

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 Regulated Industries

BILL: CS/CS/SB 614

INTRODUCER: Regulated Industries Committee, Health Policy Committee and Senator Grimsley

SUBJECT: Drug Prescription by Advanced Registered Nurse Practitioners and Physician Assistants

DATE: April 1, 2015 **REVISED:** _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Stovall</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Kraemer</u>	<u>Imhof</u>	<u>RI</u>	<u>Fav/CS</u>
3.	_____	_____	<u>RC</u>	_____

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/CS/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. However, PAs and ARNPs are prohibited from prescribing controlled substances in a pain-management clinic.

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 pilot licensure and criminal probation. Also, a PA and an ARNP are authorized to prescribe brand name drugs when medically necessary under the state employees' prescription drug program.

The bill requires the appointment of a committee to recommend a listing (formulary) of controlled substances that may not be prescribed by ARNPs, or may only be prescribed for certain uses or in limited circumstances. It provides the membership of the committee. If the committee recommends establishment of a controlled substances formulary, the Board of Nursing (board) must initiate rulemaking to adopt it. Future changes to the controlled substances formulary for ARNPs must be justified to the board. If adopted, the formulary will not apply to services that an ARNP may be authorized by the medical staff of a facility to provide, such as the ordering and administration of medication, regional, spinal, and general anesthesia.

The bill requires a hospital to notify each obstetrical physician with privileges at that hospital at least 120 days before it closes its obstetrical department or ceases to provide obstetrical services.

The bill repeals a provision designating certain hospitals as provider hospitals, which have special requirements for cesarean section operations that are paid for by the state, including a review board for such operations.

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 additional functions which may be performed, such as dispensing, administering, or handling samples.

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

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. 28, 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.

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, at page 139 (last visited Mar. 28, 2015).

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 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 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, during the period a physician's patient stays in a hospital, ambulatory surgical center, or mobile surgical facility licensed under ch. 395, F.S.¹²

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. *See* s. 458.347(9), F.S., and s. 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. 28, 2015).

⁶ *See* s. 458.347(4), F.S., and s. 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 and available to communicate by telecommunications. *See* Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

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

¹⁰ *See* s. 458.347(3) and (15), F.S., and s. 459.022(3) and (15), F.S.

¹¹ *See* s. 458.347(4)(e) and (f)1., F.S., and s. 459.022(4)(e), F.S.

¹² *See* s. 395.002(16), F.S.

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 Fiscal Year 2013-2014, there were 16,887 in-state, actively licensed ARNPs in Florida.¹⁴

An ARNP is a licensed nurse who is certified in advanced or specialized nursing.¹⁵ Florida recognizes three types of ARNPs: 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
- 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; and

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 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 *See supra* note 5. Twenty-four ARNPs are also actively licensed as Certified Nurse Specialists (ARNP/CNS).

¹⁵ Section 464.003(2), F.S., defines advanced specialized nursing practice 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 ARNP.

¹⁶ *See* s. 464.003(3), F.S. Florida certifies clinical nurse specialists as a category distinct from ARNPs. (*See* s. 464.003(7), F.S., and s. 464.0115, F.S.).

¹⁷ Section 464.003(20), F.S., defines the practice of professional nursing as actions requiring substantial specialized knowledge, judgment, and nursing skill, based upon psychological, biological, physical, and social sciences principles, including but not limited to the:

- (a) Observation, assessment, diagnosis, planning, intervention, and evaluation of care; health teaching and counseling of the ill, injured, or infirm; and the promotion of wellness, maintenance of health, and prevention of illness of others;
- (b) Administration of medications and treatments as prescribed or authorized by a duly licensed practitioner authorized by the laws of this state to prescribe such medications and treatments; and
- (c) Supervision and teaching of other personnel in the theory and performance of any of these acts.

¹⁸ *See* s. 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; 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; and the American Association of Critical-Care Nurses Adult Acute Care Nurse Practitioner Certification. *See* Rule 64B9-4.002(3), F.A.C.

²⁰ *See* Section 464.012(3), F.S.

- 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 authorize 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 Assistants

The American Academy of Physician Assistants has summarized physician assistant education as follows:²⁵

PA program applicants must complete at least two years of college courses in basic science and behavioral science as prerequisites to PA training. This is analogous to premedical studies required of medical students. PA students often take classes and do clinical rotations side by side with medical students.

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.) After the science classroom work, PA students enter the clinical phase of training. This includes classroom instruction and clinical rotations in medical and surgical specialties (family medicine, internal medicine, obstetrics and gynecology, pediatrics, general surgery, emergency medicine and psychiatry). Due to these demanding rotation requirements, PA students will have completed at least 2,000 hours of supervised clinical practice by the time they graduate.

PA education is well-structured and focused; it is recognized as highly innovative, efficient and effective. It is competency-based, meaning that students must demonstrate proficiency in various areas of medical knowledge and must meet behavioral and clinical

²¹ See Section 464.012(4), F.S.

²² See s. 456.048, F.S., and s. 456.041, F.S.

²³ See Rule 64B9-4.002(5), F.A.C.

²⁴ See s. 93.02(21), F.S., and s. 893.05(1), F.S.

²⁵ See American Academy of Physician Assistants, *PA Education - Preparation for Excellence – Issue Brief* (March 2014), (on file with the Senate Committee on Regulated Industries), and American Academy of Physician Assistants, *PAAs as Prescribers of Controlled Medications – Issue Brief* (June 2014), (on file with the Senate Committee on Regulated Industries).

learning objectives. Many other professions also offer competency-based degrees, including the MD, DO and DDS.

PA programs are accredited by the independent Accreditation Review Commission on Education for the Physician Assistant (ARC-PA), which is sponsored by the American Medical Association, American Academy of Family Physicians, American College of Surgeons, American Academy of Pediatrics, American College of Physicians, Physician Assistant Education Association and American Academy of Physician Assistants.

Accreditation standards are rigorous, and although all accredited PA programs must meet the same educational standards, they have the flexibility to offer a variety of academic degrees. More than ninety percent of PA programs offer a master's degree. However, graduation from an accredited PA education program remains the definitive credential. Regardless of the degree awarded, only graduates of accredited programs are eligible to sit for the Physician Assistant National Certifying Examination administered by the independent National Commission on Certification of Physician Assistants (NCCPA). PAs must recertify with NCCPA every ten years.

All PA educational programs have pharmacology courses and, nationally, the average amount of required formal classroom instruction in pharmacology is 75 hours. This does not include instruction 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 (the course focus is patient evaluation and management in cardiology, pediatric medicine, obstetrics and gynecology, orthopedics, etc.) is 358.9 hours, and the average length of required clinical clerkships in PA programs is 48.5 weeks. A significant percentage of time is focused on patient management, including pharmacotherapeutics.

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:²⁹

- 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;

²⁶ See Rule 64B9-4.003, F.A.C. for the program guidelines.

²⁷ See Florida Board of Nursing, *ARNP Licensure Requirements* <http://floridasnursing.gov/licensing/advanced-registered-nurse-practitioner/>, (last visited Mar. 28, 2015).

²⁸ *Id.*, and see s. 464.012(1), F.S.

²⁹ See Rule 64B9-4.003, F.A.C. respecting all of the program requirements described in this section.

- 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; and
- Providing emergency treatments.

The program must provide a minimum of 500 hours of preceptorship/supervised clinical experience³⁰ 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;
- 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; and
- 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

³⁰ 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.

those activities that are authorized under state law for the jurisdiction in which the practice is located.³¹

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,³² 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); or
- 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 these additional requirements are met:³³
 - 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.³⁴

III. Effect of Proposed Changes:

CS/CS/SB 614 authorizes physician assistants (PAs) licensed under the Medical Practice Act³⁵ or the Osteopathic Medical Practice Act³⁶ and advanced registered nurse practitioners (ARNPs) certified under the Nurse Practice Act³⁷ to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs.

For PAs, the authorization is accomplished by removing controlled substances from the formulary³⁸ of medicinal drugs that a PA is prohibiting from prescribing.³⁹ The Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act, so no changes are made

³¹ See U.S. Department of Justice, Drug Enforcement Administration, *Practitioner's Manual*, 27 (2006), p. 7, available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited Mar. 28, 2015).

³² Examples of mid-level practitioners include, but are not limited to: nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, and physician assistants.

³³ See *supra* note 31, at p. 18.

³⁴ See *supra* note 31, at p. 12.

³⁵ See ch. 458, F.S.

³⁶ See ch. 459, F.S.

³⁷ See part I, ch. 464, F.S.

³⁸ See s. 458.347(4)(f), F.S. A formulary is a list of medicines.

³⁹ See section 8 of the bill.

to that act.⁴⁰ Also, a PA licensed under either medical practice act is added to the definition of practitioner in ch. 893, F.S., which requires practitioners to hold a valid federal controlled substance registry number.⁴¹

The bill imposes practice and disciplinary standards on PAs and ARNPs similar to those applicable to physicians. Disciplinary standards that are applicable to physicians are already applicable to PAs,⁴² so no additional amendments are needed for violations relating to controlled substances.

For ARNPs, the authorization to prescribe controlled substances is accomplished through revision of existing authority pertaining to drug therapies. The bill authorizes an ARNP to “prescribe, dispense, administer, or order any” drug.⁴³ In addition, the term ARNP is added to the definition of practitioner in ch. 893, F.S., which requires practitioners to hold a valid federal controlled substance registry number.⁴⁴

The bill requires the appointment of a committee⁴⁵ to recommend whether a formulary of controlled substances (controlled substances formulary) that an ARNP may not prescribe, or may prescribe under limited circumstances, is needed to protect the public interest. The committee may recommend a controlled substances formulary applicable to all ARNPs that may be limited by specialty certification, approved uses of controlled substances, or other similar restrictions deemed necessary to protect the public interest.

A controlled substances formulary, if recommended, shall be established by rule, and only the Board of Nursing (board) may add to, delete from, or modify it. Should any change to the controlled substances be requested after adoption, the requestor has the burden of proof to show the board why the change should be made. Notices of any proposed, pending, or adopted changes to the formulary must be posted by the board on its website. Any rulemaking required to implement the committee’s initial recommendation must be initiated by the board no later than October 1, 2015.

If a controlled substances formulary is adopted by board rule, it does not apply to the following acts performed within the ARNP’s specialty under the established protocol approved by the medical staff of the facilities in which the service is performed, which are currently authorized under s. 464.012(4)(a)(3. and 4., F.S.:

- Orders for preanesthetic medications; or
- Ordering and administering regional, spinal, and general anesthesia, inhalation agents and techniques, intravenous agents and techniques, hypnosis, and other protocol procedures

⁴⁰ See Section 459.022(4)(e), F.S.

⁴¹ See section 12 of the bill.

⁴² See s. 458.347(7)(g), F.S., and s. 459.022(7)(g), F.S.

⁴³ See section 10 of the bill.

⁴⁴ See *supra* note 41.

⁴⁵ The committee membership is: three ARNPs, including a certified registered nurse anesthetist, a certified nurse midwife, and a nurse practitioner; at least one physician recommended by the Board of Medicine and one physician recommended by the Board of Osteopathic Medicine, who have experience working with APRNs; and a pharmacist licensed under ch. 465, F.S., who is not also licensed as a physician under ch. 458, F.S., an osteopathic physician under ch. 459, F.S., or an ARNP under ch. 464, F.S. The committee members are selected by the State Surgeon General.

commonly used to render the patient insensible to pain during surgical, obstetrical, therapeutic, or diagnostic clinical procedures.

The bill requires a hospital to notify each obstetrical physician with privileges at that hospital at least 120 days before it closes its obstetrical department or ceases to provide obstetrical services. The bill repeals a provision designating certain hospitals as provider hospitals, which have special requirements for cesarean section operations that are paid for by the state, including a review board for such operations.

Section 456.072(7), F.S. is revised to include disciplinary sanctions against ARNPs which mirror sanctions against physician for prescribing or dispensing a controlled substance other in the course of professional practice or for failing to meet practice standards. Additional acts added to s. 464.018(1)(p), F.S., for which discipline relating to controlled substances may be sought against an ARNP include:

- Presigning blank prescription forms;
- Prescribing a Schedule II drug 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 at the pharmacy of your choice;
- Prescribing, dispensing, or administering drugs, including controlled substances, other than in the course of his or her professional practice.;
- 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; or
- 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 Department of Health.⁴⁶ Currently, PAs do not have practitioner profiles, so the capacity for PA to establish and update practitioner profiles must be developed by the Department of Health so that compliance with this requirement will be possible.⁴⁷

The statutes regulating pain-management clinics under the Medical Practice Act and the Osteopathic Medical Practice Act are amended to limit the prescribing of controlled substances in a pain-management clinic to physicians licensed under those acts (ch. 458, F.S. and ch. 459,

⁴⁶ See section 6 of the bill.

⁴⁷ See Department of Health, *Senate Bill 614 Analysis* (Feb. 13, 2015) (on file with the Senate Committee on Regulated Industries).

F.S.). Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics.⁴⁸

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.⁴⁹ (Section 6)

Sections 1 – 4 and Section 11 of the bill amend these statutes to authorize or recognize that a PA or an ARNP may be a prescriber of controlled substances:

- Section 110.12315, F.S., relating to the state employees' prescription drug program, to authorize 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, regarding the zero tolerance for any controlled substance other than those prescribed by an authorized practitioner, to allow the presence of a controlled substance in the pilot's drug test results, if 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, to include 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. Various sections are re-enacted for the purpose of incorporating amendments made by the bill to those sections.

The bill takes effect on July 1, 2015.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

None.

C. Trust Funds Restrictions:

None.

⁴⁸ See sections 7 and 9 of the bill.

⁴⁹ See section 6 of the bill.

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.⁵⁰

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 110.12315, 310.071, 310.073, 310.081, 395.1051, 456.072, 456.44, 458.3265, 458.347, 459.0137, 464.012, 464.018, 893.02, and 948.03.

This bill re-enacts the following sections of the Florida Statutes: 310.071, 320.0848, 456.041, 456.072, 458.303, 458.331, 458.347, 458.3475, 458.348, 459.015, 459.022, 459.023, 459.025, 464.008, 464.009, 464.018, 464.0205, 465.0158, 466.02751, 775.051, 944.17, 948.001, and 948.101.

This bill repeals section 383.336 of the Florida Statutes.

⁵⁰ See *supra* note 46.

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

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

CS/CS by Regulated Industries on March 31, 2015:

CS/CS/SB 614 requires the appointment of a committee by the State Surgeon General to recommend a listing (formulary) of controlled substances that may not be prescribed by ARNPs, or may only be prescribed for certain uses or in limited circumstances. It provides the membership of the committee. If establishment of a formulary is recommended, the Board of Nursing (board) must adopt a formulary by rule. Future changes to the formulary must be justified to the board. If adopted, the formulary will not apply to certain services that an ARNP is currently authorized to perform under limited conditions when authorized by the staff of a medical facility, such as the ordering and administration of medication, regional, spinal, and general anesthesia.

The committee substitute requires a hospital to notify each obstetrical physician with privileges at that hospital at least 120 days before it closes its obstetrical department or ceases to provide obstetrical services. The committee substitute repeals a provision designating certain hospitals as provider hospitals, which have special requirements for cesarean section operations that are paid for by the state, including a review board for such operations.

CS by Health Policy on March 17, 2015:

The committee substitute limits the prescribing of controlled substances in a pain-management clinic to physicians, removes the term “certified” before a reference to nurse practitioner, and makes other technical changes.

B. Amendments:

None.