

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 Health Policy

BILL: SB 614
INTRODUCER: Senator Grimsley
SUBJECT: Drug Prescription by Advanced Registered Nurse Practitioners and Physician Assistants
DATE: March 13, 2015 REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Stovall	HP	Pre-meeting
2.			RI	
3.			RC	

I. Summary:

SB 614 authorizes physician assistants (PAs) and advanced registered nurse practitioners (ARNPs) to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs.

The bill requires PAs and ARNPs who prescribe and dispense controlled substances to comply with similar prescribing and dispensing obligations as those required for physicians. These PAs and ARNPs are subject to similar disciplinary or other sanctions as those for physicians.

The bill 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 in s. 456.44, F.S., relating to prescribing controlled substances for the treatment of chronic nonmalignant pain.

Several statutes are amended to recognize that a PA or an ARNP may be a prescriber of controlled substances. These include statutes relating to the state employees' prescription drug program, pilot licensure, and criminal probation.

II. Present Situation:

Unlike all other states, Florida does not allow ARNPs to prescribe controlled substances and is one of two states that does not allow PAs to prescribe controlled substances.¹ The states have varying permissions with respect to the Schedules² from which an ARNP or PA may prescribe as well as the

¹ DEA Diversion Control, U.S. Department of Justice, *Mid-Level Practitioners Authorization by State*, (last updated March 12, 2015), available at: http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf, (last visited Mar. 13, 2015). Kentucky does not allow PAs to prescribe controlled substances.

² Controlled substances are assigned to Schedules I - V based on their accepted medical use and potential for abuse.

additional functions, such as dispensing, administering, or handling samples, that an ARNP or PA may perform.

According to a recent study commissioned by the Safety Net Hospital Alliance of Florida:³

Florida's total current supply of primary care physicians falls short of the number needed to provide a national average level of care by approximately 6 percent. Under a traditional definition of primary care specialties (i.e., general and family practice, general internal medicine, general pediatrics and geriatric medicine) supply falls short of demand by approximately 3 percent. [Based on simulation models, the report concludes that] over the next several years, this shortfall will grow slightly as more people obtain insurance coverage as mandated by the federal Affordable Care Act. However, if current trends continue, this shortfall should disappear within a decade. While supply may be adequate at the state level to provide a national average level of care, there is substantial geographic variation in adequacy of care.

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 are regulated by both boards. Licensure of PAs is overseen jointly by the boards through the Council on Physician Assistants.⁴ During state fiscal year 2013-2014, there were 6,118 in-state, actively licensed PAs in Florida.⁵

Physician assistants are trained and required by statute to work under the supervision and control of medical physicians or osteopathic physicians.⁶ 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 direct⁷ and indirect⁸ 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

³ IHS Global Inc., *Florida Statewide and Regional Physician Workforce Analysis: Estimating Current and Forecasting Future Supply and Demand*, (January 28, 2015), as presented to the Senate Health Policy Committee on Feb. 17, 2015). The report is available in the committee meeting packet at: http://www.flsenate.gov/PublishedContent/Committees/2014-2016/HP/MeetingRecords/MeetingPacket_2854_4.pdf, (last visited March 14, 2014).

⁴ 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. (ss. 458.348(9) and 459.022(9), F.S.).

⁵ Florida Department of Health, Division of Medical Quality Assurance, *Annual Report and Long Range Plan Fiscal Year 2013-2014*, p. 14, available at: <http://mqawebteam.com/annualreports/1314/#1/z>, (last visited Mar. 14, 2015).

⁶ Sections 458.347(4) and 459.022(4), F.S.

⁷ "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.)

⁸ "Indirect supervision" requires the physician to be within reasonable physical proximity. (Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.)

knowledgeable and skilled in performing the tasks and procedures assigned.⁹ 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 is individually or collectively responsible and liable for the performance and the acts and omissions of the PA.¹⁰

Current law allows a supervisory physician to delegate authority to prescribe or dispense any medication used in the physician's practice, except controlled substances, general anesthetics, and radiographic contrast materials.¹¹ However, the law allows a supervisory physician to delegate authority to a PA 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.¹²

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.¹³ During state fiscal year 2013-2014, there were 16,887 in-state, actively licensed ARNPs in Florida¹⁴

An ARNP is a licensed nurse who is certified in advanced or specialized nursing.¹⁵ Florida recognizes three types of ARNP: nurse practitioner (NP), certified registered nurse anesthetist (CRNA), and certified nurse midwife (CNM).¹⁶ To be certified as an ARNP, a nurse must hold a current license as a registered nurse¹⁷ and submit proof to the Board of Nursing that he or she meets one of the following requirements:¹⁸

- Satisfactory completion of a formal post basic educational program of specialized or advanced nursing practice;
- Certification by an appropriate specialty board;¹⁹ or

⁹ Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

¹⁰ Sections 458.347(3) and (15) and 459.022(3) and (15), F.S.

¹¹ Sections 458.347(4)(e) and (f)1. and 459.022(4)(e), F.S.

¹² See s. 395.002(16), F.S. The facilities licensed under chapter 395 are hospitals, ambulatory surgical centers, and mobile surgical facilities.

¹³ 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.

¹⁴ *Supra* note 4. Certified Nurse Specialists account for 24 of the in-state actively licensed ARNPs.

¹⁵ "Advanced 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. (s. 464.003(2), F.S.)

¹⁶ 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.)

¹⁷ Practice of professional nursing. (See s. 464.003(20), F.S.)

¹⁸ Section 464.012(1), F.S.

¹⁹ 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;

- Completion of a master's degree program in the appropriate clinical specialty with preparation in specialty-specific 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:²⁰

- 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).²¹

ARNPs must meet financial responsibility requirements, as determined by rule of the Board of Nursing, and the practitioner profiling requirements.²² The Board of Nursing requires 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.²³

Florida does not allow ARNPs to prescribe controlled substances.²⁴ 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."

Educational Preparation

Physician Assistants²⁵

PA education is modeled on physician education. PA programs are accredited by the Accreditation Review Commission on Education for the Physician Assistant. All PA programs must meet the same set of national standards for accreditation. PA program applicants must complete at least 2 years of college courses in basic science and behavioral science as a prerequisite to PA training. The average length of PA education programs is about 26 months. Students begin their course of study with a year of basic medical science classes (anatomy, pathophysiology, pharmacology, physical diagnosis, etc.) Then the PA students enter the clinical phase of training, which includes classroom instruction and clinical rotations in medical and surgical specialties. PA students complete at least 2,000 hours of supervised clinical practice by the time they graduate.

All PA educational programs include pharmacology courses, and nationally, the average amount of required formal classroom instruction in pharmacology is 75 hours. This does not include instruction

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. (Rule 64B9-4.002(2), F.A.C.)

²⁰ Section 464.012(3), F.S.

²¹ Section 464.012(4), F.S.

²² Sections 456.0391 and 456.041, F.S.

²³ Rule 64B9-4.002(5), F.A.C.

²⁴ Sections 893.02(21) and 893.05(1), F.S.

²⁵ See American Academy of Physician Assistants, *PAs as Prescribers of Controlled Medications – Issue Brief*, (June 2014), (on file with the Senate Committee on Health Policy).

in pharmacology that students receive during clinical medicine coursework and clinical clerkships. Based on national data, the mean amount of total instruction in clinical medicine is 358.9 hours. And the average length of required clinical clerkships is 48.5 weeks. A significant percentage of time is focused on patient management, including pharmacotherapeutics. Coursework in pharmacology addresses, but is not limited to, pharmacokinetics, drug interactions, adverse effects, contraindications, indications, and dosage.

Advanced Registered Nurse Practitioners²⁶

Applicants for Florida licensure who graduated on or after October 1, 1998, must have completed requirements for a master's degree or post-master's degree.²⁷ Applicants who graduated before that date, may be or may have been eligible through a certificate program.²⁸

The curriculum of a program leading to an advanced degree must include, among other things:

- Theory and directed clinical experience in physical and biopsychosocial assessment.
- Interviewing and communication skills relevant to obtaining and maintaining a health history.
- Pharmacotherapeutics, including selecting, prescribing, initiating, and modifying medications in the management of health and illness.
- Selecting, initiating and modifying diets and therapies in the management of health and illness.
- Performance of specialized diagnostic tests that are essential to the area of advanced practice.
- Differential diagnosis pertinent to the specialty area.
- Interpretation of laboratory findings.
- Management of selected diseases and illnesses.
- Professional socialization and role realignment.
- Legal implications of the advanced nursing practice and nurse practitioner role.
- Health delivery systems, including assessment of community resources and referrals to appropriate professionals or agencies.
- Providing emergency treatments.

The program must provide a minimum of 500 hours of preceptorship/supervised clinical experience²⁹ in the performance of the specialized diagnostic procedures that are essential to practice in that specialty area.

The curriculum of a nurse practitioner certificate program is based on the philosophy and objectives of the program. It must be at least one academic year in length and include theory in the biological, behavioral, nursing, and medical sciences relevant to the area of advanced practice. It must also include clinical experience with a qualified preceptor. At a minimum, the program must include:

- Theory and directed clinical experience in comprehensive physical and biopsychosocial assessment.
- Interviewing and communication skills.
- Eliciting, recording, and maintaining a health history.

²⁶ Rule 64B9-4.003, F.A.C.

²⁷ Florida Board of Nursing: ARNP Licensure Requirements, <http://floridasnursing.gov/licensing/advanced-registered-nurse-practitioner/>, (last visited Mar. 13, 2014).

²⁸ *Id.*, and s. 464.012(1), F.S.

²⁹ Preceptorship/supervised clinical experience must be under the supervision of a qualified preceptor, who is defined as a practicing certified ARNP, a licensed medical doctor, osteopathic physician, or a dentist. *See* Rule 64B9-4.001(13), F.A.C.

- Interpretation of laboratory findings.
- Pharmacotherapeutics, to include the initiation, selection, and modification of selected medications.
- Initiation and modification of selected therapies.
- Nutrition, including modifications of diet.
- Providing emergency treatments.
- Assessment of community resources and referrals to appropriate professionals or agencies.
- Role realignment.
- Legal implications of the ARNP role.
- Health care delivery systems.
- Management of selected diseases and illnesses.

The program must provide a minimum of 500 hours of supervised clinical experience in the performance of the specialized diagnostic procedures that are essential to practice in that specialty area.

Drug Enforcement Agency Registration

The Drug Enforcement Agency (DEA) registration grants practitioners federal authority to handle controlled substances. However, the DEA registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located.³⁰

According to requirements of the DEA, a prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner,³¹ or other registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice.
- Registered with DEA or exempted from registration (that is, Public Health Service, Federal Bureau of Prisons, or military practitioners).
- An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered provided that additional requirements are met.³²

These requirements include:

- 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

³⁰ U.S. Department of Justice, Drug Enforcement Administration, *Practitioner's Manual*, 27 (2006), p. 7, available at: http://www.dea.gov/diversion/usdoj/pubs/manuals/pract/pract_manual012508.pdf (last visited Mar. 13, 2015)

³¹ Examples of mid-level practitioners include, but are not limited to: nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

³² *Supra* note 27, at p. 18.

- The hospital or other institution maintains a current list of internal codes and the corresponding practitioner.³³

III. Effect of Proposed Changes:

SB 614 authorizes physician assistants (PAs) licensed under the Medical Practice Act or the Osteopathic Medical Practice Act and advanced registered nurse practitioners (ARNPs) certified under part I of the Nurse Practice Act to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs. The bill imposes similar practice and disciplinary standards on PAs and ARNPs as those applicable to physicians.

For PAs, this is accomplished by removing controlled substances from the formulary of medicinal drugs that a PA may not prescribe in the Medical Practice Act. (Section 7) The Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act, so no changes are made to that act.³⁴ Also, a PA licensed under either medical practice act is added to the definition of practitioner in ch. 893, F.S. This definition requires the practitioner to hold a valid federal controlled substance registry number. (Section 10) Disciplinary standards that are applicable to physicians are already applicable to PAs pursuant to ss. 458.347(7)(g) and 459.022(7)(g), F.S., so no additional amendments are needed for disciplinary and enforcement action for violations of the applicable practice act relating to controlled substances.

For ARNPs, the authorization to prescribe controlled substances is accomplished by revising the authority pertaining to drug therapies. The bill authorizes an ARNP to prescribe, dispense, administer, or order any drug, which would include controlled substances. (Section 8) Additionally, an ARNP is added to the definition of practitioner in ch. 893, F.S. This definition requires the practitioner to hold a valid federal controlled substance registry number. (Section 10)

ARNP disciplinary sanctions are added to the bill in s. 456.072, F.S., (Section 5) to mirror a physician's sanctions for prescribing or dispensing a controlled substance other in the course of professional practice or failing to meet practice standards. Additional acts for which discipline may be taken against an ARNP relating to practicing with controlled substances that are added to the Nurse Practice Act (Section 8) include:

- Presigning blank prescription forms.
- Prescribing a Schedule II for office use.
- Prescribing, dispensing, or administering an amphetamine or sympathomimetic amine drug, except for specified conditions.
- Prescribing, dispensing, or administering certain hormones for muscle-building or athletic performance.
- Promoting or advertising a pharmacy on a prescription form unless the form also states that the prescription may be filled as the pharmacy of your choice.
- Prescribing, dispensing, or administering drugs, including controlled substances, other than in the course of his or her professional practice.

³³ *Supra* note 27, at p. 12.

³⁴ Section 459.022(4)(e), F.S.

- Prescribing, dispensing, or administering a controlled substance to himself or herself.
- Prescribing, dispensing, or administering laetrile.
- Dispensing a controlled substance listed in Schedule II or Schedule III in violation of the requirements for dispensing practitioners in the Pharmacy Practice Act.
- Promoting or advertising controlled substances.

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 is required to designate himself or herself as a controlled substance prescribing practitioner on his or her practitioner profile maintained by the DOH. Currently, PAs do not have practitioner profiles so the DOH will need to develop a profile for PAs to comply with this requirement.³⁵ (Section 6)

Under current law, a medical specialist who is board certified or board eligible in pain medicine by certain boards is exempted from the statutory standards of practice in s. 456.44, F.S., relating to prescribing controlled substances for the treatment of chronic nonmalignant pain. Two additional boards are added to that list. The boards are the American Board of Interventional Pain Physicians and the American Association of Physician Specialists. (Section 6)

Sections 1 – 4, and 11 amend various statutes to authorize or recognize that a PA or an ARNP may be a prescriber of controlled substances as follows:

- Section 110.12315, F.S., relating to the state employees' prescription drug program, authorizes ARNPs and PAs to prescribe brand name drugs which are medically necessary or are included on the formulary of drugs which may not be interchanged.
- Section 310.071, F.S., relating to deputy pilot certification; s. 310.073, F.S. relating to state pilot licensing; and s. 310.081, F.S., relating to licensed state pilots and certified deputy pilots, allow for the presence of a controlled substance in the pilot's drug test results, which was prescribed by an ARNP or PA whose care the pilot is under, as a part of the annual physical examination required for initial certification, initial licensure, and certification and licensure retention.
- Section 948.03, F.S., relating to terms and condition of criminal probation, includes an ARNP and PA as an authorized prescriber of drugs or narcotics that a person on probation may lawfully possess.

Additional conforming and grammatical changes are made in the bill.

The bill takes effect on July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

³⁵ Department of Health, *Senate Bill 614 Analysis* (Feb. 13, 2015) (on file with the Senate Committee on Health Policy).

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:

PAs and ARNPs who are authorized by the supervising physician or under a protocol to prescribe controlled substances may be able to care for more patients due to reduced coordination with the supervising physician each time a controlled substance is recommended for a patient. 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 involvement of a physician prescribing a needed controlled substance for treatment. Any such impacts are indeterminate.

C. Government Sector Impact:

The Department of Health indicates that it will incur costs for rulemaking, modifications to develop a profile for PAs, and workload impacts related to additional complaints and investigations. These costs can be absorbed within current resources and budget authority.³⁶

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill is silent with respect to whether a PA or an ARNP may prescribe controlled substances in a pain-management clinic. Since it is not prohibited, given the authorities in this bill, it appears that one could lawfully do so. Currently in ss. 458.3265 and 459.0137, F.S., relating to the regulation of pain-management clinics, specific responsibilities are assigned to each physician practicing in a pain-management clinic. These responsibilities include, but are limited to, ensuring compliance with requirements for certain facility and physical operations, infection control, and health and safety. These responsibilities are not applied to ARNPs.

Similarly, the two medical practice acts include as grounds for disciplinary action, failing to timely notify the department of the theft of prescription blanks from a pain-management clinic or

³⁶ *Supra* note 32.

a breach of other methods for prescribing within 24 hours in s. 458.3265(2)(pp) and s. 459.015(12)(ss). This is not included within the disciplinary grounds for ARNPs. If ARNPs may prescribe controlled substances in a pain-management clinic, consideration should be given to adding this for parity in disciplinary measures.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 110.12315, 310.071, 310.073, 310.081, 456.072, 456.44, 458.347, 464.012, 464.018, 893.02, 948.03, 466.02751, 458.303, 458.3475, 459.022, 459.023, 456.041, 458.348, 459.025, 320.0848, 464.008, 464.009, 464.0205, 775.051, 944.17, 948.001, and 948.101.

IX. Additional Information:

A. Committee Substitute – Statement of Changes:

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

None.

B. Amendments:

None.