

LEGISLATIVE ACTION

Senate House

Comm: RCS 04/09/2013

The Committee on Community Affairs (Hukill) recommended the following:

Senate Amendment (with title amendment)

Delete everything after the enacting clause and insert:

Section 1. Subsections (2) and (3) of section 456.44, Florida Statutes, are amended to read:

456.44 Controlled substance prescribing.-

(2) REGISTRATION.—Effective January 1, 2012, A physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes more than a 30-day supply of any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, over a 6-month period to any one

2 3

4

5

6

8

9

10

11

12

14 15

16

17

18

19

20

2.1

22

23

24

25

26

27 28

29

30

31

32

33

34 35

36 37

38

39

40 41



patient for the treatment of chronic nonmalignant pain, must:

- (a) Designate himself or herself as a controlled substance prescribing practitioner on the physician's practitioner profile.
- (b) Comply with the requirements of this section and applicable board rules.
- (3) STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.
- (a) A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

43

44 45

46

47

48

49

50

51

52

53

54

55

56 57

58

59

60 61

62

63

64 65

66

67

68

69 70



(b) Before or during a new patient's visit for paintreatment services at a pain-management clinic registered under s. 458.3265 or s. 459.0137, a physician shall consult the prescription drug monitoring program database provided under s. 893.055(2)(a) before prescribing a controlled substance listed in Schedule II or Schedule III in s. 893.03. The physician may designate an agent under his or her supervision to consult the database. The board shall adopt rules to establish a penalty for a physician who does not comply with this subsection.

(c) (b) Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(d) (c) The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient

72

73 74

75 76

77

78

79

80

81

82

83 84

85

86

87

88 89

90 91

92

93

94 95

96

97

98 99



outlining the patient's responsibilities, including, but not limited to:

- 1. Number and frequency of controlled substance prescriptions and refills.
- 2. Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.
- 3. An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.
- (e) (d) The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3month intervals.
- (f) (e) The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication

101 102

103

104

105

106

107 108

109

110

111

112 113

114

115

116

117

118 119

120

121

122

123

124

125

126

127

128



misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

- (g) (f) A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section, the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:
- 1. The complete medical history and a physical examination, including history of drug abuse or dependence.
 - 2. Diagnostic, therapeutic, and laboratory results.
 - 3. Evaluations and consultations.
 - 4. Treatment objectives.
 - 5. Discussion of risks and benefits.
 - 6. Treatments.
- 7. Medications, including date, type, dosage, and quantity prescribed.
 - 8. Instructions and agreements.
 - 9. Periodic reviews.
 - 10. Results of any drug testing.
- 11. A photocopy of the patient's government-issued photo identification.
- 12. If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.
- 13. The physician's full name presented in a legible manner.



(h) (g) Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or boardeligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

149 150

151

152

153

154

155

156 157

129

130

131

132

133

134

135

136 137

138

139

140

141 142

143

144 145

146

147 148

> This subsection does not apply to a board-eligible or boardcertified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the

159

160

161

162

163 164

165

166

167

168

169

170

171

172

173

174 175

176

177

178

179

180

181

182

183

184

185

186



American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395 or to a resident in a facility licensed under part II of chapter 400. This subsection does not apply to any physician licensed under chapter 458 or chapter 459 who writes fewer than 50 prescriptions for a controlled substance for all of his or her patients during a 1-year period.

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

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

- (1) "Abandoned" means the status of a pharmacy permit of a person or entity that was issued the permit but fails to commence pharmacy operations within 180 days after issuance of the permit without good cause or fails to follow pharmacy closure requirements as set by the board.
- (12) (11) (a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.
- 1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold

188

189

190

191

192

193 194

195

196

197

198

199 200

201 202

203

204

205

206

207

208

209

210

211

212

213

214

215



or where prescriptions are filled or dispensed on an outpatient basis.

- 2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.
- 3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
- 4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.
- 5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection $(14)\frac{(13)}{(13)}$.

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

465.0065 Notices; form and service.—Each notice served by the department pursuant to this chapter must be in writing and

217

218

219

220

221

222

223

224

225

226

227

228

229

230

231

232

233

234

235

236

237

238

239

240

241

242

243 244



must be delivered personally by an agent of the department or by certified mail to the pharmacy permittee or licensee. If the pharmacy permittee or licensee refuses to accept service or evades service or if the agent is otherwise unable to carry out service after due diligence, the department may post the notice in a conspicuous place at the pharmacy or at the home or business address for the licensee.

Section 4. Paragraphs (e) and (s) of subsection (1) of section 465.016, Florida Statutes, are amended, and paragraph (u) is added to that subsection, to read:

465.016 Disciplinary actions.

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (e) Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893 or rules adopted thereunder.
- (s) Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. $465.003 \frac{14}{5.003(14)}$ or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.
- (u) Misappropriating drugs, supplies, or equipment from a pharmacy permittee.

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



245 read:

246

247 248

249

250

251

252

253 254

255 256

257

258

259

260

465.022 Pharmacies; general requirements; fees.-

- (5) The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:
- (j) Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003 s. 465.003(14) or s. 893.02 when the pharmacist knowsor has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

261 262

263

264

265

266

267

2.68

269

270

271

272

273

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

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



operations.

274

275

276

277

278

279

280

281

282

283

284

285

286

287

288

289

290

291

292

293

294

295

296

297

298 299

300

301

302

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

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

465.023 Pharmacy permittee; disciplinary action.-

- (1) The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:
- (a) Obtained a permit by misrepresentation or fraud or through an error of the department or the board;
- (b) Attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation;
- (c) Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893 or rules adopted thereunder;
 - (d) Been convicted or found guilty, regardless of

304

305

306

307

308

309

310 311

312

313

314

315 316

317

318 319

320 321

322

323

324 325

326

327

328

329

330 331



adjudication, of a felony or any other crime involving moral turpitude in any of the courts of this state, of any other state, or of the United States;

- (e) Been convicted or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;
- (f) Been convicted of, or entered a plea of quilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy;
- (g) Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud; or
- (h) Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003 s.465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

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

465.1902 Preemption.—This chapter preempts to the state all regulation of the licensure, activity, and operation of pharmacies and pharmacists as defined in this chapter. A local



government or political subdivision of the state may not enact or enforce an ordinance that imposes a levy, charge, or fee upon, or that otherwise regulates, pharmacies and pharmacists as defined in this chapter, except that this preemption does not prohibit a local government or political subdivision from enacting an ordinance regarding the following:

- (1) Local business taxes adopted pursuant to chapter 205.
- (2) Land use development regulations adopted pursuant to chapter 163, which include regulation of any aspect of development, including a subdivision, building construction, sign regulation, and any other regulation concerning the development of land, landscaping, or tree protection, and which do not include restrictions on pain-management services, health care services, or the prescribing of controlled substances.

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

893.055 Prescription drug monitoring program.-

(2)

332

333

334 335

336

337

338

339

340

341 342

343

344

345

346

347

348

349

350

351

352

353 354

355

356

357

358

359

360

(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

362

363

364

365

366

367

368

369

370

371

372

373

374

375

376

377

378

379

380

381

382

383

384

385

386

387

388 389



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.

(10) All costs incurred by the department in administering the prescription drug monitoring program shall be funded through state funds, federal grants, or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the directsupport organization established pursuant to subsection (11) in seeking state funds, federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department if so long as the costs of doing so are not considered material. Nonmaterial costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(3)(f), the department shall comply with the competitivesolicitation requirements under s. 287.057 for the procurement of any goods or services required by this section. Funds provided, directly or indirectly, by prescription drug

391

392 393

394

395

396

397

398

399

400 401

402

403

404

405

406

407

408

409

410

411 412

413 414

415

416

417

418



manufacturers may not be used to implement the program.

- (11) The department may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.
- (c) The State Surgeon General shall appoint a board of directors for the direct-support organization. Members of the board shall serve at the pleasure of the State Surgeon General. The State Surgeon General shall provide quidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations, or pharmaceutical companies, that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

Section 9. Section 893.0552, Florida Statutes, is created to read:

893.0552 Preemption of regulation.

- (1) This section preempts to the state all regulation of the licensure, activity, and operation of pain-management clinics as defined in ss. 458.3265 and 459.0137 in the following circumstances:
- (a) The clinic is wholly owned and operated by a physician who performs interventional pain procedures of the type routinely billed using surgical codes, who has never been suspended or revoked for prescribing a controlled substance in Schedule II or Schedule III of s. 893.03 and drugs containing

420

421

422

423

424

425

426

42.7

428

429

430

431

432

433

434

435

436

437

438

439

440

441

442

443

444

445 446

447



Alprazolam in excessive or inappropriate quantities that are not in the best interest of a patient, and who:

- 1. Has completed a fellowship in pain medicine which is approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association;
- 2. Is board-certified in pain medicine by the American Board of Pain Medicine, board-certified by the American Board of Interventional Pain Physicians; or
- 3. Has a board certification or subcertification in pain management or pain medicine by a specialty board approved by the American Board of Medical Specialties or the American Osteopathic Association.
- (b) The clinic is wholly owned and operated by a physicianmultispecialty practice if one or more board-eligible or boardcertified medical specialists has one of the qualifications specified in subparagraph (a)1., subparagraph (a)2., or subparagraph (a)3., performs interventional pain procedures of the type routinely billed using surgical codes, and has never been suspended or revoked for prescribing a controlled substance in Schedule II or Schedule III of s. 893.03 and drugs containing Alprazolam in excessive or inappropriate quantities that are not in the best interest of a patient.
- (2) Notwithstanding subsection (1), the preemption does not prohibit a local government or political subdivision from enacting an ordinance regarding local business taxes adopted pursuant to chapter 205 and land use development regulations adopted pursuant to chapter 163. A pain-management clinic in which the regulation of its licensure, activity, and operation is preempted to the state pursuant to subsection (1) is a

449

450

451

452

453

454

455

456

457

458

459

460

461

462

463

464

465

466

467

468 469

470

471

472

473

474

475

476



permissible use in a land use or zoning category that permits hospitals and other health care facilities or clinics as defined in chapter 395 or s. 408.07. Upon the request of a local government, a pain-management clinic must annually demonstrate that it qualifies for preemption pursuant to subsection (1).

Section 10. Subsection (1) of section 409.9201, Florida Statutes, is amended to read:

409.9201 Medicaid fraud.-

- (1) As used in this section, the term:
- (a) "Prescription drug" means any drug, including, but not limited to, finished dosage forms or active ingredients that are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or by s. $465.003 \cdot s. \cdot 465.003 \cdot (8)$, s. 499.003(46) or (53) or s. 499.007(13).
- (b) "Value" means the amount billed to the Medicaid program for the property dispensed or the market value of a legend drug or goods or services at the time and place of the offense. If the market value cannot be determined, the term means the replacement cost of the legend drug or goods or services within a reasonable time after the offense.

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

Section 11. Paragraph (pp) of subsection (1) of section 458.331, Florida Statutes, is amended to read:

458.331 Grounds for disciplinary action; action by the



board and department.-

477

478

479

480

481 482

483

484

485

486

487

488

489

490

491

492

493

494

495

496

497

498

499

500

501

502

503

504 505

- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (pp) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:
- 1. Registering a pain-management clinic through misrepresentation or fraud;
- 2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;
- 3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;
- 4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States:
- 5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;
- 6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the

507

508

509

510 511

512

513 514

515

516

517

518

519

520

521

522

523

524

525

526

527

528

529 530

531

532

533

534



ability to practice, a licensed health care profession;

- 7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;
- 8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or
- 9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 458.3265(2).
- Section 12. Paragraph (rr) of subsection (1) of section 459.015, Florida Statutes, is amended to read:
- 459.015 Grounds for disciplinary action; action by the board and department.
- (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
- (rr) Applicable to a licensee who serves as the designated physician of a pain-management clinic as defined in s. 458.3265 or s. 459.0137:
- 1. Registering a pain-management clinic through misrepresentation or fraud;
- 2. Procuring, or attempting to procure, the registration of a pain-management clinic for any other person by making or causing to be made, any false representation;
- 3. Failing to comply with any requirement of chapter 499, the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the

536

537

538

539

540

541

542

543

544

545 546

547

548

549 550

551

552

553

554

555

556

557

558

559

560

561

562 563



Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Drug Abuse Prevention and Control Act; or chapter 893, the Florida Comprehensive Drug Abuse Prevention and Control Act;

- 4. Being convicted or found guilty of, regardless of adjudication to, a felony or any other crime involving moral turpitude, fraud, dishonesty, or deceit in any jurisdiction of the courts of this state, of any other state, or of the United States;
- 5. Being convicted of, or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for, any offense that would constitute a violation of this chapter;
- 6. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to the practice of, or the ability to practice, a licensed health care profession;
- 7. Being convicted of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction of the courts of this state, of any other state, or of the United States which relates to health care fraud;
- 8. Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined in s. 465.003 s.465.003(14) or s. 893.02 if the dispensing practitioner knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship; or
- 9. Failing to timely notify the board of the date of his or her termination from a pain-management clinic as required by s. 459.0137(2).

565

566

567

568

569

570

571

572

573

574

575

576

577

578

579

580

581

582

583

584

585

586

587

588 589

590

591

592



Section 13. Subsection (1) of section 465.014, Florida Statutes, is amended to read:

465.014 Pharmacy technician.

(1) A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. $465.003 ext{ s. } 465.003 ext{ (13)}$. All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the quidelines adopted by the board. The board shall establish quidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

Section 14. Paragraph (c) of subsection (2) of section 465.015, Florida Statutes, is amended to read:

465.015 Violations and penalties.-

- (2) It is unlawful for any person:
- (c) To sell or dispense drugs as defined in s. 465.003 s.465.003(8) without first being furnished with a prescription. Section 15. Subsection (8) of section 465.0156, Florida



Statutes, is amended to read:

593

594

595

596

597

598

599

600

601

602

603

604

605 606

607

608

609

610 611

612

613

614 615

616

617

618

619

620

621

465.0156 Registration of nonresident pharmacies.-

(8) Notwithstanding s. $465.003 ext{ s. } 465.003 ext{(10)}$, for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

Section 16. Subsection (4) of section 465.0197, Florida Statutes, is amended to read:

465.0197 Internet pharmacy permits.

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

Section 17. Section 465.1901, Florida Statutes, is amended to read:

465.1901 Practice of orthotics and pedorthics.-The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003 s. 465.003(13), and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under

623

624

625

626

627

628

629

630

631

632

633

634 635

636

637

638

639

640

641 642

643

644 645

646

647 648

649 650



the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

Section 18. Subsection (43) of section 499.003, Florida Statutes, is amended to read:

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

(43) "Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act or s. $465.003 \cdot \frac{1}{8}$, s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

Section 19. Subsection (22) of section 893.02, Florida Statutes, is amended to read:

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

(22) "Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by



the laws of the state to do so, and meeting the requirements of s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003 s. 465.003(8), which does not fall within the definition of a controlled substance as defined in this act.

Section 20. This act shall take effect July 1, 2013.

673 674

675

676

677

678

679

651

652

653

654

655

656

657

658

659

660

661

662

663 664

665

666

667

668

669

670

671

672

======== T I T L E A M E N D M E N T ========== And the title is amended as follows:

Delete everything before the enacting clause and insert:

A bill to be entitled

Page 24 of 26

681

682

683

684

685

686

687

688

689

690

691

692

693

694

695

696

697

698

699

700

701

702

703

704

705

706

707

708



An act relating to the provision of health care with controlled substances; amending s. 456.44, F.S.; limiting the application of requirements for prescribing controlled substances; requiring a physician to consult the prescription drug monitoring program database before prescribing certain controlled substances; authorizing the appropriate board to adopt a penalty for failure to consult the database; exempting nursing home residents and certain physicians from requirements regarding prescriptions of controlled substances; amending s. 465.003, F.S.; defining a term; conforming a cross-reference; creating s. 465.0065, F.S.; providing notice requirements for inspection of a pharmacy; amending s. 465.016, F.S.; providing additional grounds for disciplinary action; conforming a cross-reference; amending s. 465.022, F.S.; conforming a crossreference; requiring a pharmacy permittee to commence operations within 180 days after permit issuance or show good cause why operations were not commenced; requiring the Board of Pharmacy to establish rules; requiring a pharmacy permittee to be supervised by a prescription department manager or consultant pharmacist of record; amending s. 465.023, F.S.; providing additional grounds for disciplinary action; conforming a cross-reference; creating s. 465.1902, F.S.; providing that regulation of the licensure, activity, and operation of pharmacies and pharmacists is preempted to the state; prohibiting a local

710

711

712

713

714 715

716

717

718

719

720

721

722

723

724

725

726

727

728

729

730 731

732

733



government or political subdivision of the state from enacting or enforcing an ordinance that imposes a levy, charge, or fee upon, or that otherwise regulates, pharmacies and pharmacists, except for ordinances regarding local business taxes and land development; amending s. 893.055, F.S.; deleting an obsolete provision; deleting a provision that prohibits funds from prescription drug manufacturers to be used to implement the prescription drug monitoring program; revising the sources of money which are inappropriate for the direct-support organization of the prescription drug monitoring program to receive; authorizing the prescription drug monitoring program to be funded by state funds and pharmaceutical company donations; creating s. 893.0552, F.S.; providing that regulation of the licensure, activity, and operation of pain-management clinics is preempted to the state; authorizing a local government or political subdivision of the state to enact certain ordinances regarding local business taxes and land development; amending ss. 409.9201, 458.331, 459.015, 465.014, 465.015, 465.0156, 465.0197, 465.1901, 499.003, and 893.02, F.S.; conforming cross-references; providing an effective date.