By Senator Garcia

38-01115A-14

20141420

A bill to be entitled

An act relating to medical practice; amending s. 456.44, F.S.; exempting certain physicians prescribing controlled substances for the treatment of pain associated with sickle cell disease from the standards of practice for prescribing controlled substances; amending ss. 458.347 and 459.022, F.S., relating to physician assistants; removing the cap on the number of physician assistants a physician may supervise; providing that a physician assistant may perform practice-related activities unless expressly prohibited; requiring a physician assistant to certify that he or she has completed continuing medical education hours in a specialty practice in which he or she has prescriptive privileges; specifying the drugs to be included on the formulary a physician assistant may not prescribe; deleting the requirement that a person applying for licensure as a physician assistant provide two letters of recommendation; providing an effective date.

2021

1

2

3

4

5

6

7

8

9

10

11

12

13

1415

1617

18

19

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

222324

25

2627

2829

Section 1. Subsection (3) of section 456.44, Florida Statutes, is amended to read:

456.44 Controlled substance prescribing.-

(3) STANDARDS OF PRACTICE.—The standards of practice established under in this section do not supersede the level of care, skill, and treatment recognized in general law related to

Page 1 of 16

health care licensure.

30

31

32

3334

35

36

37

38 39

40

41

42

43 44

45

46

47

48 49

50

51

52

53

54

5556

57

58

- (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 $\frac{1}{2}$ 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 must shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant shall must develop a written plan for assessing the each patient's risk of aberrant drug-related behavior, which may include patient drug testing. Registrants shall then must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.
- (b) Each registrant shall must develop a written individualized treatment plan for each patient. The treatment plan must include shall state objectives for determining 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 the

38-01115A-14 20141420

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.

- (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 specifying outlining the patient's responsibilities which includes, including, but is not limited to:
- 1. The 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 $\underline{\text{will}}$ shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.
- (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

38-01115A-14 20141420

depends 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 3-month intervals.

- (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 misuse or diversion. The management of pain in patients who have 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.
- (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.

117 6. Treatments.

118

119

120

121

122

125

126

127128

129

130

131

132

133

134

135

136

137

138

139

140

141142

143

144

145

- 7. Medications, including date, type, dosage, and quantity prescribed.
 - 8. Instructions and agreements.
 - 9. Periodic reviews.
 - 10. Results of any drug testing.
- 123 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.
 - (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 must 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 $\frac{1}{2}$ shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

150151

152

153

154

155156

157

158

159

160

161

162

163

164

165

166

167

168

169

170171

172

173

174

146

147

148

149

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 American Osteopathic Association, or who is board eliqible 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; to an oncologist or hematologist prescribing medically necessary controlled substances to a patient for treatment of pain associated with progressive sickle cell disease; or. 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.

Section 2. Subsection (3), subsection (4), and paragraphs (a) and (c) of subsection (7) of section 458.347, Florida Statutes, are amended to read:

458.347 Physician assistants.—

38-01115A-14 20141420

(3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and <u>is shall be</u> individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than four currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section <u>is may</u> not be required to review and cosign charts or medical records prepared by <u>the such</u> physician assistant.

- (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—A physician assistant may perform practice-related activities in accordance with his or her education, training, and experience as delegated by a supervisory physician unless expressly prohibited under this chapter, chapter 459, or rules adopted to administer these chapters.
- (a) The boards shall adopt, by rule, the general principles that supervising physicians must use in developing the scope of practice of a physician assistant under direct supervision and under indirect supervision. These principles <u>must shall</u> recognize the diversity of both specialty and practice settings in which physician assistants are used.
- (b) This chapter does not prevent third-party payors from reimbursing employers of physician assistants for covered services rendered by licensed physician assistants.
- (c) Licensed Physician assistants may not be denied clinical hospital privileges, except for cause, so long as the supervising physician is a staff member in good standing.

38-01115A-14 20141420

(d) A supervisory physician may delegate to a licensed physician assistant, pursuant to a written protocol, the authority to act according to s. 154.04(1)(c). Such delegated authority is limited to the supervising physician's practice in connection with a county health department as defined and established <u>under pursuant to</u> chapter 154. The boards shall adopt rules governing the supervision of physician assistants by physicians in county health departments.

- (e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to paragraph (f). A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:
- 1. The A physician assistant must clearly identify to the patient that he or she is a physician assistant. Furthermore, The physician assistant must also inform the patient that the patient has the right to see the physician before a prior to any prescription is being prescribed or dispensed by the physician assistant.
- 2. The supervisory physician must notify the department of his or her intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in the prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervising physician who is registered as a dispensing practitioner under in compliance with s. 465.0276.
 - 3. At the time of license renewal, the physician assistant

38-01115A-14 20141420

must <u>certify to</u> <u>file with</u> the department <u>a signed affidavit</u> that he or she has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges <u>with each licensure</u> renewal application.

- 4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant <u>is shall</u> not be required to independently register pursuant to s. 465.0276.
- 5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, must contain the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant, the prescription must be filled in a pharmacy permitted under chapter 465 and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.
- 6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.
- (f) 1. The council shall establish a formulary of medicinal drugs that a fully licensed physician assistant having prescribing authority under this section or s. 459.022 may not prescribe. The formulary must include controlled substances listed under schedules I and II as defined in chapter 893,

2.72

38-01115A-14 20141420

general anesthetics, and radiographic contrast materials.

1.2. In establishing the formulary, the council shall consult with a pharmacist licensed under chapter 465, but not licensed under this chapter or chapter 459, who shall be selected by the State Surgeon General.

- 2.3. Only the council shall add to, delete from, or modify the formulary. Any person who requests an addition, deletion, or modification of a medicinal drug listed on the such formulary has the burden of proof to show cause why such addition, deletion, or modification should be made.
- 3.4. The boards shall adopt the formulary required by this paragraph, and each addition, deletion, or modification to the formulary, by rule. Notwithstanding any provision of chapter 120 to the contrary, the formulary rule is shall be effective 60 days after the date it is filed with the Secretary of State. Upon adoption of the formulary, the department shall mail a copy of the such formulary to each fully licensed physician assistant having prescribing authority under this section or s. 459.022, and to each pharmacy licensed by the state. The boards shall establish, by rule, a fee not to exceed \$200 to fund the provisions of this paragraph and paragraph (e).
- (g) A supervisory physician may delegate to a licensed physician assistant the authority to order medications for the supervisory physician's patient during his or her care in a facility licensed under chapter 395, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit such this delegation. For the purpose of this paragraph, an order is not considered a prescription. A licensed physician assistant working in a facility that is licensed under chapter 395 may

38-01115A-14 20141420

order any medication under the direction of the supervisory physician.

- (7) PHYSICIAN ASSISTANT LICENSURE.
- (a) \underline{A} Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:
 - 1. Is at least 18 years of age.
- 2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively practiced as a physician assistant within the immediately preceding 4 years, the applicant must retake and successfully complete the entry-level examination of the National Commission on Certification of Physician Assistants to be eligible for licensure.
- 3. Has completed the application form and remitted an application fee of up to not to exceed \$300 as set by the boards. An application for licensure made by a physician assistant must include:
- a. A certificate of completion of a physician assistant training program specified in subsection (6).
 - b. A sworn statement of any prior felony convictions.
- c. A sworn statement of any previous revocation or denial of licensure or certification in any state.
 - d. Two letters of recommendation.
 - d.e. A copy of course transcripts and a copy of the course

38-01115A-14 20141420

description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.

- (c) The license must be renewed biennially. Each renewal must include:
 - 1. A renewal fee not to exceed \$500 as set by the boards.
- 2. A sworn statement of no felony convictions in the previous 2 years.

Section 3. Subsections (3) and (4) and paragraphs (a) and (b) of subsection (7) of section 459.022, Florida Statutes, are amended to read:

459.022 Physician assistants.-

- (3) PERFORMANCE OF SUPERVISING PHYSICIAN.—Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas in which the physician assistant is to perform and <u>is shall be</u> individually or collectively responsible and liable for the performance and the acts and omissions of the physician assistant. A physician may not supervise more than four currently licensed physician assistants at any one time. A physician supervising a physician assistant pursuant to this section <u>is may</u> not be required to review and cosign charts or medical records prepared by such physician assistant.
- (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—A physician assistant may perform practice-related activities in accordance with his or her education, training, and experience as delegated by a supervisory physician unless expressly prohibited under this chapter, chapter 458, or rules adopted to administer these

chapters.

(a) The boards shall adopt, by rule, the general principles that supervising physicians must use in developing the scope of practice of a physician assistant under direct supervision and under indirect supervision. These principles shall recognize the diversity of both specialty and practice settings in which physician assistants are used.

- (b) This chapter does not prevent third-party payors from reimbursing employers of physician assistants for covered services rendered by licensed physician assistants.
- (c) Licensed Physician assistants may not be denied clinical hospital privileges, except for cause, so long as the supervising physician is a staff member in good standing.
- (d) A supervisory physician may delegate to a licensed physician assistant, pursuant to a written protocol, the authority to act according to s. 154.04(1)(c). Such delegated authority is limited to the supervising physician's practice in connection with a county health department as defined and established under pursuant to chapter 154. The boards shall adopt rules governing the supervision of physician assistants by physicians in county health departments.
- (e) A supervisory physician may delegate to a fully licensed physician assistant the authority to prescribe or dispense any medication used in the supervisory physician's practice unless such medication is listed on the formulary created pursuant to s. 458.347. A fully licensed physician assistant may only prescribe or dispense such medication under the following circumstances:
 - 1. The $\frac{A}{2}$ physician assistant must clearly identify to the

38-01115A-14 20141420

patient that she or he is a physician assistant. Furthermore, The physician assistant must <u>also</u> inform the patient that the patient has the right to see the physician <u>before a prior to any prescription is being prescribed</u> or dispensed by the physician assistant.

- 2. The supervisory physician must notify the department of her or his intent to delegate, on a department-approved form, before delegating such authority and notify the department of any change in the prescriptive privileges of the physician assistant. Authority to dispense may be delegated only by a supervisory physician who is registered as a dispensing practitioner under in compliance with s. 465.0276.
- 3. At the time of license renewal, the physician assistant must certify to file with the department a signed affidavit that she or he has completed a minimum of 10 continuing medical education hours in the specialty practice in which the physician assistant has prescriptive privileges with each licensure renewal application.
- 4. The department may issue a prescriber number to the physician assistant granting authority for the prescribing of medicinal drugs authorized within this paragraph upon completion of the foregoing requirements. The physician assistant <u>is</u> shall not be required to independently register pursuant to s. 465.0276.
- 5. The prescription must be written in a form that complies with chapter 499 and must contain, in addition to the supervisory physician's name, address, and telephone number, contain the physician assistant's prescriber number. Unless it is a drug or drug sample dispensed by the physician assistant,

38-01115A-14 20141420

the prescription must be filled in a pharmacy permitted under chapter 465, and must be dispensed in that pharmacy by a pharmacist licensed under chapter 465. The appearance of the prescriber number creates a presumption that the physician assistant is authorized to prescribe the medicinal drug and the prescription is valid.

- 6. The physician assistant must note the prescription or dispensing of medication in the appropriate medical record.
- (f) A supervisory physician may delegate to a licensed physician assistant the authority to order medications for the supervisory physician's patient during his or her care in a facility licensed under chapter 395, notwithstanding any provisions in chapter 465 or chapter 893 which may prohibit such this delegation. For the purpose of this paragraph, an order is not considered a prescription. A licensed physician assistant working in a facility that is licensed under chapter 395 may order any medication under the direction of the supervisory physician.
 - (7) PHYSICIAN ASSISTANT LICENSURE.
- (a) \underline{A} Any person desiring to be licensed as a physician assistant must apply to the department. The department shall issue a license to any person certified by the council as having met the following requirements:
 - 1. Is at least 18 years of age.
- 2. Has satisfactorily passed a proficiency examination by an acceptable score established by the National Commission on Certification of Physician Assistants. If an applicant does not hold a current certificate issued by the National Commission on Certification of Physician Assistants and has not actively

437

438439

440

441

442

443444

445446

447

448

449

450

451

452

453

454

455

456

457

458

459

460 461 38-01115A-14 20141420

practiced as a physician assistant within the immediately
preceding 4 years, the applicant must retake and successfully
complete the entry-level examination of the National Commission
on Certification of Physician Assistants to be eligible for
licensure.

- 3. Has completed the application form and remitted an application fee of up to not to exceed \$300 as set by the boards. An application for licensure made by a physician assistant must include:
- a. A certificate of completion of a physician assistant training program specified in subsection (6).
 - b. A sworn statement of any prior felony convictions.
- c. A sworn statement of any previous revocation or denial of licensure or certification in any state.

d. Two letters of recommendation.

- d.e. A copy of course transcripts and a copy of the course description from a physician assistant training program describing course content in pharmacotherapy, if the applicant wishes to apply for prescribing authority. These documents must meet the evidence requirements for prescribing authority.
- (b) The licensure must be renewed biennially. Each renewal must include:
 - 1. A renewal fee not to exceed \$500 as set by the boards.
- 2. A sworn statement of no felony convictions in the previous 2 years.
 - Section 4. This act shall take effect July 1, 2014.