HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/CS/HB 281 Drug Prescription by Advanced Registered Nurse Practitioners and Physician

Assistants

SPONSOR(S): Health & Human Services Committee; Health Innovation Subcommittee; Pigman

TIED BILLS: IDEN./SIM. BILLS: SB 532

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Innovation Subcommittee	11 Y, 0 N, As CS	Castagna	Poche
2) Health & Human Services Committee	13 Y, 4 N, As CS	Castagna	Calamas

SUMMARY ANALYSIS

Unlike all other states in the U.S., Florida does not allow advanced registered nurse practitioners (ARNPs) to prescribe controlled substances and is one of two states that does not allow physician assistants (PAs) to prescribe controlled substances.

CS/CS/HB 281 authorizes ARNPs to prescribe, dispense, order, and administer controlled substances, but only to the extent authorized under a supervising physician's protocol. The bill also authorizes PAs to prescribe controlled substances that are not listed on the formulary established by the Council on Physician Assistants, under current supervisory standards. The bill subjects ARNPs and PAs to administrative disciplinary actions, such as fines or license suspensions, for violating standards of practice in law relating to prescribing and dispensing controlled substances. The bill adds specific prohibited acts related to the prescribing of controlled substances, which constitute grounds for denial of license or disciplinary action, into the Nurse Practice Act.

The bill requires ARNPs and PAs who prescribe controlled substances for the treatment of chronic nonmalignant pain to meet certain registration and prescribing requirements, but prevents ARNPs and PAs from prescribing controlled substances in registered pain management clinics. The bill also adds the American Board of Interventional Pain Physicians and the American Association of Physician Specialists to the list of boards in which a medical specialist may be board certified or board eligible in pain medicine in order to be exempted from the statutory standards of practice.

The bill adds ARNPs and PAs into the definition of "practitioner" in the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) requiring compliance with the prescribing and dispensing requirements and limitations under the Act.

The bill makes several technical and conforming changes throughout and amends several statutes to recognize that an ARNP or a PA may be a prescriber of controlled substances. These include statutes relating to pilot licensure, criminal probation, and the state employees' prescription drug program.

The bill has an insignificant negative fiscal impact on the Department of Health and no fiscal impact on local governments.

The bill provides an effective date of July 1, 2015.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0281d.HHSC

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Physician Assistants

Regulation and Licensure

A physician assistant (PA) is a person licensed to perform health care services, in the specialty areas in which he or she has been trained, delegated by a supervising physician. Under Florida law PAs are governed under the physician practice acts for medical doctors (MDs) and doctors of osteopathic medicine (DOs). PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. Currently, there are 6,511 in-state, and 724 out-of-state, active licensed PAs.³

An applicant for a PA license must apply to the Department of Health (Department). The Department must issue a license to a person certified by the Council as having met all of the following requirements:

- At least 18 years of age;
- Satisfactorily passed a proficiency examination with an acceptable score established by the National Commission on Certification of Physician Assistants;⁴
- · Completed an application form and paid the registration fee;
- Holds a certificate of completion from a PA training program, including certain course descriptions relating to pharmacotherapy if the PA applicant seeks prescribing authority;
- Provides a sworn statement of any felony convictions;
- Provides a sworn statement of any revocation or denial of licensure or certification in any state;
 and
- Provides two letters of recommendation.

A PA license is renewed every two years by:

- Submitting an application;
- Paying a \$275 renewal fee;⁵ and
- Submitting proof of completion of at least 100 hours of continuing medical education (CME) during the two years prior to application for renewal.⁶

Supervising Physician

STORAGE NAME: h0281d.HHSC

PAGE: 2

¹ SS. 458.347(1), F.S., and 459. 022(1)(e), F.S.

² SS. 458.347, F.S., and 459.022, F.S.

³ Email correspondence with the Department of Health on March 14, 2015 (on file with subcommittee staff).

⁴ National Commission on Certification of Physician Assistants, *Physician Assistant National Certifying Exam (PANCE)*, available at https://www.nccpa.net/pance (last visited March 14, 2015).

⁵ Rule 64B8-30.019, F.A.C.

⁶ In addition to the above requirements, prescribing PAs must complete 10 hours of CME in each specialty of their supervising physician. These hours are included in general CME requirements. Florida Board of Medicine, *Physician Assistants*, available at http://flboardofmedicine.gov/renewals/physician-assistants/ (last visited March 14, 2015).

A PA practices under the delegated authority of a supervising physician. A physician supervising a PA must be qualified in the medical area in which the PA is practicing and is responsible and liable for the performance, acts, and omissions of the PA.⁷

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate is dependent upon the:

- Complexity of the task;
- Risk to the patient;
- Background, training and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.⁸

The supervising physician is required to periodically review the PA's performance.

A supervising physician may only delegate tasks and procedures to the physician assistant which are within the supervising physician's scope of practice. The decision to permit the physician assistant to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. 10 Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. 11

Delegable Tasks

The following tasks are not permitted to be delegated to a PA, except when specifically authorized by statute:

- Prescribing, dispensing, or compounding medicinal drugs; and
- Final diagnosis.

A supervising physician may delegate authority to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice; 12
- Order medicinal drugs for a hospitalized patient of the supervising physician;¹³ and
- Administer a medicinal drug under the direction and supervision of the physician.

hospitalized patients.

STORAGE NAME: h0281d.HHSC

PAGE: 3

⁷ SS. 458.347(3), F.S., and 459.022(3), F.S.; Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.

⁸ Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.

⁹Supra at FN 7. ¹⁰ Id.

¹¹ Specific procedures are not permitted to be performed under indirect supervision, including routine insertion of chest tubes, removal of pacer wires or atrial monitoring lines from cardiac stress testing, routine insertion of central venous catheters, injection of intrathecal medication without prior approval of the supervising physician, interpretation of laboratory tests, X-ray studies and EKG's without the supervising physician's interpretation and final review, and administration of general, spinal, and epidural anesthetics (this may be performed under direct supervision only by physician assistants who graduated from Board-approved programs for the education of anesthesiology assistants). See Rules in Supra at FN 7.

SS. 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal or epidural anesthetics, and radiographic contrast materials. In 2013, ss.458.347 and 459.022, F.S., were amended to clarify that a PA is authorized to order controlled substances for

Currently, PAs are prohibited from prescribing controlled substances, general, spinal, or epidural anesthetics, and radiographic contrast materials.¹⁴ However, physicians may delegate to PAs the authority to order controlled substances in facilities licensed under ch. 395, F.S.¹⁵

Advanced Registered Nurse Practitioners

Regulation and Licensure

In Florida, an advanced practice nurse (APN)¹⁶ is an advanced registered nurse practitioner (ARNP),¹⁷ and is categorized as a certified nurse practitioner, certified nurse midwife, or certified registered nurse anesthetist.¹⁸ As of March 2015, there are 17,719 ARNPs practicing in Florida.

Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include, in addition to practice of professional nursing that registered nurses are authorized to perform, advanced-level nursing acts approved by the Board of Nursing (Board) as appropriate for ARNPs to perform based on their specialized education, training, and experience. Advanced or specialized nursing acts may only be performed if authorized under a supervising physician's protocol.¹⁹

ARNPs are regulated under part I of ch. 464, F.S., the Nurse Practice Act. The Board, established under s. 464.004, F.S., provides the eligibility criteria for applicants to be certified as ARNPs and the applicable regulatory standards for ARNP nursing practices. For an applicant to be eligible to be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master's degree; and
- Submit to the Board proof of a current national advanced practice certification from a boardapproved nursing specialty board.²⁰

Pursuant to s. 456.048, F.S., all ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility. An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and before each biennial renewal. An ARNP must have professional liability coverage of at least \$100,000 per claim with a minimum annual aggregate of at least \$300,000, or an unexpired irrevocable letter of credit, which is payable to the ARNP as beneficiary, in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000. ²¹

Supervising Physician

²¹ Rule 64B9-4.002(5), F.A.C. **STORAGE NAME**: h0281d.HHSC

¹⁴ Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C.

¹⁵ SS. 458.347(4)(g), F.S., and 459.022(4)(f), F.S.; the facilities licensed in ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

¹⁶ The term APN refers to registered nurses who have completed rigorous training and advanced education, usually resulting in a master's degree or higher. The titles of APNs vary from state to state.

¹⁷ S. 464.003(3), F.S.

¹⁸ S. 464.012(4), F.S.

¹⁹ S. 464.012, F.S.

²⁰ S. 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

Under s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in a written physician protocol filed with the Board.²² Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary practice location. If the physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes:
- Assisted living facilities:
- Student health care centers or school health clinics; and
- Other government facilities. ²³

To ensure appropriate medical care, the number of ARNPs a supervising physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol:
- Complexity and risk of the procedures;
- Practice setting: and
- Availability of the supervising physician or dentist.²⁴

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty:
- Perform medical acts authorized by a joint committee; and
- Perform additional functions determined by rule. ²⁵

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.²⁶

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules. The distinguishing factors between the different drug schedules are the "potential for abuse" of the substance and whether there is a currently accepted medical use for

STORAGE NAME: h0281d.HHSC PAGE: 5 **DATE**: 4/3/2015

Allopathic and osteopathic physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. SS. 458.348 and 459.025, F.S.

SS. 458.348(4)(e), and 459.025(3)(e), F.S.

²⁴ Rule 64B9-4.010, F.A.C.

²⁵ S. 464.012(3), F.S. Section 464.012(4), F.S., authorizes additional acts that certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform within their specialty and a supervisory physician protocol. SS. 893.02(21), F.S., and 893.05(1), F.S.

the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.²⁷

The Act defines "prescription" as 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.²⁸ The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.

Controlled Substance Prescribing for Nonmalignant Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain³⁰ must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.³¹ Before prescribing controlled substances for the treatment of chronic nonmalignant pain, a practitioner must:

- Document certain characteristics about the nature of the patient's pain, success of past treatments, and a history of alcohol and substance abuse;
- Develop a written plan for assessing the patient's risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or their legal representative and by the prescribing practitioner. Such agreements must include:
 - 0 The number and frequency of permitted prescriptions and refills;
 - A statement of reasons for discontinuation of therapy, including violation of the agreement; and
 - The requirement that a patient's chronic nonmalignant pain only be treated by one practitioner at a time unless otherwise authorized and documented.

Patients treated with controlled substances for chronic nonmalignant pain must be seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained. Patients at special risk for drug abuse or diversion may require co-monitoring by an addiction medicine physician or a psychiatrist. Anyone with signs or symptoms of substance abuse must be immediately referred to a painmanagement physician, an addiction medicine specialist, or an addiction medicine facility.³²

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.³³

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or

³³Drug Enforcement Administration, *About Us*, available at http://www.deadiversion.usdoj.gov/Inside.html (last visited April 2, 2015). STORAGE NAME: h0281d.HHSC

Drug Enforcement Administration, Office of Diversion Control, Controlled Substance Schedules, available at www.deadiversion.usdoj.gov/21cfr/cfr/2108cfrt.htm (last visited April 2, 2015).

²⁸ The definition also includes protocol for out-of-state, licensed practitioners who are prescribing in Florida, pharmacist prescription verification, and prescription blank requirements for controlled substances. S. 893.02(22), F.S. SS. 893.04, F.S., and 893.05, F.S.

³⁰ "Chronic nonmalignant pain" is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. S. 456.44(1)(e), F.S.

S. 456.44(2)(a) and (b), F.S.

³² S. 456.44, F.S.

revoked upon any disciplinary action taken against a licensee.³⁴ The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law. The DEA provides that a controlled substance prescription may only be issued by a registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice; and
- Registered with the DEA, or exempt from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners); or
- An agent or employee of a hospital or other institution acting in the normal course of business or employment under the DEA registration number of the hospital or other institution which is registered in lieu of the individual practitioner being registered.³⁵

The DEA's Practitioner Manual includes requirements for valid prescriptions. The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting.³⁶

Other States' Controlled Substance Prescriptive Authority for ARNPs and PAs

ARNPs

An ARNP's ability to prescribe, dispense, or administer controlled substances is dependent on their specific state's law. Forty-nine states authorize ARNPs to prescribe controlled substances.³⁷ Twenty-six states allow an ARNP to independently diagnose and treat a patient without physician supervision, ³⁸ and 11 of these states authorize an ARNP to prescribe controlled substances to a patient without physician supervision. Twenty-two states specifically prohibit certified registered nurse anesthetists from prescribing controlled substances.³⁹

Some states have specific limitations regarding ARNPs prescribing authority for schedule II controlled substances, ⁴⁰ for example, 7 states authorize ARNPs to prescribe all levels of scheduled drugs, except for schedule II. Some states have specific education requirements for those ARNPs who wish to prescribe schedule II substances or require additional registration for ARNPs to be authorized to prescribe. ⁴¹

PAs

A PA's ability to prescribe, dispense, or administer controlled substances is dependent on their specific state's law. Forty-eight states authorize PAs to prescribe controlled substances within an agreement with a supervisory physician, with varying limitations on administration, dispensing, and independent prescribing. Of the 48 states, some have specific restrictions on PAs prescribing authority for schedule II controlled substances; for example, Texas and Hawaii only authorize PAs to order schedule

Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual- Section II*, available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm (last visited April 2, 2015).

35 Id.

³⁶ Drug Enforcement Administration, *Practitioner's Manual-Section V*, available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm (last visited April 2, 2015).

³⁷ Findings based on research conducted during 2013-2015 by professional staff of the Health and Human Services Committee.
³⁸ Alaska, Arizona, Arkansas, Colorado, Connecticut, Hawaii, Idaho, Kentucky, Maine, Michigan, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oklahoma, Oregon, Rhode Island, Utah, Vermont, Washington, West Virginia, Wisconsin, and Wyoming allow for independent practice, 7 of these states limit prescribing authority for certified registered nurse anesthetists.

³⁹ American Association of Nurse Anesthetists, AANA Journal, June 2011; 79(3):235, on file with committee staff.

⁴⁰ Schedule II substances have a high abuse potential with severe dependence liability and consist of certain narcotic, stimulant, ad depressant drugs. Drug Enforcement Administration, *Mid-Level Practitioners Authorization by State*, available at http://www.deadiversion.usdoj.gov/drugreg/practioners/ (last visited April 2, 2015).

⁴¹ Id.

⁴² Every state, except Florida and Kentucky, has some form of controlled substances prescriptive authority for PAs. Id. **STORAGE NAME**: h0281d.HHSC

II controlled substances in an inpatient hospital setting. Five states⁴³ have medication quantity restrictions on prescriptions for schedule II drugs and 4 states give PAs prescriptive authority for all levels of scheduled drugs except for schedule II.⁴⁴ Some states also have a formulary determined by the relevant PA licensing board which identifies the controlled substances that PAs are authorized to prescribe.

Effect of Proposed Changes

The bill authorizes PAs licensed under Ch. 458, F.S., the Medical Practice Act or under Ch. 459, F.S., the Osteopathic Medical Practice Act, and ARNPs certified under Part I of Ch. 464, F.S., the Nurse Practice Act, to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs.

Physician Assistants

The bill authorizes PAs to prescribe controlled substances by removing controlled substances from the formulary of medicinal drugs that a PA may not prescribe. The formulary is determined by the Council on Physician Assistants pursuant to s. 458.347(4)(f)1., F.S.⁴⁵

The bill subjects PAs to administrative disciplinary actions in s. 456.072, F.S., such as fines or license suspensions for violating standards of practice in law relating to prescribing and dispensing controlled substances.⁴⁶

<u>Advanced Registered Nurse Practitioners</u>

The bill authorizes ARNPs, regulated under s. 464.012(3)(a), F.S., to prescribe, dispense, order, or administer controlled substances, if allowed under a supervising physician's protocol. The bill adds additional acts related to the prescribing of controlled substances into s. 464.012(3), F.S., which an ARNP is prohibited from performing and which, if performed, constitute grounds for denial of license or disciplinary actions.

Section 456.072(7), F.S., is revised to include disciplinary actions against ARNPs including specific fines and license suspension, which mirror actions against physicians for prescribing or dispensing a controlled substance other than in the course of professional practice or for failing to meet practice standards.

Controlled Substances

The bill adds PAs and ARNPs to the definition of practitioner in ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act (Act), thus requiring these practitioners to comply with the prescribing and dispensing requirements and limitations under the Act. This definition also requires practitioners to hold a valid federal DEA controlled substance registry number.

The bill amends s. 456.44, F.S., to require a PA or ARNP who prescribes any controlled substance that is listed in Schedule II, Schedule III, or Schedule IV, for the treatment of chronic nonmalignant pain to register himself or herself as a controlled substance prescribing practitioner on his or her practitioner profile maintained by the Department and to meet other statutory requirements for such registrants.⁴⁷ The bill also replaces the terms physician and clinician with registrant throughout this

⁴⁷ Currently, PAs do not have practitioner profiles. Practitioner profiles contain information about a practitioner's education, training, and practice and are accessible to the public. If the bill is enacted, the Department will need to develop a profile for PAs.

STORAGE NAME: h0281d.HHSC

⁴³ Arizona, Illinois, Missouri, Montana, and North Carolina. Id.

⁴⁴ Id.

⁴⁵ S. 459.022(4)(e), F.S., of the Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act.

⁴⁶ Disciplinary sanctions against physicians apply to PAs. SS. 458.347(7)(g), F.S., and 459.022(7)(g), F.S. of the Medical and Osteopathic Medical Practice Acts state that the Board of Medicine or the Board of Osteopathic Medicine may impose any penalty authorized under ss. 456.072, F.S., 458.332(2), F.S., and 459.015(2), F.S., upon a PA if the PA or the supervising physician has been found guilty of any prohibited acts.

section of law. The bill specifies that this registration is not required to prescribe medication in a facility licensed under ch. 395, F.S. 48

Pursuant to s. 456.44, F.S., a medical specialist who is board certified or board eligible in pain medicine by certain boards is exempt from the statutory standards of practice relating to prescribing controlled substances for the treatment of chronic nonmalignant pain. The bill adds the American Board of Interventional Pain Physicians and the American Association of Physician Specialists to the authorized boards that a physician may be certified under to be exempt from the standards in s. 456.44, F.S.

The bill amends sections regulating pain-management clinics under the Medical Practice Act and the Osteopathic Medical Practice Act to only authorize physicians licensed under ch. 458, F.S., or ch. 459, F.S., to prescribe controlled substances in a pain-management clinic. Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics.

The bill makes several conforming changes to various statutes to recognize the new prescribing authority for PAs and ARNPs.

The bill provides an effective date of July 1, 2015.

B. SECTION DIRECTORY:

- **Section 1:** Amends s. 110.12315, F.S., relating to the prescription drug program.
- **Section 2:** Amends s. 310.071, F.S., relating to deputy pilot certification.
- **Section 3:** Amends s. 310.073, F.S., relating to state pilot licensing.
- **Section 4:** Amends s. 310.081, F.S., relating to the department to examine and license state pilots and certificate deputy pilots; vacancies.
- **Section 5:** Amends s. 456.072, F.S., relating to grounds for discipline; penalties; enforcement.
- **Section 6:** Amends s. 456.44, F.S., relating to controlled substance prescribing.
- Section 7: Amends s. 458.3265, F.S., relating to pain management clinics.
- **Section 8:** Amends s. 458.347, F.S., relating to physician assistants.
- Section 9: Amends s. 459.0137, F.S., relating to pain management clinics.
- **Section 10:** Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners.
- **Section 11:** Amends s. 464.018, F.S., relating to disciplinary actions.
- Section 12: Amends s. 893.02, F.S., relating to definitions.
- Section 13: Amends s. 948 03. F.S., relating to the terms and conditions of probation.
- Section 14: Reenacts s. 310.071(3), F.S., relating to deputy pilot certification.
- **Section 15:** Reenacts ss. 458.331(10), F.S., relating to grounds for disciplinary action; action by the board and department; 458.347(7)(g), F.S., relating to physician assistants; 459.015(10), F.S., relating to elating to grounds for disciplinary action; action by the board and department; 459.022(7)(f), F.S., relating to physician assistants; and 465.0158(5)(b), F.S., relating to nonresident sterile compounding permit.
- **Section 16:** Reenacts ss. 456.072(1)(mm), F.S., relating to grounds for discipline; penalties; enforcement; and 466.02751, F.S., relating to the establishment of practitioner profile for designation as a controlled substance prescribing practitioner.
- **Section 17:** Reenacts ss. 458.303(4)(e), F.S., relating to provisions not applicable to other practitioners exceptions, etc; 458.303(9)(c), F.S., relating to provisions not applicable to other practitioners, exceptions, etc; 458.3475(7)(b), F.S., relating to anesthesiologist assistants, 459.022(4)(e), F.S.; 459.022(9)(c), F.S., relating to physician assistants; and 459.023(7)(b), F.S., relating to anesthesiologist assistants.
- **Section 18:** Reenacts ss. 456.041(1)(a), F.S., relating to the practitioner profile; creation; 458.348(1) and (2), F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards; and 459.025(1), F.S., relating to formal supervisory relationships, standing orders, and established protocols; notice; standards.

⁴⁸ The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

- **Section 19:** Reenacts ss. 320.0848(11), F.S., relating to persons who have disabilities; issuance of disabled parking permits; temporary permits; permits for certain providers of transportation services to persons who have disabilities; 464.008(2), F.S., relating to licensure by examination; 464.009(5), F.S., relating to Board headquarters; 464.018(2), F.S., relating to disciplinary actions; and 464.0205(1)(b), 3(b), and (4)(b), F.S., relating to retired volunteer nurse certificate.
- **Section 20:** Reenacts s. 775.051, F.S., relating to voluntary intoxication; not a defense; evidence not admissible for certain purposes; exception.
- **Sectoin 21:** Reenacts ss. 944.17(3)(a), F.S., relating to commitments and classification; transfers; 948.001(1)(e), F.S., relating to definitions; and 948.101(1)(e), F.S., relating to terms and conditions of community control.
- **Section 22:** Provides an effective date of July 1, 2015.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill has an insignificant negative fiscal impact on the Department of Health associated with rulemaking, the creation of practitioner profiles for PAs, and workload impacts related to potential additional practitioner complaints and investigations. These impacts can be absorbed within existing resources.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Patients may see reduced health care costs and efficiencies in health care delivery as a result of having their health care needs more fully addressed by the PA or ARNP without specific additional involvement of a physician prescribing a needed controlled substance for treatment. Any such impacts are indeterminate.

PAGE: 10

D. FISCAL COMMENTS:

None.

STORAGE NAME: h0281d.HHSC

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

Applicability of Municipality/County Mandates Provision:
 Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The Board of Nursing, Board of Medicine, Board of Osteopathic Medicine, the Department of Health, and the Department of Management Services have sufficient rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 18, 2015, the Health Innovation Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment clarifies that PAs and ARNPs, acting under the supervision of a physician rather than under the direction of a physician, may order a controlled substance for a patient in a facility licensed under ch. 395, F.S.

On April 1, 2015, the Health & Human Services Committee adopted a strike all amendment and reported the bill favorably as a committee substitute. The amendment:

- Authorized ARNPs to prescribe, dispense, order, or administer certain controlled substances, but only to the extent authorized in a supervising physician's protocol.
- Authorized physician assistants PAs to prescribe controlled substances that are not listed on the formulary established by the Council on Physician Assistants.
- Subjected ARNPs and PAs to administrative disciplinary actions, such as fines or license suspensions, for violating standards of practice in law relating to prescribing and dispensing controlled substances.
- Prohibited ARNPs from performing certain acts related to prescribing controlled substances, which constitute grounds for denial of license or disciplinary action.
- Required ARNPs and PAs to register as controlled substance prescribing practitioners with the Department, if they prescribe controlled substances to treat chronic nonmalignant pain, and meet other statutory requirements for such registrants.
- Added the American Board of Interventional Pain Physicians and the American Association of Physician Specialists to the list of boards in which a medical specialist may be board certified or board eligible in pain medicine in order to be exempted from the statutory standards of practice.
- Specified that only physicians may prescribe controlled substances in registered pain management clinics.
- Required ARNPs and PAs to comply with the prescribing and dispensing requirements and limitations under the Florida Comprehensive Drug Abuse Prevention and Control Act.
- Made conforming changes to various statutes to recognize the new prescribing authority for ARNPs and PAs.
- Reenacted sections of law to implement changes being made by the bill.

The analysis is drafted to the committee substitute.

STORAGE NAME: h0281d.HHSC PAGE: 11