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 Banking and Insurance

BILL:	CS/SB 676
INTRODUCER:	Health Policy Committee and Senator Grimsley
SUBJECT:	Access to Health Care Services
DATE:	January 25, 2016 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Rossitto-Van Winkle	Stovall	HP	**Fav/CS**
2.	Johnson	Knudson	BI	**Pre-meeting**
3.			AHS	
4.			AP	

Please see Section IX. for Additional Information:

COMMITTEE SUBSTITUTE - Substantial Changes

I. Summary:

CS/SB 676 authorizes physician assistants (PAs) and advanced registered nurse practitioners (ARNPs) to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs beginning January 1, 2017; and creates additional statutory parameters for their controlled substance prescribing. An ARNP's and PA's prescribing privileges for controlled substances listed on Schedule II are limited to a 7-day supply and do not include the prescribing of psychotropic medications for children under 18 years of age, unless prescribed by an ARNP who is a psychiatric nurse, and may be limited by the controlled substance formularies themselves imposing additional limitations on PA or ARNP prescribing privileges for specific medications. An ARNP or PA may not prescribe controlled substances in a pain management clinic. The bill requires PAs and ARNPs to complete 3 hours of continuing education biennially on the safe and effective prescribing of controlled substances.

Beginning January 1, 2017, health insurers, health maintenance organizations, Medicaid managed plans, 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.

The bill requires a hospital to notify each obstetrical physician with privileges at the facility at least 90 days before it closes its obstetrical department or ceases to provide obstetrical services. The bill also repeals a provision designating certain hospitals as "provider hospitals," which have special requirements for cesarean section operations that are paid for with state or federal funds.

Most of the bill becomes effective upon becoming a law. However, the authority for a PA or an ARNP to prescribe controlled substances in accordance with the bill becomes effective January 1, 2017.

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, 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. Even if the statewide supply of primary care physicians is adequate 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 allopathic medicine by the Board of Medicine (BOM). Chapter 459, F.S., similarly sets forth the provisions for the regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine (BOOM). PAs are regulated by both boards. Licensure of PAs is overseen jointly by the boards

[1] DEA Diversion Control, U.S. Department of Justice, *Mid-Level Practitioners Authorization by State*, (last updated Nov. 10, 2015), *available at* http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf, (last visited Dec. 3, 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), https://ahca.myflorida.com/medicaid/Finance/finance/LIP-DSH/GME/docs/FINAL_Florida_Statewide_and_Regional_Physician_Workforce_Analysis.pdf, (last visited Dec. 3, 2015).

through the Council on Physician Assistants.[4] During the 2014-2015 state fiscal year, there were 6,744 in-state, actively licensed PAs in Florida.[5]

PAs are trained and required by statute to work under the supervision and control of allopathic or osteopathic physicians.[6] The BOM and the BOOM 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 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 work 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 (DOH) and are regulated by the Board of Nursing (BON).[13] During the 2014-2015 state fiscal year, there were 18,276 in-state, actively licensed ARNPs in Florida.[14]

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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. (s. 458.348(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 2014-2015*, p. 11, available at: http://www.floridahealth.gov/licensing-and-regulation/reports-and-publications/_documents/annual-report-1415.pdf , (Last visited Dec. 7, 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.

[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 BON 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 5. Certified Nurse Specialists account for 26 of the in-state actively licensed ARNPs.

An ARNP is a licensed nurse who is certified in advanced or specialized nursing.[15] Florida recognizes three types of ARNPs: nurse practitioners (NP), certified registered nurse anesthetists (CRNA), and certified nurse midwives (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 BON that the ARNP applicant meets one of the following requirements:[18]

- Satisfactory completion of a formal postbasic 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 the protocol of a supervising physician or dentist. 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]

An ARNP must meet financial responsibility requirements, as determined by rule of the BON, and the practitioner profiling requirements.[22] The BON 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 the established protocol approved by the medical staff of the facility in which the anesthetic service is performed."

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[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. (*See* 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; 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.

Educational Preparation

Physician Assistants[25]

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, on average, complete 48.5 weeks 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 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 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:

- 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;

[25] *See* American Academy of Physician Assistants, *PAs as Prescribers of Controlled Medications – Issue Brief*, (June 2014), available at: https://www.aapa.org/WorkArea/DownloadAsset.aspx?id=2549 (last viewed Dec. 3, 2015).
[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 Dec. 3, 2015).
[28] *Id.*, and s. 464.012(1), F.S.

- 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 (12.5 weeks) of preceptorship/supervised clinical experience[29] 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.[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); 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 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
- The hospital or other institution maintains a current list of internal codes and the corresponding practitioner.[33]

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[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.
[30] U.S. Department of Justice, Drug Enforcement Administration, *Practitioner's Manual*, (August 2006), p. 7, *available at* http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited Dec. 3, 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 30, at p.18.
[33] *Supra* note 30, at p.12.

Peer Review of Publically Funded C-Sections

Section 383.336, F.S., relates to public health and maternal and infant health care where all or part of the costs are paid for by state or federal funds administered by the state. It defines a "provider hospital" as one in which there are 30 or more births per year paid for in part, or in full, by state or federal funds. It directs the State Surgeon General, in consultation with the Board of Medicine and the Florida Obstetric and Gynecologic Society, to establish practice parameters for physicians in provider hospitals who perform caesarean sections; and requires each provider hospital to establish a peer review board to conduct monthly reviews of every publically funded caesarean section performed since the previous review.

Beginning in 2014, hospitals that are accredited by the Joint Commission and which performed more than 1,100 births per year were required to report on certain cesarean sections performed in the hospital as a part of their perinatal core measure set. Effective with January 1, 2016 discharges, the threshold for mandatory reporting is reduced to hospitals with 300 or more births per year. Each hospital receives a quarterly risk-adjusted performance report with their hospital's C-section rate compared to a desired target range.[34]

The Patient Protection and Affordable Care Act

In March 2010, the Congress passed and President Barack Obama signed the Patient Protection and Affordable Care Act (PPACA).[35] Among its changes to the U.S. health care system are requirements for health insurers to make coverage available to all individuals and employers. Coverage is available through an employer, the federal or state exchanges created under PPACA, or off the exchange, that meets the federal essential health benefits requirements. Florida did not establish its own state exchange under PPACA. Premium credits and other cost sharing subsidies are available to U.S. citizens and legal immigrants within certain income limits for qualified coverage purchased through the exchange.[36]

Nonpayment of Premium

Federal regulations for PPACA also govern an enrollee's coverage bought through the exchanges and for non-grandfathered plans.[37] If an exchange enrollee received an advance premium tax credit for a qualified health plan (QHP)[38] and paid at least one full month's premium during the

[34] *See* Expanded threshold for reporting Perinatal Care measure set, a Joint Commission Article published on June 24, 2015, available at: http://www.jointcommission.org/issues/article.aspx?Article=A9Im9xfNbBo97ZcgWQAj/SE KRiZJsPtdFLyHUR1bZU= (last visited Jan. 6, 2016). *See also* U.S. Hospitals Held Accountable for C-Section Rates by Rebecca Dekker, PhD, RN, APRN of www.evidencebasedbirth.com, available at: http://improvingbirth.org/2013/01/u-s-hospitals-held-accountable-for-c-section-rates/ (last visited Jan. 6, 2016).

[35] P.L. 111-148. On March 30, 2010, PPACA was amended by P.L. 111-152, the Health Care and Education Reconciliation Act of 2010.

[36] Centers for Medicare and Medicaid Services, *Health Insurance Marketplace - Will I Qualify for Lower Costs on Monthly Premiums?* https://www.healthcare.gov/will-i-qualify-to-save-on-monthly-premiums/ (last visited Jan. 23, 2016).

[37] Certain plans received "grandfather status" under PPACA. A grandfathered health plan is a plan that existed on March 23, 2010, and had at least one person continuously covered for 1 year. Some consumer protections elements do not apply to grandfathered plans.

[38] A "qualified health plan" is an insurance plan certified by the applicable Health Insurance Marketplace, provides the essential health benefits, established limits on cost sharing and meets other requirements. *See*

benefit year, and is terminated for non-payment of premium, the insurer must provide the enrollee a 3-month grace period before cancellation of coverage.[39] During the grace period, the insurer must pay claims for services rendered in the first month but may pend claims for the second and third months.[40] The insurer is also required to notify providers of the possibility for denied claims when an enrollee is in the second or third months of the grace period. The insurer is also required to provide the enrollee with notice of such payment delinquency. If an insurer terminates an enrollee's coverage after the 3-month grace period, the insurer must provide written notice of termination 14 days before the effective date. If coverage is terminated, the termination date is the last day of the first month of the 90-day grace period and the insurer may not recoup any claims paid during the first month of the grace period.

The federal regulations do not affect those enrollees who are not enrolled in an exchange plan or do not receive a subsidy. The grace period for these individuals remains at the length required under s. 627.608, F.S., which varies by the length of the premium payment interval. Cancellation of coverage is effective the first day of the grace period if payment is not received.

Retroactive Denial of Claims by Health Insurers

Section 627.6131, F.S., and s. 641.3155, F.S., prohibit a health insurer and HMO, respectively, from retroactively denying a claim because of insured ineligibility more than 1 year after the date the claim is paid. There is, however, no redress for erroneous authorization and an insured's reliance on that authorization.

III. Effect of Proposed Changes:

ARNP and PA Authorized to Prescribe Controlled Substances

CS/SB 676 authorizes PAs licensed under the Medical Practice Act or the Osteopathic Medical Practice Act, and ARNPs certified under part I of the Nurse Practice Act, to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs beginning January 1, 2017; and it creates additional statutory parameters on their controlled substance prescribing. Specifically, an ARNP's and PA's prescribing privileges, for controlled substances listed on Schedule II, are limited to a 7-day supply, do not include prescribing psychotropic medications for children under 18 years of age except by an ARNP who is also a psychiatric nurse as defined by s. 394.455, F.S.,[41] and may be limited by the controlled substance formularies themselves which impose additional limitations on PA or ARNP prescribing privileges for specific medications. (Sections 12 – 15)

For PAs, the bill creates the ability to prescribe controlled substances by removing controlled substances from the formulary of medicinal drugs that a PA may not prescribe in the Medical

https://www.healthcare.gov/glossary/qualified-health-plan/ for more information on qualified health plans (last visited Jan. 23, 2016).

[39] 45 CFR 156.270 and 45 CFR 430.

[40] 45 CFR 156.270.

[41] Section 394.55(23), F.S., defines a "psychiatric nurse" as an advanced registered nurse practitioner certified under s. 464.012, F.S., who has a master's or doctoral degree in psychiatric nursing, holds a national advanced practice certification as a psychiatric mental health advanced practice nurse, and has 2 years of post-master's clinical experience under the supervision of a physician.

Practice Act. The Osteopathic Medical Practice Act refers to the formulary in the Medical Practice Act, so no changes are made to that act. (Section 12)

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. However, a master's or doctoral degree in a clinical nursing specialty area with training in specialized practitioner skills is required to prescribe or dispense controlled substances. (Section 15)

Additionally, CS/SB 676, adds an ARNP and PA 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 21).

The bill requires the appointment of a committee[42] 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.[43] The formulary must also limit 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. (Section 14)

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. Language establishing the joint committee and references to it are removed from law in Sections 13, 23, and 24 of the bill.

The formulary committee consists of three Florida-certified ARNPs who are recommended by the BON, 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 and is recommended by the Board of Pharmacy.

The BON is to establish the controlled substances formulary for ARNPs by January 1, 2017. The bill requires the board to 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 BON is required to adopt the formulary committee's initial recommendation by October 31, 2016.

[42] 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.

[43] 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 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., 4., and 9., F.S:

- Orders for pre-anesthetic medications;
- 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; or
- Managing a patient while in the postanesthesia recovery area.

CS/SB 676 requires a PA and ARNP to have three hours of continuing education on the safe and effective prescription of controlled substances and specifies several statutorily pre-approved providers of those continuing education hours. (Sections 11 and 16)

A PA or ARNP who prescribes controlled substances that are 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 respective 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. (Section 8)

The bill imposes the same disciplinary standards on PAs and ARNPs as those applicable to physicians for failing to meet minimal standards of acceptable and prevailing practice in prescribing and dispensing of controlled substances.

ARNP disciplinary sanctions are added to the bill in s. 456.072, F.S., (Section 7) to mirror a physician's sanctions for prescribing or dispensing a controlled substance other than 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 17) include:

- Pre-signing blank prescription forms;
- Prescribing for office use any medicinal drug appearing on Schedule II in chapter 893.
- Prescribing, ordering, dispensing, administering, supplying, selling, amphetamines, sympathomimetic amines, or a compound designated in s. 893.03(2), F.S., as a Schedule II controlled substance, to anyone except for:
    - Treating narcolepsy,[44] hyperkinesis,[45] behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractibility, short

[44] *Narcolepsy* is a medical condition in which someone suddenly falls into a deep sleep while talking, working, *etc.* Miriam-Webster Dictionary, Encyclopedia Britannica Company, *available at*: http://www.merriam-webster.com/dictionary/narcolepsy, (Last visited Dec. 7, 2015).

[45] *Hyperkinesis* is defined as an abnormally increased and sometimes uncontrollable activity or muscular movements; 2. a condition especially of childhood characterized by hyperactivity. Miriam-Webster Dictionary, Encyclopedia Britannica Company, *available at*: http://www.merriam-webster.com/dictionary/hyperkinesis, (Last visited Dec. 7, 2015).

attention span, hyperactivity, emotional lability,[46] and impulsivity; or drug-induced brain dysfunction;
    - The diagnostic and treatment of depressions; and
    - Clinical investigations which have been approved by the department before such investigation is begun.
- Prescribing, ordering, dispensing, administering, supplying, selling, or giving growth hormones, testosterone or its analogs, human chorionic gonadotropin (HCG), or other hormones for the purpose of muscle building or to enhance athletic performance;[47]
- Promoting or advertising on any prescription form a community pharmacy unless the form also states: "This prescription may be filled at any pharmacy of your choice";
- Prescribing, dispensing, or administering a medicinal drug appearing on any schedule set forth in chapter 893 to himself or herself, except a drug prescribed, dispensed, or administered to the ARNP by another practitioner authorized to prescribe, dispense, or administer medicinal drugs;
- Prescribing, ordering, dispensing, administering, supplying, selling, or giving amygdalin (laetrile) to any person;[48]
- Dispensing a substance controlled in Schedule II or Schedule III, in violation of s. 465.0276, F.S.; and
- Promoting or advertising through any communication medium the use, sale, or dispensing of a substance designated in s. 893.03, F.S., as a controlled substance.

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.

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 ch. 458, F.S., or ch. 459, F.S. Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics. (Sections 9 and 10)

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 8).

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[46] *Emotional lability* is a condition of excessive emotional reactions and frequent mood changes. Mosby's Medical Dictionary, 9th edition. 2009, Elsevier, *available at*: http://medical-dictionary.thefreedictionary.com/emotional+lability , (Last visited Dec. 7, 2015).

[47] Bill section 17 amends s. 464.018, F.S., to add subpart (1)(p)4., which prohibits the prescribing of certain hormones for the purpose of "muscle building"; but excludes the treatment of an injured muscle from the definition of "muscle building" as used in this section; and pharmacists receiving prescriptions for the listed hormones may dispense them with the presumption that the prescription is for legitimate medical use.

[48] Laetrile is an allegedly antineoplastic drug consisting chiefly of amygdalin derived from apricot pits. It has not been proven to have any beneficial use. Farlex Partner Medical Dictionary Farlex 2012, *available at*: http://medical-dictionary.thefreedictionary.com/laetrile, (Last visited Dec. 7, 2015).

Sections 1 – 4, and 22 of the bill 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 1)
- 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, allows the presence of a controlled substance in a 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. (Sections 2, 3, and 4)
- Section 948.03, F.S., relating to terms and conditions of criminal probation, includes an ARNP and PA as an authorized prescriber of drugs or narcotics that a person on probation may lawfully possess. (Section 22)

Hospital Regulation

The bill requires a hospital to notify each obstetrical physician with privileges at the facility at least 90 days before it closes its obstetrical department or ceases to provide obstetrical services. (Section 6)

The bill also repeals a provision designating certain hospitals as "provider hospitals," which have special requirements for cesarean section operations that are paid for with state or federal funds, including a peer review board that reviews the procedures performed and establishes practice parameters for such operations. (Section 5)

Prior Authorization Forms

CS/SB 676 creates s. 627.42392, F.S., to require insurers offering health insurance, managed care plans, health maintenance organizations, or their pharmacy benefits managers, that do not use electronic prior authorization forms for their contract providers, to only use prior authorization forms approved by the Financial Services Commission to obtain prior authorization for medical procedures, courses of treatment, and prescription drugs beginning January 1, 2017. The Commission must adopt by rule guidelines for these forms to ensure general uniformity of the forms; and the forms may not exceed two pages, excluding instructions. (Section 18)

Retroactive Denial of Claims

CS/SB 676 amends ss. 627.6131 and 641.3155, F.S., to preclude a health insurer or an HMO from retroactively denying a claim because of an insured's ineligibility after the health insurer or HMO has previously verified eligibility at the time of treatment and provided an authorization number. (Sections 19 and 20)

Technical Revisions and Effective Date

Sections 25 –33 reenact multiple statutes for the purpose of incorporating the amendments made by the bill to ss. 456.072, 456.44, 458.347, 464.003, 464.012, 464.013, 464.018, 893.02, and 948.03, F.S., in references thereto.

Additional conforming and grammatical changes are made in the bill.

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, 2017.

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.

Eliminating the ability of a health insurer or HMO to subsequently deny a claim once authorized will avoid unanticipated additional financial obligations to a patient and potential unexpected loss of revenues to healthcare providers.

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

C. Government Sector Impact:

The DOH may incur costs for rulemaking, modifications to develop a profile for PAs, and workload impacts related to additional complaints and investigations.

VI. Technical Deficiencies:

Section 18 of the bill defines a "health insurer," to mean an insurer, HMO, and managed care plans as defined in s. 409.901(13), F.S. According to the Agency for Health Care Administration (agency), all Florida Medicaid managed care plans providing services under the State Medicaid Managed Care program (SMMC) contract with the Agency for Health Care Administration (agency) pursuant to the provisions established in Part IV of Chapter 409, F.S., and are specifically defined in sections 409.962(6) and (9), F.S. The agency no longer has any managed care contracts that operate under the authority specified in this bill (section 409.901, F.S.) once the SMMC program was fully implemented.

Section 18, which amends the Insurance Code, requires a health insurer, or a pharmacy benefit managers (PBMs) acting on behalf of the health insurer, which does not use an electronic prior authorization form for its network providers to use the prior authorization form that the Financial Services Commission adopts by rule. Further, the commission is required to adopt by rule guidelines for all prior authorization forms.

The Office of Insurance Regulation does not regulate pharmacy benefit managers. Insurers and HMOs, and other risk bearing entities that are regulated by the OIR, who contract with a PBM or other third party, would be subject to this statutory provision and would be subject to enforcement by the OIR for noncompliance.

Since the prior authorization forms and guidelines rules that are to be adopted by the commission would be applicable to commercial plans as well as Medicaid managed care plans, it might be advantageous for the commission to adopt such rules in consultation with the Agency for Health Care Administration.

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, 459.0137, 458.347, 464.003, 464.012, 464.013, 464.018, 627.6131, 641.3155, 893.02, 948.03, 458.348, 459.025, 458.331, 459.015, 459.022, 465.0158, 466.02751, 458.303, 458.3475, 459.023, 456.041, 464.012, 464.0205, 320.0848, 464.008, 464.009, 775.051, 893.02, 944.17, 948.001, 948.03, 948.101

This bill creates section 627.42392 of the Florida Statutes.

This bill repeals section 383.336 of the Florida Statutes.

IX. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

CS by Health Policy on January 11, 2016:
The CS amends SB 676 to add the American Association of Nurse Anesthetists to the list of statutorily pre-approved providers for continuing education for ARNPs.

B. Amendments:

None.