

**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.)

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Prepared By: The Professional Staff of the Committee on Appropriations

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BILL: CS/CS/CS/SB 676

INTRODUCER: Appropriations Committee; Banking and Insurance Committee; Health Policy Committee; and Senator Grimsley

SUBJECT: Access to Health Care Services

DATE: February 22, 2016      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	<u>Rossitto-Van Winkle</u>	<u>Stovall</u>	<u>HP</u>	<u>Fav/CS</u>
2.	<u>Johnson</u>	<u>Knudson</u>	<u>BI</u>	<u>Fav/CS</u>
3.	<u>Brown</u>	<u>Kynoch</u>	<u>AP</u>	<u>Fav/CS</u>

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

COMMITTEE SUBSTITUTE - Substantial Changes

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**I. Summary:**

CS/CS/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. Under the bill, an ARNP's and PA's prescribing privileges for controlled substances listed on Schedule II are limited to a seven-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 that impose 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 three 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 the Financial Services Commission adopts by rule. If a health insurer or health maintenance organization verifies 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.

The bill provides that s. 464.012, F.S., shall be known as “The Barbara Lumpkin Prescribing Act.”

The bill is estimated to have no fiscal impact.

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 advanced registered nurse practitioners (ARNPs) to prescribe controlled substances and is one of two states that does not allow physician assistants (PAs) to prescribe controlled substances.<sup>1</sup> States have varying authority with respect to the schedules<sup>2</sup> from which an ARNP or PA may prescribe, as well as the performance of additional functions by ARNPs and PAs, such as dispensing, administering, or handling samples.

### Physician Shortages

According to a recent study commissioned by the Safety Net Hospital Alliance of Florida,<sup>3</sup> Florida’s total current supply of primary care physicians falls short of the national average of physicians per patient by approximately six 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 three percent.

### 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

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<sup>1</sup> DEA Diversion Control, U.S. Department of Justice, *Mid-Level Practitioners Authorization by State* (last updated November 10, 2015) available at [http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp\\_by\\_state.pdf](http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf) (last visited Feb. 1, 2016). Kentucky does not allow PAs to prescribe controlled substances.

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

<sup>3</sup> IHS Global Inc., *Florida Statewide and Regional Physician Workforce Analysis: Estimating Current and Forecasting Future Supply and Demand*, (January 28, 2016) available at [https://ahca.myflorida.com/medicaid/Finance/finance/LIP-DSH/GME/docs/FINAL\\_Florida\\_Statewide\\_and\\_Regional\\_Physician\\_Workforce\\_Analysis.pdf](https://ahca.myflorida.com/medicaid/Finance/finance/LIP-DSH/GME/docs/FINAL_Florida_Statewide_and_Regional_Physician_Workforce_Analysis.pdf), (last visited Feb. 1, 2016).

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

Physician Assistants are trained and required by statute to work under the supervision and control of allopathic or osteopathic physicians.<sup>6</sup> 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<sup>7</sup> and indirect<sup>8</sup> 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.<sup>9</sup> 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.<sup>10</sup>

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.<sup>11</sup> However, the law allows a supervisory physician to delegate authority to a PA to order any medication, including controlled substances, general anesthetics, and radiographic contrast materials, for a patient during the patient's stay in a facility licensed under ch. 395, F.S.<sup>12</sup>

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<sup>4</sup> 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.)

<sup>5</sup> Florida Dep't 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 Feb. 1, 2016).

<sup>6</sup> Sections 458.347(4), and 459.022(4), F.S.

<sup>7</sup> "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.).

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

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

<sup>10</sup> Sections 458.347(3) and (15) and 459.022(3) and (15), F.S.

<sup>11</sup> Sections 458.347(4)(e) and (f)1., and 459.022(4)(e), F.S.

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

## 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).<sup>13</sup> During the 2014-2015 fiscal year, there were 18,276 in-state, actively licensed ARNPs in Florida.<sup>14</sup>

An ARNP is a licensed nurse who is certified in advanced or specialized nursing.<sup>15</sup> Florida recognizes three types of ARNPs: nurse practitioners (NP), certified registered nurse anesthetists (CRNA), and certified nurse midwives (CNM).<sup>16</sup> To be certified as an ARNP, a nurse must hold a current license as a registered nurse<sup>17</sup> and submit proof to the BON that the ARNP applicant meets one of the following requirements:<sup>18</sup>

- Satisfactory completion of a formal, post-basic educational program of specialized or advanced nursing practice;
- Certification by an appropriate specialty board;<sup>19</sup> 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:<sup>20</sup>

- 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).<sup>21</sup>

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<sup>13</sup> 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.

<sup>14</sup> *Supra*, note 5. Certified Nurse Specialists account for 26 of the in-state actively licensed ARNPs.

<sup>15</sup> "Advanced specialized nursing practice" is defined as the performance of advanced-level nursing acts approved by the BON which, by virtue of postbasic specialized education, training and experience, are appropriately performed by an ARNP. (*See* s. 464.003(2), F.S.)

<sup>16</sup> Section 464.003(3), F.S. Florida certifies clinical nurse specialists as a category distinct from ARNPs. (*See* ss. 464.003(7) and 464.0115, F.S.).

<sup>17</sup> Practice of professional nursing. (*See* s. 464.003(20), F.S.)

<sup>18</sup> Section 464.012(1), F.S.

<sup>19</sup> Specialty boards expressly recognized by the BON: 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.)

<sup>20</sup> Section 464.012(3), F.S.

<sup>21</sup> Section 464.012(4), F.S.

An ARNP must meet financial responsibility requirements, as determined by rule of the BON, and the practitioner profiling requirements.<sup>22</sup> 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.<sup>23</sup>

Florida does not allow ARNPs to prescribe controlled substances.<sup>24</sup> 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.”

## **Educational Preparation**

### ***Physician Assistants***<sup>25</sup>

Physician assistant 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 two 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. A student begins his or her course of study with a year of basic medical science classes (anatomy, pathophysiology, pharmacology, physical diagnosis, etc.) Then the student enters 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. Coursework in pharmacology addresses, but is not limited to, pharmacokinetics, drug interactions, adverse effects, contraindications, indications, and dosage.

### ***Advanced Registered Nurse Practitioners***<sup>26</sup>

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

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<sup>22</sup> Sections 456.0391 and 456.041, F.S.

<sup>23</sup> Rule 64B9-4.002(5), F.A.C.

<sup>24</sup> Sections 893.02(21) and 893.05(1), F.S.

<sup>25</sup> 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 Feb. 1, 2016).

<sup>26</sup> Rule 64B9-4.003, F.A.C.

<sup>27</sup> Florida Board of Nursing, *ARNP Licensure Requirements* <http://floridasnursing.gov/licensing/advanced-registered-nurse-practitioner/>, (last visited Feb.1, 2016).

<sup>28</sup> *Id.*, and s. 464.012(1), F.S.

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

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

The program must provide a minimum of 500 hours (12.5 weeks) of preceptorship/supervised clinical experience<sup>29</sup> in the performance of the specialized diagnostic procedures that are essential to practice in that specialty area.

### **Drug Enforcement Agency Registration**

The Drug Enforcement Administration (DEA) within the U.S. Department of Justice grants practitioners federal authority to handle controlled substances. However, a DEA-registered practitioner may only engage in those activities that are authorized under state law for the jurisdiction in which the practice is located.<sup>30</sup>

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

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice;
- Registered with the DEA or exempted from registration; 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, including:<sup>32</sup>

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<sup>29</sup> 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.

<sup>30</sup> U.S. Department of Justice, Drug Enforcement Administration, *Practitioner's Manual*, (August 2006), p. 7, available at [http://www.dea diversion.usdoj.gov/pubs/manuals/pract/pract\\_manual012508.pdf](http://www.dea diversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf), (last visited Feb. 1, 2016).

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

<sup>32</sup> *Supra*, note 30, at 18.

- The dispensing, administering, or prescribing must be in the usual course of professional practice;
- The practitioner must be authorized to do so by the state in which he or she practices;
- The hospital or other institution must verify that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state;
- The practitioner must act only within the scope of employment in the hospital or other institution;
- The hospital or other institution must authorize the practitioner to administer, dispense, or prescribe under its registration and must assign a specific internal code number for each practitioner; and
- The hospital or other institution must maintain a current list of internal codes for the corresponding practitioner.<sup>33</sup>

### **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 BOM 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 caesarean section rate compared to a desired target range.<sup>34</sup>

### **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).<sup>35</sup> Among its changes to the U.S. health insurance system are requirements for health insurers to make coverage available to all individuals and employers. Coverage available through an employer, the federal or state exchanges created under the PPACA, or off the exchange, must meet the federal essential health benefits requirements. Premium credits and other cost sharing subsidies are available to U.S. citizens and legal

<sup>33</sup> *Supra*, note 30, at 12.

<sup>34</sup> 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/SEKRiZJsPtdFLyHUR1bZU=> (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](http://www.evidencebasedbirth.com), available at: <http://improvingbirth.org/2013/01/u-s-hospitals-held-accountable-for-c-section-rates/> (last visited Jan. 6, 2016).

<sup>35</sup> 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.

immigrants within certain income limits for qualified coverage purchased through a PPACA exchange.<sup>36</sup>

### ***Nonpayment of Premium***

Federal regulations for the PPACA also govern an enrollee's coverage bought through the exchanges and for non-grandfathered plans.<sup>37</sup> If an exchange enrollee received an advance premium tax credit for a qualified health plan (QHP)<sup>38</sup> and paid at least one full month's premium during the benefit year, and is terminated for non-payment of premium, the insurer must provide the enrollee a three-month grace period before cancellation of coverage.<sup>39</sup> 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.<sup>40</sup> 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 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 grace period and the insurer may not recoup any claims paid during the first month of the grace period.

The federal regulations for the grace period do not affect individuals 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 a health maintenance organization (HMO), respectively, from retroactively denying a claim because of insured ineligibility more than one 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:**

### **ARNPs and PAs Authorized to Prescribe Controlled Substances**

Sections 12 through 15 of the bill authorize physician assistants (PAs) licensed under the Medical Practice Act or the Osteopathic Medical Practice Act, and advanced registered nurse

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<sup>36</sup> 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).

<sup>37</sup> 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.

<sup>38</sup> 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* <https://www.healthcare.gov/glossary/qualified-health-plan/> for more information on qualified health plans (last visited Jan. 23, 2016).

<sup>39</sup> 45 CFR 156.270 and 45 CFR 430.

<sup>40</sup> 45 CFR 156.270.

practitioners (ARNPs) certified under part I of the Nurse Practice Act, to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs, 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 seven-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.,<sup>41</sup> and may be limited by the controlled substance formularies that impose additional limitations on PA or ARNP prescribing privileges for specific medications.

Section 12 creates, for PAs, the ability to prescribe controlled substances by removing controlled substances from the formulary of medicinal drugs that a PA currently may not prescribe in the Medical 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 15 authorizes ARNPs to prescribe controlled substances 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 21 adds ARNPs and PAs to the definition of practitioner in ch. 893, F.S. This definition requires the practitioner to hold a valid federal controlled substance registry number.

Under Section 14, the bill amends s. 464.012, F.S., to require the appointment of a committee<sup>42</sup> 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.<sup>43</sup> The formulary must also limit the prescribing of controlled substances in Schedule II to a seven-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.

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<sup>41</sup> 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.

<sup>42</sup> 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.

<sup>43</sup> 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 bill also provides that s. 464.012, F.S., shall be known as “The Barbara Lumpkin Prescribing 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. 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 Board of Nursing (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 (BOM), and a Florida-licensed pharmacist who holds a doctor of pharmacy degree and is recommended by the Board of Pharmacy.

The BON is directed to establish the controlled substances formulary for ARNPs by January 1, 2017. The bill requires the BON to adopt recommendations for the formulary that are made by the committee and which are supported by evidence-based clinical findings presented by the BOM, the BOOM, or the Board of Dentistry. The BON is required to adopt the formulary committee’s initial recommendation by October 31, 2016.

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 post-anesthesia recovery area.

Sections 11 and 16 of the bill require 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.

Section 8 requires 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, to designate himself or herself as a controlled substance prescribing practitioner on his or her respective practitioner profile maintained by the Department of Health (DOH). Currently, PAs do not have practitioner profiles so the DOH will need to develop a profile for PAs to comply with this requirement.

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.

Section 7 adds ARNP disciplinary sanctions under s. 456.072, F.S., 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.

Section 17 adds additional acts to the Nurse Practice Act for which discipline may be taken against an ARNP relating to practicing with controlled substances, including:

- 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, 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;<sup>44</sup>
- 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;<sup>45</sup>
- Dispensing a substance controlled in Schedule II or Schedule III, in violation of s. 465.0276, F.S.;
- 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; and
- 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,<sup>46</sup> hyperkinesia,<sup>47</sup> behavioral syndrome in children characterized by the developmentally inappropriate symptoms of moderate to severe distractibility, short attention span, hyperactivity, emotional lability,<sup>48</sup> and impulsivity; or drug-induced brain dysfunction;
  - The diagnostic and treatment of depressions; and

<sup>44</sup> 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.

<sup>45</sup> 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).

<sup>46</sup> 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).

<sup>47</sup> Hyperkinesia 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/hyperkinesia>, (Last visited Dec. 7, 2015).

<sup>48</sup> 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).

- Clinical investigations which have been approved by the department before such investigation is begun.

Disciplinary standards that are applicable to physicians are already applicable to PAs under 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.

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, sections 9 and 10 of the bill prohibit PAs and ARNPs from prescribing controlled substances in pain-management clinics.

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. Section 8 of the bill adds two additional boards to that list: the American Board of Interventional Pain Physicians and the American Association of Physician Specialists.

Sections 1 through 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, is amended 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, are amended to allow the presence of a controlled substance in a pilot's drug test results if the substance was prescribed by an ARNP or PA whose care the pilot is under, as a part of the annual physical examination required for initial certification, initial licensure, and certification and licensure retention.
- Section 948.03, F.S., relating to terms and conditions of criminal probation, is amended to include ARNPs and PAs as authorized prescribers of drugs or narcotics that a person on probation may lawfully possess.

### **Hospital Regulation**

Section 5 of the bill deletes 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 6 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.

**Prior Authorization Forms**

Section 18 of the bill creates s. 627.42392, F.S., to require insurers, Medicaid managed care plans, HMOs, 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, in consultation with the Agency for Health Care Administration (AHCA), to obtain prior authorization for medical procedures, courses of treatment, and prescription drugs, beginning January 1, 2017. The Commission, in consultation with the AHCA, 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.

**Retroactive Denial of Claims**

Sections 19 and 20 of the bill amend ss. 627.6131 and 641.3155, F.S., respectively, to preclude a health insurer or an HMO from retroactively denying a claim because of an insured's ineligibility if the health insurer or HMO has previously verified eligibility at the time of treatment and provided an authorization number.

**Technical Revisions and Effective Date**

Sections 25 through 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:**

Under CS/CS/CS/SB 676, physician assistants (PAs) and advanced registered nurse practitioners (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.

Eliminating the ability of a health insurer or HMO to subsequently deny a claim once authorized will prevent unanticipated additional financial obligations being placed on persons who are authorized for coverage while not actually having coverage for the services rendered. This will simultaneously impose additional financial liability on a health insurer or HMO that provides authorization for an individual who is later confirmed to not be covered for the services rendered.

**C. Government Sector Impact:**

The Department of Health (DOH) may incur costs for rulemaking, modifications to develop a profile for PAs, and workload impacts related to additional complaints and investigations. The DOH advises that its current resources are adequate to absorb these additional costs.<sup>49</sup>

**VI. Technical Deficiencies:**

Section 18 of the bill, which amends s. 627.42392, F.S., a provision in the Insurance Code, requires a health insurer, or a pharmacy benefit manager (PBM) 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, in consultation with the Agency for Health Care Administration (AHCA), adopts by rule. Further, the Commission, in consultation with the AHCA, is required to adopt by rule guidelines for all prior authorization forms. However, the Office of Insurance Regulation (OIR) does not regulate PBMs. Insurers, HMOs, and other risk-bearing entities that are regulated by the OIR, who contract with a PBM or other third party, are subject to this statutory provision and would be subject to enforcement by the OIR for noncompliance, but not so for a PBM itself.

**VII. Related Issues:**

None.

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<sup>49</sup> The Department of Health, *2016 Agency Legislative Bill Analysis, SB 676*, on file with the Appropriations Subcommittee on Health and Human Services.

**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, and 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/CS/CS by Appropriations on February 18, 2016:**

The CS/CS/CS provides that s. 464.012, F.S., shall be known as “The Barbara Lumpkin Prescribing Act.”

**CS/CS by Banking and Insurance on January 26, 2016:**

The CS/CS provides that the Financial Services Commission in consultation with the Agency for Health Care Administration (AHCA) will adopt by rule a prior authorization form and guidelines. The CS also corrects a cross reference.

**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.