269 (11) of that section is amended, and a new subsection (1) is  
270 added to that section, to read:

271 465.003 Definitions.—As used in this chapter, the term:

272 (1) "Abandoned" means the status of a pharmacy permit of a  
273 person or entity that was issued the permit but fails to  
274 commence pharmacy operations within 180 days after issuance of  
275 the permit without good cause or fails to follow pharmacy  
276 closure requirements as set by the board.

277 (12)~~(11)~~(a) "Pharmacy" includes a community pharmacy, an  
278 institutional pharmacy, a nuclear pharmacy, a special pharmacy,  
279 and an Internet pharmacy.

280 1. The term "community pharmacy" includes every location  
281 where medicinal drugs are compounded, dispensed, stored, or sold  
282 or where prescriptions are filled or dispensed on an outpatient  
283 basis.

284 2. The term "institutional pharmacy" includes every  
285 location in a hospital, clinic, nursing home, dispensary,  
286 sanitarium, extended care facility, or other facility,  
287 hereinafter referred to as "health care institutions," where  
288 medicinal drugs are compounded, dispensed, stored, or sold.

289 3. The term "nuclear pharmacy" includes every location  
290 where radioactive drugs and chemicals within the classification

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291 of medicinal drugs are compounded, dispensed, stored, or sold.  
292 The term "nuclear pharmacy" does not include hospitals licensed  
293 under chapter 395 or the nuclear medicine facilities of such  
294 hospitals.

295 4. The term "special pharmacy" includes every location  
296 where medicinal drugs are compounded, dispensed, stored, or sold  
297 if such locations are not otherwise defined in this subsection.

298 5. The term "Internet pharmacy" includes locations not  
299 otherwise licensed or issued a permit under this chapter, within  
300 or outside this state, which use the Internet to communicate  
301 with or obtain information from consumers in this state and use  
302 such communication or information to fill or refill  
303 prescriptions or to dispense, distribute, or otherwise engage in  
304 the practice of pharmacy in this state. Any act described in  
305 this definition constitutes the practice of pharmacy as defined  
306 in subsection (14) ~~(13)~~.

307 Section 3. Section 465.0065, Florida Statutes, is created  
308 to read:

309 465.0065 Notices; form and service.—Each notice served by  
310 the department pursuant to this chapter must be in writing and  
311 must be delivered personally by an agent of the department or by  
312 certified mail to the pharmacy permittee or licensee. If the  
313 pharmacy permittee or licensee refuses to accept service or  
314 evades service or if the agent is otherwise unable to carry out  
315 service after due diligence, the department may post the notice  
316 in a conspicuous place at the pharmacy or at the home or  
317 business address for the licensee.

318 Section 4. Paragraphs (e) and (s) of subsection (1) of  
319 section 465.016, Florida Statutes, are amended, and paragraph

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320 (u) is added to that subsection, to read:

321 465.016 Disciplinary actions.—

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

324 (e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as  
325 the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et  
326 seq., known as the Comprehensive Drug Abuse Prevention and  
327 Control Act; or chapter 893 or rules adopted thereunder.

328 (s) Dispensing any medicinal drug based upon a  
329 communication that purports to be a prescription as defined by  
330 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows  
331 or has reason to believe that the purported prescription is not  
332 based upon a valid practitioner-patient relationship.

333 (u) Misappropriating drugs, supplies, or equipment from a  
334 pharmacy permittee.

335 Section 5. Paragraph (j) of subsection (5) of section  
336 465.022, Florida Statutes, is amended, present subsections (10)  
337 through (14) are renumbered as subsections (11) through (15),  
338 respectively, present subsection (10) of that section is  
339 amended, and a new subsection (10) is added to that section, to  
340 read:

341 465.022 Pharmacies; general requirements; fees.—

342 (5) The department or board shall deny an application for a  
343 pharmacy permit if the applicant or an affiliated person,  
344 partner, officer, director, or prescription department manager  
345 or consultant pharmacist of record of the applicant:

346 (j) Has dispensed any medicinal drug based upon a  
347 communication that purports to be a prescription as defined by  
348 s. 465.003 ~~s. 465.003(14)~~ or s. 893.02 when the pharmacist knows

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349 or has reason to believe that the purported prescription is not  
350 based upon a valid practitioner-patient relationship that  
351 includes a documented patient evaluation, including history and  
352 a physical examination adequate to establish the diagnosis for  
353 which any drug is prescribed and any other requirement  
354 established by board rule under chapter 458, chapter 459,  
355 chapter 461, chapter 463, chapter 464, or chapter 466.

356  
357 For felonies in which the defendant entered a plea of guilty or  
358 nolo contendere in an agreement with the court to enter a  
359 pretrial intervention or drug diversion program, the department  
360 shall deny the application if upon final resolution of the case  
361 the licensee has failed to successfully complete the program.

362 (10) The permittee shall commence pharmacy operations  
363 within 180 days after issuance of the permit, or show good cause  
364 to the department why pharmacy operations were not commenced.  
365 Commencement of pharmacy operations includes, but is not limited  
366 to, acts within the scope of the practice of pharmacy, ordering  
367 or receiving drugs, and other similar activities. The board  
368 shall establish rules regarding commencement of pharmacy  
369 operations.

370 (11)~~(10)~~ A pharmacy permittee shall be supervised by a  
371 prescription department manager or consultant pharmacist of  
372 record at all times. A permittee must notify the department, on  
373 a form approved by the board, within 10 days after any change in  
374 prescription department manager or consultant pharmacist of  
375 record.

376 Section 6. Subsection (1) of section 465.023, Florida  
377 Statutes, is amended to read:

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378 465.023 Pharmacy permittee; disciplinary action.—

379 (1) The department or the board may revoke or suspend the  
380 permit of any pharmacy permittee, and may fine, place on  
381 probation, or otherwise discipline any pharmacy permittee if the  
382 permittee, or any affiliated person, partner, officer, director,  
383 or agent of the permittee, including a person fingerprinted  
384 under s. 465.022(3), has:

385 (a) Obtained a permit by misrepresentation or fraud or  
386 through an error of the department or the board;

387 (b) Attempted to procure, or has procured, a permit for any  
388 other person by making, or causing to be made, any false  
389 representation;

390 (c) Violated any of the requirements of this chapter or any  
391 of the rules of the Board of Pharmacy; of chapter 499, known as  
392 the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392,  
393 known as the "Federal Food, Drug, and Cosmetic Act"; of 21  
394 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse  
395 Prevention and Control Act; or of chapter 893 or rules adopted  
396 thereunder;

397 (d) Been convicted or found guilty, regardless of  
398 adjudication, of a felony or any other crime involving moral  
399 turpitude in any of the courts of this state, of any other  
400 state, or of the United States;

401 (e) Been convicted or disciplined by a regulatory agency of  
402 the Federal Government or a regulatory agency of another state  
403 for any offense that would constitute a violation of this  
404 chapter;

405 (f) Been convicted of, or entered a plea of guilty or nolo  
406 contendere to, regardless of adjudication, a crime in any

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407 jurisdiction which relates to the practice of, or the ability to  
408 practice, the profession of pharmacy;

409 (g) Been convicted of, or entered a plea of guilty or nolo  
410 contendere to, regardless of adjudication, a crime in any  
411 jurisdiction which relates to health care fraud; or

412 (h) Dispensed any medicinal drug based upon a communication  
413 that purports to be a prescription as defined by s. 465.003 ~~s.~~  
414 ~~465.003(14)~~ or s. 893.02 when the pharmacist knows or has reason  
415 to believe that the purported prescription is not based upon a  
416 valid practitioner-patient relationship that includes a  
417 documented patient evaluation, including history and a physical  
418 examination adequate to establish the diagnosis for which any  
419 drug is prescribed and any other requirement established by  
420 board rule under chapter 458, chapter 459, chapter 461, chapter  
421 463, chapter 464, or chapter 466.

422 Section 7. Section 465.1902, Florida Statutes, is created  
423 to read:

424 465.1902 Preemption.—The regulation of pharmacies and  
425 pharmacists is expressly preempted to the state. No local  
426 ordinance, rule, or regulation shall be enacted or remain in  
427 effect which regulates or attempts to regulate pharmacies or  
428 pharmacists in subject matters regulated under this chapter,  
429 including, but not limited to, licensure, discipline, pharmacy  
430 permitting, and the dispensing of controlled substances.

431 Section 8. Paragraph (b) of subsection (2), paragraph (b)  
432 of subsection (7), subsection (10), and paragraph (c) of  
433 subsection (11) of section 893.055, Florida Statutes, are  
434 amended to read:

435 893.055 Prescription drug monitoring program.—

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

(b) A pharmacy, prescriber, designated agent under the supervision of a health care practitioner, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and



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465 to the designated program and support staff, who may act only at  
466 the direction of the program manager or, in the absence of the  
467 program manager, as authorized. Access by the program manager or  
468 such designated staff is for prescription drug program  
469 management only or for management of the program's database and  
470 its system in support of the requirements of this section and in  
471 furtherance of the prescription drug monitoring program.  
472 Confidential and exempt information in the database shall be  
473 released only as provided in paragraph (c) and s. 893.0551. The  
474 program manager, designated program and support staff who act at  
475 the direction of or in the absence of the program manager, and  
476 any individual who has similar access regarding the management  
477 of the database from the prescription drug monitoring program  
478 shall submit fingerprints to the department for background  
479 screening. The department shall follow the procedure established  
480 by the Department of Law Enforcement to request a statewide  
481 criminal history record check and to request that the Department  
482 of Law Enforcement forward the fingerprints to the Federal  
483 Bureau of Investigation for a national criminal history record  
484 check.

485 (10) All costs incurred by the department in administering  
486 the prescription drug monitoring program shall be funded through  
487 state funds, federal grants, or private funding applied for or  
488 received by the state. The department may not commit funds for  
489 the monitoring program without ensuring funding is available.  
490 ~~The prescription drug monitoring program and the implementation~~  
491 ~~thereof are contingent upon receipt of the nonstate funding.~~ The  
492 department and state government shall cooperate with the direct-  
493 support organization established pursuant to subsection (11) in

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494 seeking state funds, federal grant funds, other nonstate grant  
495 funds, gifts, donations, or other private moneys for the  
496 department ~~if so long as~~ the costs of doing so are not  
497 considered material. Nonmaterial costs for this purpose include,  
498 but are not limited to, the costs of mailing and personnel  
499 assigned to research or apply for a grant. Notwithstanding the  
500 exemptions to competitive-solicitation requirements under s.  
501 287.057(3)(f), the department shall comply with the competitive-  
502 solicitation requirements under s. 287.057 for the procurement  
503 of any goods or services required by this section. ~~Funds~~  
504 ~~provided, directly or indirectly, by prescription drug~~  
505 ~~manufacturers may not be used to implement the program.~~

506 (11) The department may establish a direct-support  
507 organization that has a board consisting of at least five  
508 members to provide assistance, funding, and promotional support  
509 for the activities authorized for the prescription drug  
510 monitoring program.

511 (c) The State Surgeon General shall appoint a board of  
512 directors for the direct-support organization. Members of the  
513 board shall serve at the pleasure of the State Surgeon General.  
514 The State Surgeon General shall provide guidance to members of  
515 the board to ensure that moneys received by the direct-support  
516 organization are not received from inappropriate sources.  
517 Inappropriate sources include, but are not limited to, donors,  
518 grantors, persons, ~~or~~ organizations, or pharmaceutical  
519 companies, that may monetarily or substantively benefit from the  
520 purchase of goods or services by the department in furtherance  
521 of the prescription drug monitoring program.

522 Section 9. Paragraphs (d) and (e) of subsection (3) of

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523 section 893.0551, Florida Statutes, are amended to read:

524 893.0551 Public records exemption for the prescription drug  
525 monitoring program.—

526 (3) The department shall disclose such confidential and  
527 exempt information to the following entities after using a  
528 verification process to ensure the legitimacy of that person's  
529 or entity's request for the information:

530 (d) A health care practitioner or a designated agent under  
531 his or her supervision who certifies that the information is  
532 necessary to provide medical treatment to a current patient in  
533 accordance with ss. 893.05 and 893.055.

534 (e) A pharmacist or a designated agent under his or her  
535 supervision who certifies that the requested information will be  
536 used to dispense controlled substances to a current patient in  
537 accordance with ss. 893.04 and 893.055.

538 Section 10. Section 893.0552, Florida Statutes, is created  
539 to read:

540 893.0552 Preemption of regulation.—

541 (1) This section preempts to the state all regulation of  
542 the licensure, activity, and operation of pain-management  
543 clinics as defined in ss. 458.3265 and 459.0137 in the following  
544 circumstances:

545 (a) The clinic is wholly owned and operated by a physician  
546 who performs interventional pain procedures of the type  
547 routinely billed using surgical codes, who has never been  
548 suspended or revoked for prescribing a controlled substance in  
549 Schedule II or Schedule III of s. 893.03 and drugs containing  
550 Alprazolam in excessive or inappropriate quantities that are not  
551 in the best interest of a patient, and who:

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552 1. Has completed a fellowship in pain medicine which is  
553 approved by the Accreditation Council for Graduate Medical  
554 Education or the American Osteopathic Association;

555 2. Is board-certified in pain medicine by the American  
556 Board of Pain Medicine, board-certified by the American Board of  
557 Interventional Pain Physicians; or

558 3. Has a board certification or subcertification in pain  
559 management or pain medicine by a specialty board approved by the  
560 American Board of Medical Specialties or the American  
561 Osteopathic Association.

562 (b) The clinic is wholly owned and operated by a physician-  
563 multispecialty practice if one or more board-eligible or board-  
564 certified medical specialists has one of the qualifications  
565 specified in subparagraph (a)1., subparagraph (a)2., or  
566 subparagraph (a)3., performs interventional pain procedures of  
567 the type routinely billed using surgical codes, and has never  
568 been suspended or revoked for prescribing a controlled substance  
569 in Schedule II or Schedule III of s. 893.03 and drugs containing  
570 Alprazolam in excessive or inappropriate quantities that are not  
571 in the best interest of a patient.

572 (2) Notwithstanding subsection (1), the preemption does not  
573 prohibit a local government or political subdivision from  
574 enacting an ordinance regarding local business taxes adopted  
575 pursuant to chapter 205 and land use development regulations  
576 adopted pursuant to chapter 163. A pain-management clinic in  
577 which the regulation of its licensure, activity, and operation  
578 is preempted to the state pursuant to subsection (1) is a  
579 permissible use in a land use or zoning category that permits  
580 hospitals and other health care facilities or clinics as defined

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581 in chapter 395 or s. 408.07. Upon the request of a local  
582 government, a pain-management clinic must annually demonstrate  
583 that it qualifies for preemption pursuant to subsection (1).

584 Section 11. Subsection (1) of section 409.9201, Florida  
585 Statutes, is amended to read:

586 409.9201 Medicaid fraud.—

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

588 (a) "Prescription drug" means any drug, including, but not  
589 limited to, finished dosage forms or active ingredients that are  
590 subject to, defined by, or described by s. 503(b) of the Federal  
591 Food, Drug, and Cosmetic Act or by s. 465.003 ~~s. 465.003(8)~~, s.  
592 499.003(46) or (53) or s. 499.007(13).

593 (b) "Value" means the amount billed to the Medicaid program  
594 for the property dispensed or the market value of a legend drug  
595 or goods or services at the time and place of the offense. If  
596 the market value cannot be determined, the term means the  
597 replacement cost of the legend drug or goods or services within  
598 a reasonable time after the offense.

599  
600 The value of individual items of the legend drugs or goods or  
601 services involved in distinct transactions committed during a  
602 single scheme or course of conduct, whether involving a single  
603 person or several persons, may be aggregated when determining  
604 the punishment for the offense.

605 Section 12. Paragraph (pp) of subsection (1) of section  
606 458.331, Florida Statutes, is amended to read:

607 458.331 Grounds for disciplinary action; action by the  
608 board and department.—

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

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

611 (pp) Applicable to a licensee who serves as the designated  
612 physician of a pain-management clinic as defined in s. 458.3265  
613 or s. 459.0137:

614 1. Registering a pain-management clinic through  
615 misrepresentation or fraud;

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

619 3. Failing to comply with any requirement of chapter 499,  
620 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
621 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
622 the Drug Abuse Prevention and Control Act; or chapter 893, the  
623 Florida Comprehensive Drug Abuse Prevention and Control Act;

624 4. Being convicted or found guilty of, regardless of  
625 adjudication to, a felony or any other crime involving moral  
626 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
627 the courts of this state, of any other state, or of the United  
628 States;

629 5. Being convicted of, or disciplined by a regulatory  
630 agency of the Federal Government or a regulatory agency of  
631 another state for, any offense that would constitute a violation  
632 of this chapter;

633 6. Being convicted of, or entering a plea of guilty or nolo  
634 contendere to, regardless of adjudication, a crime in any  
635 jurisdiction of the courts of this state, of any other state, or  
636 of the United States which relates to the practice of, or the  
637 ability to practice, a licensed health care profession;

638 7. Being convicted of, or entering a plea of guilty or nolo

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639 contendere to, regardless of adjudication, a crime in any  
640 jurisdiction of the courts of this state, of any other state, or  
641 of the United States which relates to health care fraud;

642 8. Dispensing any medicinal drug based upon a communication  
643 that purports to be a prescription as defined in s. 465.003 ~~s.~~  
644 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or  
645 has reason to believe that the purported prescription is not  
646 based upon a valid practitioner-patient relationship; or

647 9. Failing to timely notify the board of the date of his or  
648 her termination from a pain-management clinic as required by s.  
649 458.3265(2).

650 Section 13. Paragraph (rr) of subsection (1) of section  
651 459.015, Florida Statutes, is amended to read:

652 459.015 Grounds for disciplinary action; action by the  
653 board and department.-

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

656 (rr) Applicable to a licensee who serves as the designated  
657 physician of a pain-management clinic as defined in s. 458.3265  
658 or s. 459.0137:

659 1. Registering a pain-management clinic through  
660 misrepresentation or fraud;

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

664 3. Failing to comply with any requirement of chapter 499,  
665 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the  
666 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,  
667 the Drug Abuse Prevention and Control Act; or chapter 893, the

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668 Florida Comprehensive Drug Abuse Prevention and Control Act;

669 4. Being convicted or found guilty of, regardless of  
670 adjudication to, a felony or any other crime involving moral  
671 turpitude, fraud, dishonesty, or deceit in any jurisdiction of  
672 the courts of this state, of any other state, or of the United  
673 States;

674 5. Being convicted of, or disciplined by a regulatory  
675 agency of the Federal Government or a regulatory agency of  
676 another state for, any offense that would constitute a violation  
677 of this chapter;

678 6. Being convicted of, or entering a plea of guilty or nolo  
679 contendere to, regardless of adjudication, a crime in any  
680 jurisdiction of the courts of this state, of any other state, or  
681 of the United States which relates to the practice of, or the  
682 ability to practice, a licensed health care profession;

683 7. Being convicted of, or entering a plea of guilty or nolo  
684 contendere to, regardless of adjudication, a crime in any  
685 jurisdiction of the courts of this state, of any other state, or  
686 of the United States which relates to health care fraud;

687 8. Dispensing any medicinal drug based upon a communication  
688 that purports to be a prescription as defined in s. 465.003 ~~s.~~  
689 ~~465.003(14)~~ or s. 893.02 if the dispensing practitioner knows or  
690 has reason to believe that the purported prescription is not  
691 based upon a valid practitioner-patient relationship; or

692 9. Failing to timely notify the board of the date of his or  
693 her termination from a pain-management clinic as required by s.  
694 459.0137(2).

695 Section 14. Subsection (1) of section 465.014, Florida  
696 Statutes, is amended to read:



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697 465.014 Pharmacy technician.—

698 (1) A person other than a licensed pharmacist or pharmacy  
699 intern may not engage in the practice of the profession of  
700 pharmacy, except that a licensed pharmacist may delegate to  
701 pharmacy technicians who are registered pursuant to this section  
702 those duties, tasks, and functions that do not fall within the  
703 purview of s. 465.003 ~~s. 465.003(13)~~. All such delegated acts  
704 shall be performed under the direct supervision of a licensed  
705 pharmacist who shall be responsible for all such acts performed  
706 by persons under his or her supervision. A pharmacy registered  
707 technician, under the supervision of a pharmacist, may initiate  
708 or receive communications with a practitioner or his or her  
709 agent, on behalf of a patient, regarding refill authorization  
710 requests. A licensed pharmacist may not supervise more than one  
711 registered pharmacy technician unless otherwise permitted by the  
712 guidelines adopted by the board. The board shall establish  
713 guidelines to be followed by licensees or permittees in  
714 determining the circumstances under which a licensed pharmacist  
715 may supervise more than one but not more than three pharmacy  
716 technicians.

717 Section 15. Paragraph (c) of subsection (2) of section  
718 465.015, Florida Statutes, is amended to read:

719 465.015 Violations and penalties.—

720 (2) It is unlawful for any person:

721 (c) To sell or dispense drugs as defined in s. 465.003 ~~s.~~  
722 ~~465.003(8)~~ without first being furnished with a prescription.

723 Section 16. Subsection (8) of section 465.0156, Florida  
724 Statutes, is amended to read:

725 465.0156 Registration of nonresident pharmacies.—

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726 (8) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes  
727 of this section, the registered pharmacy and the pharmacist  
728 designated by the registered pharmacy as the prescription  
729 department manager or the equivalent must be licensed in the  
730 state of location in order to dispense into this state.

731 Section 17. Subsection (4) of section 465.0197, Florida  
732 Statutes, is amended to read:

733 465.0197 Internet pharmacy permits.—

734 (4) Notwithstanding s. 465.003 ~~s. 465.003(10)~~, for purposes  
735 of this section, the Internet pharmacy and the pharmacist  
736 designated by the Internet pharmacy as the prescription  
737 department manager or the equivalent must be licensed in the  
738 state of location in order to dispense into this state.

739 Section 18. Section 465.1901, Florida Statutes, is amended  
740 to read:

741 465.1901 Practice of orthotics and pedorthics.—The  
742 provisions of chapter 468 relating to orthotics or pedorthics do  
743 not apply to any licensed pharmacist or to any person acting  
744 under the supervision of a licensed pharmacist. The practice of  
745 orthotics or pedorthics by a pharmacist or any of the  
746 pharmacist's employees acting under the supervision of a  
747 pharmacist shall be construed to be within the meaning of the  
748 term "practice of the profession of pharmacy" as set forth in s.  
749 465.003 ~~s. 465.003(13)~~, and shall be subject to regulation in  
750 the same manner as any other pharmacy practice. The Board of  
751 Pharmacy shall develop rules regarding the practice of orthotics  
752 and pedorthics by a pharmacist. Any pharmacist or person under  
753 the supervision of a pharmacist engaged in the practice of  
754 orthotics or pedorthics is not precluded from continuing that

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755 practice pending adoption of these rules.

756 Section 19. Subsection (43) of section 499.003, Florida  
757 Statutes, is amended to read:

758 499.003 Definitions of terms used in this part.—As used in  
759 this part, the term:

760 (43) "Prescription drug" means a prescription, medicinal,  
761 or legend drug, including, but not limited to, finished dosage  
762 forms or active pharmaceutical ingredients subject to, defined  
763 by, or described by s. 503(b) of the Federal Food, Drug, and  
764 Cosmetic Act or s. 465.003 ~~s. 465.003(8)~~, s. 499.007(13), or  
765 subsection (11), subsection (46), or subsection (53), except  
766 that an active pharmaceutical ingredient is a prescription drug  
767 only if substantially all finished dosage forms in which it may  
768 be lawfully dispensed or administered in this state are also  
769 prescription drugs.

770 Section 20. Subsection (22) of section 893.02, Florida  
771 Statutes, is amended to read:

772 893.02 Definitions.—The following words and phrases as used  
773 in this chapter shall have the following meanings, unless the  
774 context otherwise requires:

775 (22) "Prescription" means and includes an order for drugs  
776 or medicinal supplies written, signed, or transmitted by word of  
777 mouth, telephone, telegram, or other means of communication by a  
778 duly licensed practitioner licensed by the laws of the state to  
779 prescribe such drugs or medicinal supplies, issued in good faith  
780 and in the course of professional practice, intended to be  
781 filled, compounded, or dispensed by another person licensed by  
782 the laws of the state to do so, and meeting the requirements of  
783 s. 893.04. The term also includes an order for drugs or

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784 medicinal supplies so transmitted or written by a physician,  
785 dentist, veterinarian, or other practitioner licensed to  
786 practice in a state other than Florida, but only if the  
787 pharmacist called upon to fill such an order determines, in the  
788 exercise of his or her professional judgment, that the order was  
789 issued pursuant to a valid patient-physician relationship, that  
790 it is authentic, and that the drugs or medicinal supplies so  
791 ordered are considered necessary for the continuation of  
792 treatment of a chronic or recurrent illness. However, if the  
793 physician writing the prescription is not known to the  
794 pharmacist, the pharmacist shall obtain proof to a reasonable  
795 certainty of the validity of said prescription. A prescription  
796 order for a controlled substance shall not be issued on the same  
797 prescription blank with another prescription order for a  
798 controlled substance which is named or described in a different  
799 schedule, nor shall any prescription order for a controlled  
800 substance be issued on the same prescription blank as a  
801 prescription order for a medicinal drug, as defined in s.  
802 465.003 ~~s. 465.003(8)~~, which does not fall within the definition  
803 of a controlled substance as defined in this act.

804 Section 21. This act shall take effect July 1, 2013.