

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Committee on Finance and Tax

BILL: CS/SB 532

INTRODUCER: Health Policy Committee and Senator Grimsley

SUBJECT: Ordering of Medication

DATE: April 10, 2015

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Harper/Stovall</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Gross</u>	<u>Diez-Arguelles</u>	<u>FT</u>	<u>Pre-meeting</u>
3.	_____	_____	<u>AP</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 532 provides express authority for an advanced registered nurse practitioner to order any medication for administration to a patient in a hospital, ambulatory surgical center, or mobile surgical facility within the framework of an established protocol. The bill provides express authority in ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, for a supervisory physician to authorize a physician assistant or an advanced registered nurse practitioner to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, or mobile surgical facility.

The bill also makes changes in ch. 212, F.S., relating to tax exemptions, ch. 465, F.S., relating to pharmacy, and ch. 893, F.S., relating to drug abuse prevention and control, to clarify the distinction between a prescription and an order for administration.

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

II. Present Situation:

Regulation of Physician Assistants in Florida

Chapter 458, F.S., sets forth the provisions for the regulation of the practice of medicine by the Board of Medicine. Chapter 459, F.S., similarly sets forth the provisions for the regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine. Physician assistants

(PAs) are regulated by both boards. Licensure of PAs is overseen jointly by the boards through the Council on Physician Assistants.¹

Physician assistants are trained and required by statute to work under the supervision and control of medical physicians or osteopathic physicians.² The Board of Medicine and the Board of Osteopathic Medicine have adopted rules that set out the general principles a supervising physician must use in developing the scope of practice of the PA under both direct³ and indirect⁴ supervision. A supervising physician's decision to permit a PA to perform a task or procedure under direct or indirect supervision must be based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient. The supervising physician must be certain that the PA is knowledgeable and skilled in performing the tasks and procedures assigned.⁵ Each physician or group of physicians supervising a licensed PA must be qualified in the medical areas in which the PA is to perform and must be individually or collectively responsible and liable for the performance and the acts and omissions of the PA.⁶

Current law allows a supervisory physician to delegate to a licensed PA the authority to prescribe or dispense any medication used in the physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials.⁷ However, Florida law does allow a supervisory physician to delegate to a licensed PA the authority to order any medication, which would include controlled substances, general anesthetics, and radiographic contrast materials, for a patient of the physician during the patient's stay in a facility licensed under ch. 395, F.S.^{8,9}

Regulation of Advanced Registered Nurse Practitioners in Florida

Chapter 464, F.S., governs the licensure and regulation of nurses in Florida. Nurses are licensed by the Department of Health and are regulated by the Board of Nursing.¹⁰

¹ The council consists of three physicians who are members of the Board of Medicine; one physician who is a member of the Board of Osteopathic Medicine; and a physician assistant appointed by the State Surgeon General. (*See* ss. 458.347(9) and 459.022(9), F.S.)

² Sections 458.347(4) and 459.022(4), F.S.

³ "Direct supervision" requires the physician to be on the premises and immediately available. (*See* Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.)

⁴ "Indirect supervision" refers to the easy availability of the supervising physician to the physician assistant, which includes the ability to communicate by telecommunications, and requires the physician to be within reasonable physical proximity. (*See* Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.)

⁵ Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

⁶ Sections 458.347(3) and 459.022(3), F.S.

⁷ Sections 458.347(4)(e) and (f)1. and 459.022(4)(e), F.S.

⁸ Section 458.347(4)(g)

⁹ *See* s. 395.002(16), F.S. The facilities licensed under ch. 395, F.S., are hospitals, ambulatory surgical centers, and mobile surgical facilities.

¹⁰ The Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. Seven of the 13 members must be nurses who reside in Florida and have been engaged in the practice of professional nursing for at least 4 years. Of those seven members, one must be an advanced registered nurse practitioner, one a nurse educator at an approved nursing program, and one a nurse executive. Three members of the BON must be licensed practical nurses who reside in the state and have engaged in the practice of practical nursing for at least 4 years. The remaining three members must be Florida residents who have never been licensed as nurses and are in no way connected to the practice of nursing, any health care facility, agency, or insurer. Additionally, one member must be 60 years of age or older. (*See* s. 464.004(2), F.S.)

An advanced registered nurse practitioner (ARNP) is a licensed nurse who is certified in advanced or specialized nursing.¹¹ Florida recognizes three types of ARNP: nurse practitioner (NP), certified registered nurse anesthetist (CRNA), and certified nurse midwife (CNM).¹² To be certified as an ARNP, a nurse must hold a current license as a registered nurse¹³ and submit proof to the Board of Nursing that he or she meets one of the following requirements:¹⁴

- Satisfactory completion of a formal postbasic educational program of specialized or advanced nursing practice;
- Certification by an appropriate specialty board;¹⁵ or
- Graduation from a master's degree program in a nursing clinical specialty area with preparation in specialized practitioner skills.
- Advanced or specialized nursing acts may only be performed under protocol of a supervising physician. Within the established framework of the protocol, an ARNP may:¹⁶
- Monitor and alter drug therapies.
- Initiate appropriate therapies for certain conditions.
- Order diagnostic tests and physical and occupational therapy.

The statute further describes additional acts that may be performed within an ARNP's specialty certification (CRNA, CNM, and NP).¹⁷

Advanced registered nurse practitioners must meet financial responsibility requirements, as determined by rule of the Board of Nursing, and the practitioner profiling requirements.¹⁸ The Board of Nursing, currently, requires ARNPs to carry 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 in the same amounts payable to the ARNP.¹⁹

Florida does not allow ARNPs to prescribe controlled substances.²⁰ However, s. 464.012(4)(a), F.S., provides express authority for a CRNA to order certain controlled substances "to the extent authorized by established protocol approved by the medical staff of the facility in which the anesthetic service is performed."

¹¹ "Advanced or specialized nursing practice" is defined as the performance of advanced-level nursing acts approved by the Board of Nursing which, by virtue of postbasic specialized education, training and experience, are appropriately performed by an advanced registered nurse practitioner. (*See* s. 464.003(2), F.S.)

¹² Section 464.003(3), F.S. Florida certifies clinical nurse specialists as a category distinct from advanced registered nurse practitioners. (*See* ss. 464.003(7) and 464.0115, F.S.)

¹³ Practice of professional nursing. (*See* s. 464.003(20), F.S.)

¹⁴ Section 464.012(1), F.S.

¹⁵ Specialty boards expressly recognized by the Board of Nursing include: Council on Certification of Nurse Anesthetists, or Council on Recertification of Nurse Anesthetists; American College of Nurse Midwives; American Nurses Association (American Nurses Credentialing Center); National Certification Corporation for OB/GYN, Neonatal Nursing Specialties; National Board of Pediatric Nurse Practitioners and Associates; National Board for Certification of Hospice and Palliative Nurses; American Academy of Nurse Practitioners; Oncology Nursing Certification Corporation; American Association of Critical-Care Nurses Adult Acute Care Nurse Practitioner Certification. (*See* Rule 64B9-4.002(2), F.A.C.)

¹⁶ Section 464.012(3), F.S.

¹⁷ Section 464.012(4), F.S.

¹⁸ Sections 456.0391 and 456.041, F.S.

¹⁹ Rule 64B9-4.002(5), F.A.C.

²⁰ Sections 893.02(21) and 893.05(1), F.S.

Definitions related to the Ordering of Medicinal Drugs

Chapter 464, F.S., does not contain a definition of the terms “order” or “prescribe.” Chapter 465, F.S., relating to pharmacy, defines “prescription” as “any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist.”²¹ “Dispense” is defined as “the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent.”²² “Administration” is defined as “the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.”²³ Chapter 893, F.S., relating to drug abuse prevention and control, contains similar definitions.²⁴

ARNP Petition for Declaratory Statement

On January 22, 2014, a petition for declaratory statement²⁵ was filed with the Board of Nursing which asked “Can ARNPs legally order narcotics for patients we treat in the institution with written protocols from our attending Doctors [sic]?”²⁶ The petition noted that prior to January 1, 2014, ARNPs ordered controlled substances for patients. Effective January 1, 2014, the hospital disallowed the practice and required all ARNPs to get an order from a physician. The hospital cited passage of legislation in 2013 which clarified the authority of physician assistants to order controlled substances, but did not address the authority of ARNPs.²⁷ The Board of Nursing dismissed the petition finding that it failed to comply with the requirements of ch. 120 and that it sought an opinion regarding the scope of practice of a category of licensees based on an employer’s policies.

Drug Enforcement Agency Registration

An individual practitioner²⁸ who is an agent or employee of another practitioner (other than a mid-level practitioner²⁹) registered to dispense controlled substances, may, when acting in the normal course of business or employment, administer or dispense (other than by issuance of a prescription) controlled substances if and to the extent authorized by state law, under the registration of the employer or principal practitioner in lieu of being registered himself or herself.³⁰

²¹ Section 465.003(14), F.S.

²² Section 465.003(6), F.S.

²³ Section 465.003(1), F.S.

²⁴ See ss. 893.02(1), 893.02(7), and 893.02(22), F.S.

²⁵ A declaratory statement is an agency’s opinion regarding the applicability of a statutory provision, rule, or agency order to a petitioner’s set of circumstances. (*See* s. 120.565(1), F.S.)

²⁶ Petition for Declaratory Statement filed by Carolann Robley ARNP, MSN, BC, FNP (on file with the Senate Committee on Health Policy).

²⁷ *See* ch. 2013-127, Laws of Fla.

²⁸ “Practitioner” means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States of the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research. (21 U.S.C. s.802(21))

²⁹ Examples of mid-level practitioners include, but are not limited to: nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

³⁰ 21 C.F.R. 1301.22.

Health care practitioners who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:

- The dispensing, administering, or prescribing is in the usual course of professional practice;
- The practitioner is authorized to do so by the state in which he or she practices;
- The hospital or other institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state;
- The practitioner acts only within the scope of employment in the hospital or other institution;
- The hospital or other institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner; and
- The hospital or other institution maintains a current list of internal codes and the corresponding practitioner.³¹

Tax Exemption for the Sale of Medicinal Drugs

Section 465.187, F.S., makes the sale of drugs dispensed “upon the order of a practitioner” exempt from sales tax as provided in s. 212.08, F.S.

Section 212.08(2)(a), F.S., exempts from taxation “medical products and supplies or medicine dispensed according to an individual prescription or prescriptions written by a prescriber authorized by law to prescribe medicinal drugs”

Section 212.08(2)(b)4. defines “prescription” using language that is virtually identical to the language in the definition of “prescription” in s. 465.003(14), F.S.

Currently, the Department of Revenue construes the provision in s. 212.08, F.S., as exempting the sale of medicine that is dispensed for outpatient use or administration within a licensed healthcare facility.³²

III. Effect of Proposed Changes:

Section 1 amends s. 212.08(2)(a) and (b), F.S., related to medical sales tax exemptions, to conform to changes made elsewhere in the bill. The bill revises the definition of “prescription” and clarifies that any medical products and supplies or medicine dispensed according to “an order for administration” are exempt from sales tax under ch. 212, F.S. These technical changes do not alter the current exemption status of medical products and supplies or medicine as described in s. 212.08(2)(a) and (b), F.S.

Sections 2 and 3 make conforming changes to ss. 458.347(4)(g) and 459.022(4)(f), F.S., related to the authority of a PA to order medications, but does not alter the authority of supervisory physicians or PAs.

³¹ *Id.*; See also U.S. Department of Justice, Drug Enforcement Administration, *Practitioner’s Manual*, 27 (2006), available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited Mar. 27, 2015).

³² Conversation with Mark Zych, Director of Technical Assistance and Dispute Resolution, Florida Department of Revenue (Jan. 20, 2015).

Sections 4 and 8 provide express authority for an ARNP to order any medication for administration to a patient in a hospital, ambulatory surgical center, or mobile surgical facility within the framework of an established protocol. The bill also provides express authority in ch. 893, F.S., for a supervisory physician to authorize a PA or ARNP to order controlled substances for administration to a patient in a hospital, ambulatory surgical center, or mobile surgical facility.

Sections 5, 6, and 7 clarify the distinction between a prescription and an order for administration by amending the definition of “prescription” in chs. 465 and 893, F.S., to exclude an order that is dispensed for administration and making conforming changes in s. 893.04, F.S. The bill also revises the definition of “administer” in ch. 893, F.S. to include the term “administration.”

Sections 9 - 14 reenact various sections of Florida law as required to incorporate amendments made thereto.

Section 15 provides a July 1, 2015, effective date.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Physicians who utilize ARNPs to serve hospitalized patients or physicians who supervise ARNPs with a hospital practice, and hospitals that employ ARNPs, may see increased efficiencies if ARNPs can order controlled substances directly without the need for obtaining a physician’s order. These efficiencies include time savings for the practitioners and better utilization of potentially limited space, such as emergency room beds where patients might otherwise wait while a supervising physician is located.

C. Government Sector Impact:

The impact described in V. B., above, would also apply to public hospitals and physicians employed in public hospitals.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 212.08, 458.347, 459.022, 464.012, 465.003, 893.02, 893.04, and 893.05.

This bill reenacts the following sections of the Florida Statutes: 112.0455(5)(i), 381.986(7)(b), 400.462(26), 401.445(1), 409.906(18), 409.9201(1)(a), 440.102(1)(l), 458.331(1)(pp), 459.015(1)(rr), 465.014(1), 465.015(2)(c), 465.015(3), 465.016(1)(s), 465.022(5)(j), 465.023(1)(h), 465.1901, 499.003(43), 499.0121(14), 766.103(3), 768.36(1)(b), 810.02(3)(f), 812.014(2)(c), 831.30(1), 856.015(1)(c), 893.0551(3)(d), 893.0551(3)(e), 944.47(1)(a), 951.22(1), 985.711(1)(a), 1003.57(1)(i), and 1006.09(8).

IX. Additional Information:**A. Committee Substitute – Statement of Changes:**

(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on March 31, 2015:

The committee substitute amends s. 212.08, F.S., related to medical sales tax exemptions, to conform to changes made elsewhere in the bill. The CS revises the definition of “prescription” and clarifies that any medical products and supplies or medicine dispensed according to “an order for administration” are exempt from sales tax under ch. 212, F.S.

B. Amendments:

None.