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 Rules

BILL: CS/CS/CS/SB 614

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

SUBJECT: Health Care

DATE: April 22, 2015 REVISED:

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|---|---|---|---|---|
| 1. | Stovall | Stovall | HP | **Fav/CS** |
| 2. | Kraemer | Imhof | RI | **Fav/CS** |
| 3. | Stovall | Phelps | RC | **Fav/CS** |

**Please see Section IX. for Additional Information:**

COMMITTEE SUBSTITUTE - Substantial Changes

## I. Summary:

CS/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, as well as additional conditions. Prescriptions for controlled substances in Schedule II are limited to a 7-day supply, limitations are imposed on prescribing psychotropic medications to children under 18 years of age, and additional limitations may be imposed pursuant to a formulary applicable to practice as a PA or an ARNP. A PA and ARNP may not prescribe controlled substances in a pain management clinic and the practice of interventional pain medicine, as defined in the bill, is limited. The bill requires PAs and ARNPs to complete three hours of continuing education biennially on the safe and effective prescribing of controlled substances.

The bill also facilitates access to medications through an expedited override process for or bypass of step-therapy or fail-first protocols that are imposed by Medicaid managed care plans, health insurers, and health maintenance organizations. Beginning January 1, 2016, health insurers and pharmacy benefits managers which do not use an online prior authorization form must use a standardized prior authorize form that has been adopted by rules of the Financial Services Commission. If a health insurer or health maintenance organization verified the eligibility of an insured at the time of treatment, it may not retroactively deny a claim because of the insured’s ineligibility.

A hospital is required to notify each obstetrical physician with privileges at that hospital at least 90 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.

The bill has an insignificant fiscal impact on governmental entities arising from rulemaking and potential disciplinary action.

Most of the bill becomes effective upon becoming law. However, the authority for a PA or an ARNP to prescribe controlled substances in accordance with the bill becomes effective January 1, 2016,

## 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 Schedules[2] 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 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

[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).

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 physicians must use in developing the scope of practice of the PA under both direct[7] and indirect[8] 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]

**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

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[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.

[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.

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 nurse[17] 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
- 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

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[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.

[21] *See* Section 464.012(4), F.S.

[22] *See* s. 456.048, F.S., and s. 456.041, F.S.

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

[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, *PAs as Prescribers of Controlled Medications – Issue Brief* (June 2014), (on file with the Senate Committee on Regulated Industries).

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 Practitioners***[26]

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;
- 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.

[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.

The program must provide a minimum of 500 hours of preceptorship/supervised clinical experience[30] in the performance of the specialized diagnostic procures 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 procures 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.[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:

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[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.

[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.

- 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:

The bill expresses Legislative recognition of the status of access to primary health care in this state. The Legislature recognizes the importance of access to primary health care, especially for those citizens residing in medically underserved areas of the state. The Legislature further recognizes the shortage of primary care providers, both statewide and nationally, which necessitates the removal of regulatory barriers that prevent physician assistants and advanced registered nurse practitioners from practicing to the full extent of their education, training, and certification.

**Prescribing Controlled Substances by PAs and ARNPs**

CS/CS/CS/SB 614 authorizes physician assistants (PAs) licensed under the Medical Practice Act[35] or the Osteopathic Medical Practice Act[36] and advanced registered nurse practitioners (ARNPs) certified under the Nurse Practice Act[37] to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs, effective January 1, 2016. Conditions for such prescribing are included in the bill and those as well as other restrictions are authorized to be adopted in rule as recommended by formulary committees.

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[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.

For PAs, the authorization is accomplished by removing controlled substances generally from the formulary[38] of medicinal drugs that a PA is prohibiting from prescribing.[39] However, the bill requires the formulary to limit the prescription of Schedule II controlled substances to a 7-day supply.[40] The formulary must also restrict the prescribing of psychiatric mental health controlled substances for children under 18 years of age.

The Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act, so no changes are made to that act.[41] 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.[42]

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,[43] so no additional amendments are needed for violations relating to controlled substances.

For ARNPs, the authorization to prescribe controlled substances is effective January 1, 2016, and is accomplished through revision of existing authority pertaining to drug therapies. The bill authorizes an ARNP to "prescribe, dispense, administer, or order any" drug if the ARNP has a master's degree in a clinical nursing specialty area with training in specialized practitioner skills, and as described below, is not included in the formulary of controlled substances applicable to ARNPs.[44] 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.[45]

The bill requires the appointment of a committee[46] to recommend an evidence-based formulary of controlled substances (controlled substances formulary) that an ARNP may not prescribe, or may prescribe under limited circumstances, as 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. At a minimum, the formulary must restrict the prescribing of psychiatric mental health controlled substances for children under 18 years of age to psychiatric nurses as defined in the Baker Act.[47] The formulary must also limit

[38] *See* s. 458.347(4)(f), F.S. A formulary is a list of medicines.
[39] *See* section 14 of the bill.
[40] A controlled substances in Schedule II has a high potential for abuse, has a currently accepted but severely restricted medical use in treatment, and abuse of the substance may lead to severe psychological or physical dependence. Oxycodone, hydrocodone, and fentanyl are examples of substances in Schedule II. *See* s. 893.03(2), F.S.
[41] *See* Section 459.022(4)(e), F.S.
[42] *See* section 25 of the bill.
[43] *See* s. 458.347(7)(g), F.S., and s. 459.022(7)(g), F.S.
[44] *See* sections 16 and 17 of the bill.
[45] *See supra* note 41.
[46] 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.
[47] The Baker Act is also known as the Florida Mental Health Act and the definition of a psychiatric nurse is found in s. 394.455, F.S.

the prescribing of controlled substances in Schedule II to a 7-day supply, similar to the limitation imposed for PAs, except this limitation does not apply to a psychiatric medication prescribed by a psychiatric nurse under the Baker Act.

The committee formed to recommend the controlled substances formulary is a replacement to a joint committee that was established in law for other purposes but which has been dormant for many years. The formulary committee consists of three Florida-certified ARNPs who are recommended by the Board of Nursing (board), three physicians licensed under ch. 458 or ch. 459 who have had work experience with ARNPs and who are recommended by the Board of Medicine, and a Florida-licensed pharmacist who holds a Doctor of Pharmacy degree who is recommended by the Board of Pharmacy.

The board shall establish the controlled substances formulary for ARNPs by January 1, 2016. The board shall adopt recommendations for the formulary that are made by the committee and which are supported by evidence-based clinical findings presented by the Board of Medicine, the Board of Osteopathic Medicine, or the Board of Dentistry.

The controlled substances formulary adopted by board rule 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 commonly used to render the patient insensible to pain during surgical, obstetrical, therapeutic, or diagnostic clinical procedures.

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.

Both PAs and ARNPs are required to complete three hours of their mandatory hours of continuing education on a course addressing the safe and effective prescribing of controlled substances. The required course shall be offered by a statewide professional association of physicians in Florida accredited to provide educational activities by specified entities.[48]

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.[49] Currently, PAs do not have practitioner profiles, so the capacity for a PA to establish and update practitioner profiles must be developed by the Department of Health so that compliance with this requirement will be possible.[50]

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, F.S.). Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics.[51]

The term “interventional pain medicine” is defined in the bill to mean the practice of medicine devoted to the diagnosis and treatment of pain-related disorders, principally with the application of interventional techniques in managing chronic, intractable pain, independently or in conjunction with other treatment modalities. The bill describes these interventional techniques to include several minimally invasive procedures and surgical techniques. The bill prohibits a person from practicing or offering to practice interventional pain medicine unless the practice is performed in a hospital, ambulatory surgical center, or mobile surgical facility or under the direct supervision of a licensed physician.[52]

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.[53]

**Sections 1 – 4 and Section 26** of the bill amend these statutes to authorize or recognize that a PA or an ARNP may be a prescriber of controlled substances:

[48] *See* sections 13 and 18 of the bill.
[49] *See* section 9 of the bill.
[50] *See* Department of Health, *Senate Bill 614 Analysis* (Feb. 13, 2015) (on file with the Senate Committee on Regulated Industries).
[51] *See* sections 11 and 12 of the bill.
[52] *See* section 10 of the bill.
[53] *See* section 9 of the bill.

- 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.

**Step Therapy / Fail First / Prior Authorization**

The bill facilitates access to medications through an expedited override process for or bypass of step-therapy or fail-first protocols that are imposed by Medicaid managed care plans, other health insurers, and health maintenance organizations (referred to collectively as insurer). Typically a step-therapy or fail-first protocol requires a patient to use certain medication therapies which may be more cost efficient, have fewer side effects for the general population, or the like. These provisions will allow a patient to receive recommended treatment more expeditiously without undergoing known or medically-determined ineffective therapy first. This may be especially helpful for a patient that is stabilized on a medication but who changes health plans.

The bill amends ss. 409.967, 627.6466, and 641.393, F.S., to require insurers to provide a clear and convenient process for prescribing providers to request an override of a step-therapy or fail-first protocol. The insurer is required to grant an override of the protocol within 24 hours when the prescribing provider determines the treatment has been ineffective for the patient's disease or medical condition, is expected to be ineffective given the specific characteristics and medical history of the patient, or will likely cause an adverse reaction or other physical harm to the patient.

If a prescribing provider allows a patient to enter a step-therapy or fail-first protocol, the duration of participation may not exceed the period determined appropriate by the prescribing provider. If the prescribing provider determines the treatment to be clinically ineffective, the patient may receive the recommended therapy without the prescribing provider seeking approval from the insurer.

Health insurers, managed care plans, health maintenance organizations, and pharmacy benefits managers which do not use an online prior authorization form must use a standardized prior authorize form that has been adopted by rules of the Financial Services Commission beginning January 1, 2016.

**Hospital Regulation**

The bill requires a hospital to notify each obstetrical physician with privileges at that hospital at least 90 days before it closes its obstetrical department or ceases to provide obstetrical services. This notification period will allow for the physician and patient to make alternate plans for delivery within a safer time of pregnancy. 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.

**Technical Revisions & Effective Date**

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.

Except as otherwise expressly provided in the bill, the bill takes effect upon becoming law.

## 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:

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.

Patients who are able to initiate therapy recommended by their health care provider more quickly, may see a reduction in overall health care costs through among other things, improved health status more quickly.

Limiting paper prior authorization forms to a single format may expedite completion of the forms for greater efficiencies in a medical practice.

### 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.[54]

## VI. Technical Deficiencies:

None.

## VII. Related Issues:

The bill does not require physician assistants under the Osteopathic Medical Practice Act (ch. 459, F.S.) to obtain 3 hours of continuing education on the safe and effective prescribing of controlled substances on a comparable basis to that required of physician assistants under the Medical Practice Act (ch. 458, F.S.). Similar general continuing education language is found in s. 459.022(4)(e)3, F.S.

The bill limits the prescribing of psychiatric mental health controlled substances for children under 18 years of age. This term is not defined.

## VIII. Statutes Affected:

This bill substantially amends the following sections of the Florida Statutes: 110.12315, 310.071, 310.073, 310.081, 395.1051, 409.967, 456.072, 456.44, 458.326, 458.3265, 458.347, 458.348, 459.0137, 459.025, 464.003, 464.012, 464.013, 464.018, 627.6131, 627.6466, 641.3155, 641.393, 893.02, and 948.03.

The bill creates section 627.42392 of the Florida Statutes.

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.

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[54] *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/CS by Rules on April 20, 2015:**

- Reduces the advance notice requirement from 120 days to 90 for a hospital to notify obstetrical physicians with privileges at the hospital that the hospital will be closing its obstetrical department.
- Restricts certain practices relating to interventional pain medicine to persons under direct supervision of a physician, or to acts performed within a facility licensed under ch. 395, F.S., which includes a hospital, ambulatory surgical center, or mobile surgical facility.
- Requires PAs and ARNPS to attend at least 3 hours of continuing education on the safe and effective prescription of controlled substances.
- Effective January 1, 2016, authorizes PAs to prescribe controlled substances in accordance with limitations in the bill, including prescriptions for Schedule II controlled substances may not exceed a 7-day supply and prohibiting the prescribing of controlled substances that are psychotropic medications to children under age 18.
- Changes the representatives on the formulary committee for ARNPs practices with controlled substances to be made up of 3 ARNPs (removes representation from each sub-classification); 3 physicians licensed under ch. 458 or ch. 459, all of whom are appointed by the Board of Medicine; and a pharmacist.
- Effective January 1, 2016, authorizes ARNPs to prescribe, dispense, administer, or order controlled substances if the ARNP has graduated from a program with a master's degree in a clinical nursing specialty area with training in specialized practitioner skills.
- Limits ARNP-issued prescriptions for Schedule II controlled substances to a 7-day supply, except for a psychiatric nurse, and only a psychiatric nurse under the Baker Act may prescribe a controlled substance that is a psychotropic medication to a child under age 18.
- Requires a convenient process for a prescribing provider to request an override to a step-therapy or fail-first protocol, receive a response within 24 hours under specified circumstances, and proceed directly to the preferred medication if a step-therapy or fail-first treatment is clinically ineffective.
- Requires insurers that do not use online prior authorization forms to use a prior authorization form adopted by the Financial Services Commission beginning January 1, 2016.
- Prohibits an insurer from retroactively denying a claim for ineligibility if the insurer or health maintenance organization verified the eligibility of the insured at the time of treatment.
- Changes the effective date of the bill from July 1, 2105, to upon becoming a law and to reflect alternate effective dates for specific provisions.

**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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.