

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 281 Prescription Medication
SPONSOR(S): 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		Castagna	Calamas

SUMMARY ANALYSIS

Currently, physician assistants (PAs) are authorized to order medicinal drugs for a hospitalized patient of their supervising physician. Florida law does not authorize advanced registered nurse practitioners (ARNPs) to do the same.

HB 281 authorizes ARNPs, acting under the supervision of a physician, to order medications, including controlled substances, for a patient in a facility licensed under ch. 395, F.S., including hospitals, ambulatory surgical centers, and mobile surgical facilities. The bill amends the Pharmacy Act in chapter 465, F.S., and the Controlled Substances Act in chapter 893, F.S., to exempt from the definition of prescription an order for medication that is dispensed in a facility licensed under chapter 395, F.S., to a patient.

The bill appears to have no fiscal impact on state or local governments.

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

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.¹ PAs are governed under the respective physician practice acts for medical doctors (MDs) and doctors of osteopathic medicine (DOs).² 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

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).

Supervising Physician

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 that responsible supervision of a PA is the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. The following factors are used to determine if PA supervision is adequate:

- The complexity of the task;
- The risk to the patient;
- The background, training and skill of the PA;
- The adequacy of the direction in terms of its form;
- The setting in which the tasks are performed;
- The availability of the supervising physician;
- The necessity for immediate attention; and
- The 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.⁹ 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.

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.

⁹ Supra 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.

¹² 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.

¹³ In 2013, ss.458.347 and 459.022, F.S., were amended to clarify that a PA is authorized to order controlled substances for hospitalized patients.

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 is an advanced registered nurse practitioner (ARNP),¹⁶ and is categorized as a certified nurse practitioner, certified nurse midwife, or certified registered nurse anesthetist.¹⁷ 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.¹⁸

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 board-approved nursing specialty board.¹⁹

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 \$300,000.²⁰

Supervising Physician

Under s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in a written physician protocol filed with the Board.²¹ 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:

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 S. 464.003(3), F.S.

¹⁷ S. 464.012(4), F.S.

¹⁸ S. 464.012, F.S.

¹⁹ 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.

²⁰ Rule 64B9-4.002(5), F.A.C.

²¹ 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.

- 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.²²

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.²³

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.²⁴

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.²⁵

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 the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances.²⁶

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.²⁷ The Act includes provisions on required

²² SS. 458.348(4)(e), and 459.025(3)(e), F.S.

²³ Rule 64B9-4.010, F.A.C.

²⁴ 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.

²⁵ SS. 893.02(21), F.S., and 893.05(1), F.S.

²⁶ Drug Enforcement Administration, Office of Diversion Control, *Controlled Substance Schedules*, available at www.deadiversion.usdoj.gov/21cfr/cfr/2108cfr.htm (last visited March 14, 2015).

²⁷ 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.

protocols for prescribing and administration of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.²⁸

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the federal Drug Enforcement Administration (DEA).²⁹ Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.³⁰ 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. Registration numbers must be renewed every three years.³¹

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, serves to enforce the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.³²

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.³³ The DEA provides that a controlled substance prescription may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice;
- 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.³⁴

Effect of Proposed Changes

HB 281 permits an ARNP to order medications and controlled substances for hospitalized patients, if acting within the framework of an established protocol with a licensed physician. Such permission is limited to ordering medications and controlled substances in a licensed facility under chapter 395, F.S. The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities. The bill also clarifies the authority of a PA, delegated by a supervising physician, to order medications for administration to the physician's patient in a facility licensed under chapter 395 F.S.

The bill amends s. 465.003, F.S., to clarify that the term "prescription" does not include an "order" that is dispensed for administration to a patient in a facility licensed under ch. 395, F.S. The bill clarifies that the sale of medicinal drugs dispensed as a prescription is eligible for the sales tax exemption under s. 212.08, F.S.

²⁸ SS. 893.04, F.S., and 893.05, F.S.

²⁹ U.S. Department of Justice, Drug Enforcement Administration, Office of Diversion Control, *Questions & Answers-Registration*, available at <http://www.deadiversion.usdoj.gov/drugreg/faq.htm#> (last visited on March 14, 2015).

³⁰ Drug Enforcement Administration, *Practitioners Manual- Section II*, available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section2.htm> (last visited March 16, 2015).

³¹ Id..

³² Drug Enforcement Administration, *About Us*, available at <http://www.deadiversion.usdoj.gov/Inside.html> (last visited March 16, 2015).

³³ Drug Enforcement Administration, *Practitioner's Manual-Section V*, available at <http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section5.htm> (last visited March 14, 2015).

³⁴ Id.

The bill amends several sections of the Controlled Substances Act to clarify the difference between a prescription and an order in a facility licensed under chapter 395, F.S. In s. 893.02, F.S., the definition of prescription is amended to clarify that a prescription does not include an order that is dispensed for administration to a patient in a facility licensed under ch. 395, F.S. The bill authorizes a PA or ARNP, acting under the supervision of a physician, to order a controlled substance for administration to a patient in a facility licensed under chapter 395, F.S.

The bill makes other technical changes to conform statutory language to changes made by the bill.

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

B. SECTION DIRECTORY:

Section 1: Amends s. 458.347, F.S., relating to physician assistants.

Section 2: Amends s. 459.022, F.S., relating to physician assistants.

Section 3: Amends s. 464.012, F.S., relating to certification of advanced registered nurse practitioners, fees.

Section 4: Amends s. 465.003, F.S., relating to definitions.

Section 5: Amends s. 465.187, F.S., relating to the sale of medicinal drugs.

Section 6: Amends s. 893.02, F.S., relating to definitions.

Section 7: Amends s. 893.04, F.S., relating to pharmacists and practitioner.

Section 8: Amends s. 893.05, F.S., relating to practitioners and persons administering controlled substances in their absence.

Section 9: 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:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. 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:

None.

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. The analysis is drafted to the committee substitute.