

HOUSE OF REPRESENTATIVES FINAL BILL ANALYSIS

BILL #: HB 423

FINAL HOUSE FLOOR ACTION:

SPONSOR(S): Pigman; Campbell and others

117 Y's

1 N's

COMPANION CS/CS/CS/SB 676
BILLS:

GOVERNOR'S ACTION: Pending

SUMMARY ANALYSIS

HB 423 passed the House on March 2, 2016. The bill was amended in the Senate on March 9, 2016, and was returned to the House. The bill was further amended in the House on March 10, 2016, and the House concurred with the Senate amendment as amended. The bill was returned to and further amended in the Senate, and the Senate concurred with the Senate amendment as amended. The House concurred with the Senate amendments and passed the bill as amended on March 11, 2016. The bill contains a portion of HB 1431.

Effective January 1, 2017, the bill authorizes ARNPs to prescribe, dispense, order, and administer controlled substances, but only to the extent authorized under a supervising physician's protocol. The bill establishes a committee to recommend a formulary of controlled substances that an ARNP may not prescribe or may only prescribe for a specific use or in limited quantities. The Board of Nursing must adopt the recommended formulary by rule by October 1, 2016, along with any revisions recommended by the Board of Medicine, Board of Osteopathic Medicine, or Board of Dentistry. The bill designates s. 464.012, F.S., as the "Barbara Lumpkin Prescribing Act."

The bill also authorizes PAs to prescribe controlled substances but limits the prescribing of Schedule II controlled substances to a 7-day supply and restricts prescribing psychiatric mental health controlled substances for children under the age of 18.

The bill subjects ARNPs and PAs to administrative disciplinary actions, such as fines or license suspensions, for violating standards of practice in law relating to prescribing and dispensing controlled substances. The bill adds specific prohibited acts related to the prescribing of controlled substances, which constitute grounds for denial of license or disciplinary action, into the Nurse Practice Act. The bill requires ARNPs and prescribing PAs to complete three hours of continuing education on the safe and effective prescribing of controlled medications each biennial licensure renewal.

The bill also expands the health care practitioners who are exempt from the registration requirements for prescribing controlled substances to treat nonmalignant chronic pain to certain board eligible or board certified physicians. Additionally, the bill provides that only a physician may dispense medication or prescribe controlled substances on the premises of a registered pain-management clinic.

The bill requires, on or after January 1, 2017, health insurers or pharmacy benefits managers to use a standardized prior authorization form adopted in rule by the Financial Services Commission, if an electronic prior authorization form is not used. An electronic prior authorization approval does not preclude an insurer from performing a benefit verification or medical review.

The bill permits a free clinic to receive an appropriation or grant from a governmental entity or nonprofit corporation to support the delivery of contracted services by uncompensated, volunteer health care providers without jeopardizing its sovereign immunity under the Access to Health Care Act.

Subject to the Governor's veto powers, the effective date of this bill is upon becoming law, except as otherwise expressly provided in the bill.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

STORAGE NAME: h0423z.HQS

DATE: March 21, 2016

I. SUBSTANTIVE INFORMATION

A. EFFECT OF CHANGES:

Physician Assistants

Licensure and Regulation

A physician assistant (PA) is a person who has completed an approved medical training program and is licensed to perform medical services, as delegated by a supervising physician.¹ PAs licensure is governed by ss. 458.347(7) and 459.022(7), F.S. The Department of Health (DOH) licenses PAs, and the Florida Council on Physician Assistants (Council) regulates the practice of PAs in conjunction with either the Florida Board of Medicine (Board of Medicine) for PAs licensed under ch. 458, F.S., or the Board of Osteopathic Medicine (Osteopathic Board) for PAs licensed under ch. 459, F.S. Currently, 7,987 PAs hold active licenses in Florida.²

To be licensed as a PA, an applicant must demonstrate to the Council that he or she has met the following requirements:

- Satisfactory passage of the proficiency examination administered by the National Commission on Certification of Physician Assistants;
- Completion of an application and remittance of the applicable fees to the DOH;³
- Completion of an approved PA training program;
- Submission of a sworn statement of any prior felony convictions;
- Submission of a sworn statement of any revocation or denial of licensure or certification in any state;
- Submission of two letters of recommendation; and
- If the applicant is seeking prescribing authority, a submission of a copy of course transcripts and the course description from a PA training program describing the course content in pharmacotherapy.⁴

Licenses are renewed biennially.⁵ At the time of renewal, a PA must demonstrate that he or she has met the continuing medical education requirements of 100 hours and must submit a sworn statement that he or she has not been convicted of any felony in the previous two years.⁶ If a PA is licensed as a prescribing PA, an additional 10 hours of continuing medical education in the specialty areas of his or her supervising physician must be completed.⁷

Education of PAs

According to the American Academy of Physician Assistants, all accredited PA educational programs include pharmacology courses, and the average amount of formal classroom instruction in pharmacology is 75 hours.⁸ Course topics include pharmacokinetics, drug interactions, adverse effects, contraindications, indications, and dosage, generally by doctoral-level pharmacologists or

¹ Sections 458.347(2)(e) and 459.022(2)(e), F.S.

² Email correspondence with the Department of Health on November 9, 2015. The number of active-licensed PAs include both in-state and out-of-state licensees, as of November 9, 2015.

³ The application fee is \$100 and the initial license fee is \$200. Applicants must also pay an unlicensed activity fee of \$5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.

⁴ Sections 458.347(7) and 459.022(7), F.S.

⁵ For timely renewed licenses, the renewal fee is \$275 and the prescribing registration fee is \$150. Additionally, at the time of renewal, the PA must pay an unlicensed activity fee of \$5. See Rules 64B8-30.019 and 64B15-6.013, F.A.C.

⁶ Sections 458.347(7)(c)-(d) and 459.022(7)(c)-(d), F.S.

⁷ Rules 64B8-30.005(6) and 64B15-6.0035(6), F.A.C.

⁸ American Academy of Physician Assistants, *PAs as Prescribers of Controlled Medications*, Professional Issues – Issue Brief (Dec. 2013), (on file with the staff of the Health and Human Services committee).

clinical pharmacists.⁹ Additionally, pharmacology education occurs on all clinical clerkships or rotations.¹⁰

Supervision of PAs

A PA may only practice under the delegated authority of a supervising physician. A supervising physician may only delegate tasks and procedures to the PA that are within the supervising physician's scope of practice.¹¹ Supervision is defined as responsible supervision and control that requires the easy availability or physical presence of the licensed physician for consultation and direction of the PA.¹² A physician may not supervise more than four PAs at any time.¹³

The Board of Medicine and the Osteopathic Board have prescribed by rule what constitutes adequate responsible supervision. Responsible supervision is the ability of a supervising physician to reasonably exercise control and provide direction over the services or tasks performed by the PA.¹⁴ Whether the supervision of the PA is adequate is dependent on the:

- Complexity of the task;
- Risk to the patient;
- Background, training, and skill of the PA;
- Adequacy of the direction in terms of its form;
- Setting in which the tasks are performed;
- Availability of the supervising physician;
- Necessity for immediate attention; and
- Number of other persons that the supervising physician must supervise.¹⁵

Direct supervision refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed.¹⁶ Indirect supervision refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication.¹⁷ The decision to permit a PA to perform a task or procedure under direct or indirect supervision is made by the supervising physician based on reasonable medical judgment regarding the probability of morbidity and mortality to the patient.¹⁸

Delegable Tasks

Rules of both the Board of Medicine and the Osteopathic Board place limitations on a supervising physician's ability to delegate certain tasks. Prescribing, dispensing, or compounding medicinal drugs and making a final diagnosis are not permitted to be delegated to a PA, except when specifically authorized by statute.¹⁹

⁹ *Id.*

¹⁰ *Id.*

¹¹ Rules 64B8-30.012(1) and 64B15-6.010(1), F.A.C. The term "scope of practice" refers to those tasks and procedures that the supervising physician is qualified by training or experience to support.

¹² Sections 458.347(2)(f) and 459.022(2)(f), F.S.

¹³ Sections 458.347(3) and 459.022(3), F.S.

¹⁴ Rules 64B8-30.001(3) and 64B15-6.001(3), F.A.C.

¹⁵ *Id.*

¹⁶ Rules 64B8-30.001(4) and 64B15-6.001(4), F.A.C.

¹⁷ Rules 64B8-30.001(5) and 64B15-6.001(5), F.A.C.

¹⁸ Rules 64B8-30.012(2) and 64B15-6.010(2), F.A.C.

¹⁹ *Supra* note 12.

A supervising physician may delegate authority to a PA the authority to:

- Prescribe or dispense any medicinal drug used in the supervising physician's practice;²⁰
- Order medicinal drugs for a hospitalized patient of the supervising physician;²¹ and
- Administer a medicinal drug under the direction and supervision of the physician.

Currently, PAs are prohibited from prescribing controlled substances, anesthetics, and radiographic contrast materials.²² However, physicians may delegate the authority to order controlled substances in facilities licensed under ch. 395, F.S.²³

Regulation of Advanced Registered Nurse Practitioners

Part I of ch. 464, F.S., governs the licensure and regulation of advanced registered nurse practitioners (ARNPs) in Florida. Nurses are licensed by the DOH and are regulated by the Board of Nursing.²⁴ There are 22,003 actively licensed ARNPs in Florida.²⁵

In Florida, an ARNP is a licensed nurse who is certified in advanced or specialized nursing practice and may practice as a certified registered nurse anesthetist, a certified nurse midwife, or a nurse practitioner.²⁶ Section 464.003(2), F.S., defines "advanced or specialized nursing practice" to include 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.²⁷

Florida recognizes three types of ARNPs: nurse anesthetist, certified nurse midwife, and nurse practitioner. The Board of Nursing, created by s. 464.004, F.S., establishes the eligibility criteria for an applicant to be certified as an ARNP and the applicable regulatory standards for ARNP nursing practices.²⁸ To be certified as an ARNP, the applicant must:

- Have a registered nurse license;
- Have earned, at least, a master's degree; and
- Submit proof to the Board of Nursing of holding a current national advanced practice certification obtained from a board-approved nursing specialty board.²⁹

²⁰ Sections 458.347(4)(f)1., F.S., and 459.022(4)(e), F.S., directs the Council to establish a formulary listing the medical drugs that a PA may not prescribe. The formulary in Rules [64B8-30.008](#) and 64B15-6.0038, F.A.C., prohibits PAs from prescribing controlled substances, as defined in Chapter 893, F.S., general, spinal, or epidural anesthetics, and radiographic contrast materials.

²¹ Sections 458.347(4)(g), and 459.022(4)(f), F.S., provides that an order is not a prescription.

²² Rules 64B8-30.008, F.A.C., and 64B15-6.0038, F.A.C.

²³ Sections 458.347(4)(g), F.S., and 459.022(4)(f), F.S.; the facilities licensed in ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

²⁴ Pursuant to s. 464.004, F.S., the Board of Nursing is comprised of 13 members appointed by the Governor and confirmed by the Senate who serve 4-year terms. The Board is comprised of three licensed practical nurses who have practiced for at least four years, seven members who are registered nurses who have practiced for at least 4 years; three Florida residents who have never been licensed as nurses, are not connected to the practice of nursing, and have no financial interest in any health care facility, agency, or insurer; and seven members who are registered nurses who have practiced at least four years. Among the seven members who are registered nurses, there must be at least one must be an ARNP, one nurse educator of an approved program, and one nurse executive.

²⁵ E-mail correspondence with the Department of Health (Nov. 9, 2015) (on file with the staff of the Health and Human Services Committee). This number includes all active licenses, including out of state practitioners.

²⁶ Section 464.003(3), F.S.

²⁷ Section 464.003(2), F.S.

²⁸ Section 464.012(2), F.S.

²⁹ Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C. A nursing specialty board must attest to the competency of nurses in a clinical specialty area, require nurses to take a written examination prior to certification, require nurses to complete a formal program prior to eligibility of examination, maintain program accreditation, and identify standards or scope of practice statements appropriate for each nursing specialty.

All ARNPs must carry malpractice insurance or demonstrate proof of financial responsibility.³⁰ An applicant for certification is required to submit proof of coverage or financial responsibility within sixty days of certification and with each biennial renewal.³¹ An ARNP must have 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, which is payable to the ARNP as beneficiary, in the amount of at least \$100,000 per claim with a minimum aggregate availability of at least \$300,000.³²

Supervision of ARNPs

Pursuant to s. 464.012(3), F.S., ARNPs may only perform nursing practices delineated in an established protocol filed with the Board of Nursing that is filed within 30 days of entering into a supervisory relationship with a physician and upon biennial license renewal.³³ Florida law allows a primary care physician to supervise ARNPs in up to four offices, in addition to the physician's primary practice location.³⁴ If the physician provides specialty health care services, then only two medical offices, in addition to the physician's primary practice location, may be supervised.

The supervision limitations do not apply in the following facilities:

- Hospitals;
- Colleges of medicine or nursing;
- Nonprofit family-planning clinics;
- Rural and federally qualified health centers;
- Nursing homes;
- Assisted living facilities;
- Student health care centers or school health clinics; and
- Other government facilities.³⁵

To ensure appropriate medical care, the number of ARNPs a supervising physician may supervise is limited based on consideration of the following factors:

- Risk to the patient;
- Educational preparation, specialty, and experience in relation to the supervising physician's protocol;
- Complexity and risk of the procedures;
- Practice setting; and
- Availability of the supervising physician or dentist.³⁶

Delegable Tasks

Within the framework of a written physician protocol, an ARNP may:

- Monitor and alter drug therapies;
- Initiate appropriate therapies for certain conditions;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty;
- Perform medical acts authorized by a joint committee; and

³⁰ Section 456.048, F.S.

³¹ Rule 64B9-4.002(5), F.A.C.

³² *Id.*

³³ Physicians are also required to provide notice of the written protocol and the supervisory relationship to the Board of Medicine or Board of Osteopathic Medicine, respectively. See ss. 458.348 and 459.025, F.S.

³⁴ Sections 458.348(4) and 459.025(3), F.S.

³⁵ Sections 458.348(4)(e), and 459.025(3)(e), F.S.

³⁶ Rule 64B9-4.010, F.A.C.

- Perform additional functions determined by rule.³⁷

Florida law does not authorize ARNPs to prescribe, independently administer, or dispense controlled substances.³⁸

Controlled Substances

Controlled substances are drugs with the potential for abuse. Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act (Act) and classifies controlled substances into five categories, known as schedules.³⁹ The distinguishing factors between the different drug schedules are the “potential for abuse” of the substance and whether there is a currently accepted medical use for the substance. Schedules are used to regulate the manufacture, distribution, preparation and dispensing of the substances. The Act provides requirements for the prescribing and administering of controlled substances by health care practitioners and proper dispensing by pharmacists and health care practitioners.⁴⁰

Controlled Substance Prescribing for Nonmalignant Pain in Florida

As of January 1, 2012, every physician, podiatrist, or dentist, who prescribes controlled substances in the state for the treatment of chronic nonmalignant pain,⁴¹ must register as a controlled substance prescribing practitioner and comply with certain practice standards specified in statute and rule.⁴² Before prescribing controlled substances for the treatment of chronic nonmalignant pain, a practitioner must:

- Document certain characteristics about the nature of the patient’s pain, success of past treatments, and a history of alcohol and substance abuse;
- Develop a written plan for assessing the patient’s risk for aberrant drug-related behavior and monitor such behavior throughout the course of controlled substance treatment;
- Develop an written individualized treatment plan for each patient stating the objectives that will be used to determine treatment success; and
- Enter into a controlled substance agreement with each patient that must be signed by the patient or their legal representative and by the prescribing practitioner. Such agreements must include:
 - The number and frequency of prescriptions and refills;
 - A statement outlining expectations for patient compliance and reasons for which the drug therapy may be discontinued, such as violation of the agreement; and
 - An agreement that the patient’s chronic nonmalignant pain only be treated by a single treating practitioner unless otherwise authorized and documented in the medical record.⁴³

³⁷ Section 464.012(3), F.S. Pursuant to s. 464.012(4), F.S., certified registered nurse anesthetists, certified nurse midwives, and certified nurse practitioners are authorized to perform additional acts that are within their specialty and authorized under an established supervisory protocol.

³⁸ Sections 893.02(21) and 893.05(1), F.S. The definition of practitioner does not include ARNPs.

³⁹ See s. 893.03, F.S.

⁴⁰ Sections 893.04 and 893.05, F.S.

⁴¹ “Chronic nonmalignant pain” is defined as pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery. Section 456.44(1)(e), F.S.

⁴² Chapter 2011-141, s. 3, Laws of Fla. (creating ss. 456.44, F.S., effective July 1, 2011).

⁴³ Section 465.44(3), F.S.

Patients being treated with controlled substances for chronic nonmalignant pain must be seen by their prescribing practitioners at least once every three months to monitor progress and compliance, and detailed medical records relating to such treatment must be maintained.⁴⁴ Patients at special risk for drug abuse or diversion may require consultation with or a referral to an addiction medicine physician or a psychiatrist.⁴⁵ Anyone with signs or symptoms of substance abuse must be immediately referred to a pain-management physician, an addiction medicine specialist, or an addiction medicine facility.⁴⁶

Drug Enforcement Administration

The Drug Enforcement Administration (DEA), housed within the U.S. Department of Justice, enforces the controlled substances laws and regulations of the United States, including preventing and investigating the diversion of controlled pharmaceuticals.⁴⁷

Any health care professional wishing to prescribe controlled substances must apply for a registration number from the DEA. Registration numbers are linked to state licenses and may be suspended or revoked upon any disciplinary action taken against a licensee.⁴⁸ The DEA will grant registration numbers to a wide range of health care professionals, including physicians, nurse practitioners, physician assistants, optometrists, dentists, and veterinarians, but such professionals may only prescribe controlled substances as authorized under state law.⁴⁹ The DEA provides that a controlled substance prescription may only be issued by a registered practitioner who is:

- Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice; and
- Registered with the DEA, or exempt from registration (e.g., Public Health Service, Federal Bureau of Prisons, or military practitioners); or
- An qualified agent or employee of a hospital or other institution acting in the normal course of business or employment under the DEA registration number of the hospital or other institution which is registered in lieu of the individual practitioner being registered.⁵⁰

The DEA's Practitioner Manual includes requirements for valid prescriptions. The DEA defines "prescription" as an order for medication which is dispensed to or for an ultimate user, but is not an order for a medication dispensed for immediate administration to the user, such as an order to dispense a drug to a patient in a hospital setting.⁵¹

Controlled Substance Prescriptive Authority for ARNPs and PAs in Other States

ARNPs

An ARNP's ability to prescribe, dispense, or administer controlled substances is dependent on his or her specific state's law. Forty-nine states authorize ARNPs to prescribe controlled substances.⁵²

Twenty-one states and the District of Columbia allow an ARNP to practice independently, including evaluating, diagnosing, ordering, and interpreting diagnostic tests, and managing treatment, including

⁴⁴ Section 465.44(3)(d), F.S.

⁴⁵ Section 465.44(3)(e), F.S.

⁴⁶ Section 456.44(3)(g), F.S.

⁴⁷ Drug Enforcement Administration, *About Us*, available at <http://www.deadiversion.usdoj.gov/Inside.html> (last visited March 15, 2016).

⁴⁸ Registration numbers must be renewed every three years. Drug Enforcement Administration, *Practitioners Manual*, 7(2006), available at http://www.deadiversion.usdoj.gov/pubs/manuals/pract/pract_manual012508.pdf (last visited March 15, 2016).

⁴⁹ *Id.* at 7.

⁵⁰ DEA, *Practitioner Manual*, 18.

⁵¹ *Id.*

⁵² Drug Enforcement Agency, *Mid-Level Practitioners Authorization by State* (Feb. 4, 2016), available at http://www.deadiversion.usdoj.gov/drugreg/practioners/mlp_by_state.pdf (last visited March 15, 2016). The Commonwealth of Puerto Rico also prohibits ARNPs from prescribing controlled substances.

prescribing medications, of a patient without physician supervision.⁵³ Twenty-two states specifically prohibit certified registered nurse anesthetists from prescribing controlled substances.⁵⁴

Some states have specific limitations regarding ARNPs prescribing authority for Schedule II controlled substances.⁵⁵ For example, 7 states authorize ARNPs to prescribe all levels of scheduled drugs, except for Schedule II. Some states have specific education requirements for those ARNPs who wish to prescribe Schedule II substances or require additional registration for ARNPs to be authorized to prescribe.⁵⁶

PAs

A PA's ability to prescribe, dispense, or administer controlled substances is dependent on their specific state's law. Forty-eight states authorize PAs to prescribe controlled substances within an agreement with a supervisory physician, with varying limitations on administration, dispensing, and independent prescribing.⁵⁷

Of the 48 states, some have specific restrictions on PAs' prescribing authority for schedule II controlled substances; for example, Texas and Hawaii only authorize PAs to order schedule II controlled substances in an inpatient hospital setting. Some states have medication quantity restrictions on prescriptions for schedule II drugs and some states give PAs' prescriptive authority for all levels of scheduled drugs except for schedule II.⁵⁸ Some states also have a formulary determined by the relevant PA licensing board which identifies the controlled substances that PAs are authorized to prescribe.

Prior Authorizations

Insurers may require prior authorization for certain services as a cost control and quality measure. Florida law prohibits requirements for prior authorization for certain services and requires direct access within specified guidelines for certain services, such as dermatology.⁵⁹ Prior authorization is generally not required for an emergency procedure.⁶⁰ State law currently does not provide a specific standard form or review timeline for a prior authorization process for health care services covered by an insurer, managed care plan, or health maintenance organization. Each insurer establishes its own prior authorization process and form based on the situation and the type of authorization, service, course of treatment, or prescription.

⁵³ Alaska, Arizona, Colorado, Connecticut, District of Columbia, Hawaii, Idaho, Iowa, Maine, Maryland, Minnesota, Montana, Nebraska, Nevada, New Hampshire, New Mexico, North Dakota, Oregon, Rhode Island, Vermont, Washington, and Wyoming allow for independent practice. See American Association of Nurse Practitioners, *State Practice Environment*, available at <https://www.aanp.org/legislation-regulation/state-legislation/state-practice-environment/66-legislation-regulation/state-practice-environment/1380-state-practice-by-type> (last visited March 15, 2016).

⁵⁴ American Association of Nurse Anesthetists, AANA Journal, June 2011; 79(3):235, on file with committee staff.

⁵⁵ *Supra* note 51.

⁵⁶ *Id.*

⁵⁷ *Id.* Every state, except Florida and Kentucky, has some form of controlled substance prescriptive authority for PAs.

⁵⁸ *Id.*

⁵⁹ Section 641.31(33), F.S., provides direct access to dermatologists for up to five visits and testing annually.

⁶⁰ See e.g. s. 409.9128, F.S., which prohibits a Medicaid managed care program or the MediPass program from requiring prior authorization for emergency services and care; s. 641.513, F.S., which prohibits a health maintenance organization from requiring prior authorization for emergency services and care; Florida Blue, *When You Need a Prior Authorization for Medical Services* (Feb. 2016, available at <https://www.floridablue.com/members/tools-resources/prior-authorization-for-medical-services>); and Aetna, *Emergency Room Services Q&A*, available at <https://www.aetna.com/health-reform-connection/questions-answers/emergency-room-services.html> (last visited March 21, 2016).

Sovereign Immunity

The legal doctrine of sovereign immunity prevents a government from being sued in its own courts without its consent.⁶¹ According to United States Supreme Court Justice Oliver Wendell Holmes, citing the noted 17th century Hobbes work, *Leviathan*, “a sovereign is exempt from suit, not because of any formal conception or obsolete theory, but on the logical and practical ground that there can be no legal right as against the authority that makes the law on which the right depends.”⁶² State governments in the United States, as sovereigns, inherently possess sovereign immunity.⁶³

Article X, section 13 of the Florida Constitution recognizes the concept of sovereign immunity and gives the Legislature the power to waive immunity in part or in full by general law. Section 768.28, F.S., contains the limited waiver of sovereign immunity applicable to the state. Under this statute, officers, employees, and agents of the state⁶⁴ will not be held personally liable in tort or named as a party defendant in any action for any injury or damage suffered as a result of any act, event, or omission of action in the scope of her or his employment or function. However, personal liability may result from actions committed in bad faith or with malicious purpose or in a manner exhibiting wanton and willful disregard of human rights, safety, or property.⁶⁵

When an officer, employee, or agency of the state is sued, the state steps in as the party litigant and defends against the claim. The recovery by any one person is limited to \$200,000 for one incident and the total for all recoveries related to one incident is limited to \$300,000.⁶⁶ The sovereign immunity recovery caps do not prevent a plaintiff from obtaining a judgment in excess of the caps, but the plaintiff cannot recover the excess damages without action by the Legislature.⁶⁷

Whether sovereign immunity applies turns on the degree of control of the agent of the state retained by the state.⁶⁸ In *Stoll v. Noel*, the Florida Supreme Court explained that independent contractor physicians may be agents of the state for purposes of sovereign immunity:⁶⁹

One who contracts on behalf of another and subject to the other’s control except with respect to his physical conduct is an agent and also independent contractor.

The Court examined the employment contract between the physicians and the state to determine whether the state’s right to control was sufficient to create an agency relationship.⁷⁰ The facts of the case demonstrated the state’s control over the independent contractor physicians and, therefore, the Court held that an agency relationship existed.⁷¹

⁶¹ Black’s Law Dictionary, 3rd Pocket Edition, 2006.

⁶² *Kawananakoa v Polyblank*, 205 U.S. 349, 353 (1907).

⁶³ See, e.g., Fla. Jur. 2d, Government Tort Liability, Sec. 1.

⁶⁴ The statutes define state agencies or subdivisions to include executive departments, the legislature, the judicial branch, and independent establishments of the state, such as state university boards of trustees, counties and municipalities, and corporations primarily acting as instrumentalities or agencies of the state, including the Florida Space Authority. Section 768.28(2), F.S.

⁶⁵ Section 768.28(9)(a), F.S.

⁶⁶ Section 768.28(5), F.S.

⁶⁷ *Id.*

⁶⁸ *Stoll v. Noel*, 694 So. 2d 701, 703 (Fla. 1997).

⁶⁹ *Id.* at 703, quoting from the *Restatement (Second) of Agency* s. 14N (1957).

⁷⁰ *Id.*

⁷¹ *Id.* at 703.

Section 766.1115, F.S., is entitled “The Access to Health Care Act” (Act). It was enacted in 1992 to encourage health care providers to provide care to low-income persons.⁷² The DOH through the Volunteer Health Services Program administers the Act.⁷³ Volunteers complete an enrollment application with the DOH, which includes personal reference and background checks.⁷⁴

This section of law extends sovereign immunity to health care providers who execute a contract with a governmental contractor⁷⁵ and who, as agents of the state, provide volunteer, uncompensated health care services to low-income individuals. These health care providers are considered agents of the state under s. 768.28(9), F.S., for purposes of extending sovereign immunity while acting within the scope of duties required under the Act.⁷⁶

A contract under the Act must pertain to volunteer, uncompensated services. For services to qualify as volunteer, uncompensated services, the health care provider must receive no compensation from the governmental contractor for any services provided under the contract and must not bill or accept compensation from the recipient or any public or private third-party payor for the specific services provided to the low-income recipients covered by the contract.⁷⁷

The Act establishes several contractual requirements for government contractors and health care providers. The contract must require the government contractor to retain the right of dismissal or termination of any health care provider delivering services under the contract⁷⁸ and to have access to the patient records of any health care provider delivering services under the contract.⁷⁹ The health care provider must, under the contract, report adverse incidents and information on treatment outcomes to the governmental contractor.⁸⁰ The governmental contractor or the health care provider must make patient selection and initial referrals.⁸¹ The health care provider is subject to supervision and regular inspection by the governmental contractor.⁸²

Health care providers under the Act include:⁸³

- A birth center licensed under ch. 383, F.S.
- An ambulatory surgical center licensed under ch. 395, F.S.
- A hospital licensed under ch. 395, F.S.
- A physician or physician assistant licensed under ch. 458, F.S.
- An osteopathic physician or osteopathic physician assistant licensed under ch. 459, F.S.
- A chiropractic physician licensed under ch. 460, F.S.
- A podiatric physician licensed under ch. 461, F.S.

⁷² Low-income persons include a person who is Medicaid-eligible, a person who is without health insurance and whose family income does not exceed 200 percent of the federal poverty level, or any eligible client of the DOH who voluntarily chooses to participate in a program offered or approved by the department. Section 766.1115(3)(e), F.S. A single individual whose annual income does not exceed \$23,540 is at 200 percent of the federal poverty level using Medicaid data. *2015 Poverty Guidelines*, U.S. Department of Health and Human Services(Sept. 3 2015), available at <http://aspe.hhs.gov/poverty/15poverty.cfm> (last visited March 15, 2016).

⁷³ DOH, *Volunteer Health Services*, available at <http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteer-health-services-opportunities/index.html> (last visited March 15, 2016); and Rule Chapter 64I-2, F.A.C.

⁷⁴ DOH, *Volunteer Services Policy* (July 2013) pp. 7-8, <http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteer-health-services-opportunities/VHS2PolicyDOHP380-7-14.pdf> (last visited March 15, 2016).

⁷⁵ A governmental contractor is the DOH, a county health department, a special taxing district having health care responsibilities, or a hospital owned and operated by a governmental entity. Section 766.1115(3)(c), F.S.

⁷⁶ Section 766.1115(4), F.S.

⁷⁷ Section 766.1115(3)(a), F.S.

⁷⁸ Section 766.1115(4)(a), F.S.

⁷⁹ Section 766.1115(4)(b), F.S.

⁸⁰ Section 766.1115(4)(c), F.S.

⁸¹ Section 766.1115(4)(d), F.S.

⁸² Section 766.1115(4)(f), F.S.

⁸³ Section 766.1115(3)(d), F.S.

- A registered nurse, nurse midwife, licensed practical nurse, or advanced registered nurse practitioner licensed or registered under part I of ch. 464, F.S., or any facility that employs nurses licensed or registered under part I of ch. 464, F.S., to supply all or part of the care delivered under the Act.
- A dentist or dental hygienist licensed under ch. 466, F.S.
- A midwife licensed under ch. 467, F.S.
- A health maintenance organization certificated under part I of ch. 641, F.S.
- A health care professional association and its employees or a corporate medical group and its employees.
- Any other medical facility the primary purpose of which is to deliver human medical diagnostic services or which delivers nonsurgical human medical treatment, and which includes an office maintained by a provider.
- A free clinic that delivers only medical diagnostic services or nonsurgical medical treatment free of charge to all low-income recipients.
- Any other health care professional, practitioner, provider, or facility under contract with a governmental contractor, including a student enrolled in an accredited program that prepares the student for licensure as a physician, physician assistant, nurse, or midwife.
- Any nonprofit corporation qualified as exempt from federal income taxation under s. 501(a) of the Internal Revenue Code, and described in s. 501(c) of the Internal Revenue Code, that delivers health care services provided by the listed licensed professionals, any federally funded community health center, and any volunteer corporation or volunteer health care provider that delivers health care services.

The governmental contractor must provide written notice to each patient, or the patient's legal representative, receipt of which must be acknowledged in writing, that the provider is covered under s. 768.28, F.S., for purposes of legal actions alleging medical negligence.⁸⁴

According to the department, from July 1, 2014, through June 30, 2015, 12,569 licensed health care volunteers (plus an additional 9,938 clinic staff volunteers) provided 373,588 health care patient visits with a total value of donated goods and services of more than \$271 million, under the Act.⁸⁵ The Florida Department of Financial Services, Division of Risk Management, reported that as of January 7, 2015, that 10 claims had been filed against the Volunteer Health Care Provider Program under s. 766.1115, F.S., since February 15, 2000.⁸⁶

Legislative Appropriation to Free and Charitable Clinics

The use of legislative appropriations by the Florida Association of Free and Charitable Clinics, a health care provider under the Act, is restricted to clinic capacity building purposes by the contract with the DOH. Clinic capacity building is limited to products or processes that increase skills, infrastructure, and resources of clinics. The DOH does not authorize these funds to be used to build capacity through the employment of clinical personnel.⁸⁷

The Florida Association of Free and Charitable Clinics received a \$9.5 million appropriation in the 2015-2016 General Appropriations Act through the DOH.⁸⁸ However, the Governor vetoed this appropriation

⁸⁴ Section 766.1115(5), F.S.

⁸⁵ DOH, *Volunteer Health Services 2014-2015 Annual Report* (Dec. 1, 2015), available at <http://www.floridahealth.gov/provider-and-partner-resources/getting-involved-in-public-health/volunteer-health-services-opportunities/VHS1415annualreport.pdf> (last visited March 15, 2016).

⁸⁶ *Id.* at A-1.

⁸⁷ Correspondence from the DOH staff to the Health Quality Subcommittee dated January 29, 2016, on file with the Health Quality Subcommittee.

⁸⁸ Chapter 2015-232, Laws of Fla., line item 441.

“because the funds could not be used for services, and therefore it is not a statewide priority for improving cost, quality, and access in healthcare.”⁸⁹

Effect of the Bill

The bill authorizes licensed PAs and licensed ARNPs to prescribe controlled substances under current supervisory standards for PAs and protocols for ARNPs.

Physician Assistants

Effective January 1, 2017, the bill authorizes PAs to prescribe controlled substances by removing the requirement that the formulary of medicinal drugs that a PA may not prescribe include controlled substances. However, the bill requires the formulary to restrict the prescribing of Schedule II controlled substances to a 7-day supply and restrict the prescribing of psychiatric mental health controlled substances for children under age 18.

The bill subjects PAs to administrative disciplinary actions in s. 456.072, F.S., such as fines or license suspensions for violating standards of practice in law relating to prescribing and dispensing controlled substances.⁹⁰

The bill requires a prescribing PA to complete three hours of continuing education each biennial licensure renewal on the safe and effective prescribing of controlled substance medications offered by a statewide professional association of physicians that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or designated by the American Academy of Physician Assistants as a Category 1 credit.⁹¹

Advanced Registered Nurse Practitioners

Effective January 1, 2017, the bill authorizes ARNPs to prescribe, dispense, order, or administer controlled substances, if allowed under a supervising physician's protocol. The bill adds additional acts related to the prescribing of controlled substances into s. 464.018, F.S., which an ARNP is prohibited from performing and which, if performed, constitute grounds for denial of license or disciplinary actions.

The bill requires the appointment of a committee⁹² to recommend an evidence-based formulary of controlled substances that an ARNP may not prescribe or may only prescribe under limited circumstances or in limited quantities. The committee may recommend a formulary applicable to all ARNPs which is limited by specialty certification, is limited to approved uses of controlled substances, or is subject to other restrictions the committee finds is necessary to protect the health, safety, and welfare of the public. The formulary must restrict the prescribing of Schedule II controlled substances to a 7-day supply, excluding psychiatric medications prescribed by psychiatric nurses. The Board of Nursing must adopt the recommended formulary by rule by October 1, 2016, along with any revisions which it finds supported by evidence-based clinical findings presented by the Board of Medicine, the Board of Osteopathic Medicine, or the Board of Dentistry.

⁸⁹ Governor Rick Scott, *Veto Message to Secretary of State Ken Detzner* (June 23, 2015), p. 35, available at <http://www.flgov.com/wp-content/uploads/2015/06/Transmittal%20Letter%206.23.15%20-%20SB%202500-A.pdf> (last visited March 15, 2016).

⁹⁰ Disciplinary sanctions against physicians apply to PAs. Sections 458.347(7)(g) and 459.022(7)(g), F.S., state that the Board of Medicine or the Board of Osteopathic Medicine may impose any penalty authorized under ss. 456.072, 458.332(2), and [459.015\(2\)](#), F.S., on a PA if the PA or the supervising physician has been found guilty of any prohibited acts.

⁹¹ The American Medical Association Physician Recognition Award and the American Academy of Physician Assistants Category I designation are accreditation programs for continuing medical education programs for the respective organization. Additional information may be found at <http://www.ama-assn.org/ama/pub/education-careers/continuing-medical-education/physicians-recognition-award-credit-system.page>? and <https://www.aapa.org/cme/cme-accreditation/>, respectively (last visited March 15, 2016).

⁹² The committee is to be composed of three licensed ARNPs, three licensed physicians with experience working with ARNPs, and a licensed pharmacist.

The bill revises s. 456.072(7), F.S., to include disciplinary actions against ARNPs, including specific fines and license suspension, which mirror actions against physicians for prescribing or dispensing a controlled substance other than in the course of professional practice or for failing to meet practice standards.

The bill requires ARNPs to complete three hours of continuing education each biennial licensure renewal on the safe and effective prescribing of controlled substance medications offered by a statewide professional association of physicians that is accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award Category 1 credit or designated by the American Academy of Physician Assistants as a Category 1 credit.⁹³

The bill designates s. 464.012, F.S., as the "Barbara Lumpkin Prescribing Act."

Controlled Substances

The bill adds PAs and ARNPs to the definition of practitioner in ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act (Act), thus requiring these practitioners to comply with the prescribing and dispensing requirements and limitations under the Act. This definition also requires practitioners to hold a valid federal DEA controlled substance registry number.

The bill amends s. 456.44, F.S., to require 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 to register as a controlled substance prescribing practitioner on the practitioner profile maintained by the DOH, and to meet other statutory requirements for such registrants.⁹⁴ The bill also replaces the terms physician and clinician with registrant throughout this section of law. The bill specifies that this registration is not required to order medication in a facility licensed under ch. 395, F.S.⁹⁵

The bill amends sections regulating pain-management clinics under the Medical Practice Act and the Osteopathic Medical Practice Act to only authorize physicians licensed under ch. 458, F.S., or ch. 459, F.S., to prescribe controlled substances in a pain-management clinic. Accordingly, PAs and ARNPs are prohibited from prescribing controlled substances in pain-management clinics.

The bill expands the health care practitioners who are exempt from the registration requirements for prescribing controlled substances to treat nonmalignant chronic pain. Specifically, the bill exempts from registration a medical specialist board-eligible or board-certified in pain medicine by the American Board of Interventional Pain Physicians or the American Association of Physician Specialists.

The bill makes several conforming changes to various statutes to recognize the new prescribing authority for PAs and ARNPs.

⁹³ *Id.*

⁹⁴ Currently, PAs do not have practitioner profiles. Practitioner profiles contain information about a practitioner's education, training, and practice and are accessible to the public. If the bill is enacted, the Department will need to develop a profile for PAs.

⁹⁵ The facilities licensed under ch. 395, F.S., include hospitals, ambulatory surgical centers, and mobile surgical facilities.

Free Clinics

Access to Health Care Act

The bill authorizes a health care provider to receive and use appropriations or grants from a governmental entity or nonprofit corporation to support the delivery of contracted services by volunteer health care providers under the Act without those funds being deemed compensation which might jeopardize the sovereign immunity protections afforded in the Act. The bill authorizes these appropriations or grants to be used for the employment of health care providers to supplement, coordinate, or support the delivery of services by volunteer health care providers. The bill states that the receipt and use of the appropriation or grant does not constitute the acceptance of compensation for the specific services provided to the low-income recipients covered by the contract.

Prior Authorizations

On or after January 1, 2017, the bill requires health insurers, managed care plans, health maintenance organizations, and their pharmacy benefit managers, that do not use electronic prior authorization forms, to only use the prior authorization form approved by the Financial Services Commission, in consultation with the Agency for Health Care Administration, to obtain approval for a medical procedure, course of treatment, or prescription drug benefit. The form must be limited to two pages, excluding instructions. The Financial Services Commission, in consultation with the Agency for Health Care Administration, must adopt a rule providing guidelines for all prior authorization forms to ensure uniformity of such forms.

The bill provides that an electronic prior authorization does not preclude an insurer from performing a benefit verification or medical review.

The bill provides that except as otherwise expressly provided in the act, the act shall take effect upon becoming a law.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill may have an insignificant negative fiscal impact on the DOH associated with rulemaking, the creation of practitioner profiles for PAs, and workload impacts related to potential additional practitioner complaints and investigations. Current budget authority and revenues are adequate to absorb any additional workload.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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 additional involvement of a physician prescribing a needed controlled substance for treatment. Any such impacts are indeterminate.

Free clinics will be able to use certain funds to pay for support services without compromising sovereign immunity.

D. FISCAL COMMENTS:

None.