HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 129 Health Care Practitioner Regulation

SPONSOR(S): Health Quality Subcommittee; Plasencia

TIED BILLS: IDEN./SIM. BILLS:

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	14 Y, 0 N, As CS	Siples	McElroy
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

Advanced registered nurse practitioners (ARNPs) are licensed registered nurses with post-graduate education in nursing that prepares them to perform advanced or specialized nursing. ARNPs may perform nursing or medical acts that are authorized pursuant to a written protocol with a physician. ARNPs may only sign those documents that are directly related to the performance of the nursing or medical acts authorized pursuant to a protocol, unless otherwise prohibited by law.

Physician assistants (PAs) complete specialized education that prepares them to perform medical services and practice as a part of a health care team. PAs practice under the delegated authority of a supervising physician. A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and do not, by law, require a physician's signature.

HB 129 authorizes ARNPs and PAs to sign, certify, stamp, verify, or endorse any document required by law to be signed by a physician.

The Health Care Clinic Act (Act) was enacted in 2003 to reduce fraud and abuse in the personal injury protection insurance system. Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics, ensures that such clinics meet basic standards, and provide administrative oversight.

Health care clinics must appoint a medical director that agrees in writing to accept legal responsibility for performing certain administrative activities on behalf of the clinic. A medical director must be a licensed allopathic, osteopathic, chiropractic, or podiatric physician, except for limited circumstances.

The bill authorizes an ARNP or a PA to serve as the medical director of a health care clinic.

The bill has no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2017.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives. STORAGE NAME: h0129a.HOS

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Advanced Registered Nurse Practitioners

Advanced registered nurse practitioners (ARNPs) are regulated under part I of ch. 464, F.S., the Nurse Practice Act. The Board of Nursing (BON), established under s. 464.004, F.S., provides by rule the eligibility criteria for applicants to be certified as ARNPs and the applicable regulatory standards for ARNP nursing practices. Additionally, the BON is responsible for administratively disciplining an ARNP who commits an act prohibited under ss. 464.018 or 456.072, F.S.

To be eligible to be certified as an ARNP, the applicant must be licensed as a registered nurse, have a master's degree in a nursing clinical specialty area with preparation in specialized practitioner skills, and submit proof that the applicant holds a current national advanced practice certification from a board-approved nursing specialty board.¹ 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 for examination;
- Maintain program accreditation or review mechanism that adheres to criteria which are substantially equivalent to requirements in Florida; and
- Identify standards or scope of practice statements appropriate for each nursing specialty.²

ARNPs are authorized to perform advanced or specialized nursing to include, in addition to practices of professional nursing that registered nurses are authorized to perform, advanced-level nursing acts approved by the BON as appropriate for ARNPs to perform by virtue of their post-basic specialized education, training, and experience. Advanced or specialized nursing acts may only be performed if authorized under a supervising physician's protocol.³

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

- Prescribe, dispense, administer, or order any drug;⁴
- Initiate appropriate therapies for certain conditions;
- Perform additional functions as may be determined by Board rule;
- Order diagnostic tests and physical and occupational therapy;
- Perform certain acts within his or her specialty; and
- Perform medical acts authorized as authorized within the framework of an established supervisory physician's protocol.⁵

An ARNP may sign only those documents that are directly related to the performance of authorized nursing or medical acts performed pursuant to a physician's protocol and which do not, by law, require a physician's signature.

Sections 464.012(3),(4), and 464.003, F.S.

DATE: 2/23/2017

STORAGE NAME: h0129a.HQS PAGE: 2

¹ Section 464.012(1), F.S., and Rule 64B9-4.002, F.A.C.

² Rule 64B9-4.002(3), F.A.C.

³ Section 464.003(2), F.S.

⁴ Controlled substances may only be prescribed or dispensed if the ARNP has graduated from a program leading to a master's or doctoral degree in a clinical specialty area with training in specialized practitioner skills.

Physician Assistants

Under Florida law, physician assistants are governed under the physician practice acts for medical doctors and doctors of osteopathic medicine. PAs are regulated by the Florida Council on Physician Assistants (Council) in conjunction with either the Board of Medicine for PAs licensed under ch. 458. F.S., or the Board of Osteopathic Medicine for PAs licensed under ch. 459, F.S. As of February 2017, there are 7,527 active licensed PAs.⁶

An applicant for a PA license must apply to the Department of Health (Department). The Department must issue a license to a person certified by the Council as having met all of the following requirements:

- Satisfactorily passes the National Commission on Certification of Physician Assistants exam;
- Completes an application form and remit the registration fee;
- Completes an approved PA training program;
- Provides an acknowledgement of any prior felony convictions;
- Provides an acknowledgement of any revocation or denial of licensure or certification in any
- If the applicant wishes to apply for prescribing authority, submits of a copy of course transcripts and a copy of the course description from a PA training program describing the course content in pharmacotherapy.7

In Florida, a PA practices under the delegated authority of a supervising physician. A physician supervising a PA must be gualified in the medical area in which the PA is practicing and is responsible and liable for the performance, acts, and omissions of the PA.8

The Boards have established by rule that "responsible supervision" of a PA means the ability of the supervising physician to exercise control and provide direction over the services or tasks performed by the PA. Whether the supervision of a PA is adequate, is dependent upon 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.⁹

A supervising physician may only delegate tasks and procedures to the PA which are within the supervising physician's scope of practice. 10 The decision to permit the 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. 11

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

STORAGE NAME: h0129a.HQS PAGE: 3 **DATE**: 2/23/2017

⁶ E-mail correspondence with the Department of Health dated February 2, 2017, (on file with the staff of the Health Quality Subcommittee).

See s. 458.347 and s. 459.022, F.S.

⁹ Rules 64B8-30.001, F.A.C., and 64B15-6.001, F.A.C.

¹⁰ Supra note 7.

^{11 &}quot;Direct supervision" refers to the physical presence of the supervising physician so that the physician is immediately available to the PA when needed. "Indirect supervision" refers to the reasonable physical proximity of the supervising physician to the PA or availability by telecommunication. Supra note9.

⁸ Sections 458.347(3), F.S., and 459.022(3), F.S.; and Rules 64B8-30.012, F.A.C., and 64B15-6.010, F.A.C.

- Prescribe or dispense any medicinal drug used in the supervising physician's practice unless such medication is listed in the formulary established by the Council;¹²
- Order any medication for administration for administration to the supervising physician's patient in a hospital or other facility licensed under chapter 395, F.S., or a nursing homes licensed under part II of chapter 400, F.S.:¹³ and
- Any other services that are not expressly prohibited in ch. 458, F.S., ch. 459, F.S., or the rules adopted thereunder.¹⁴

A PA may sign only those documents that are directly related to the performance of medical services performed as delegated by a supervising physician and which do not, by law, require a physician's signature.

Health Care Clinics

Regulation of Health Care Clinics

The Health Care Clinic Act (Act), ss. 400.990 – 400.995, F.S., was enacted in 2003 to reduce fraud and abuse in the personal injury protection (PIP) insurance system. ¹⁵ Pursuant to the Act, the Agency for Health Care Administration (AHCA) licenses health care clinics, ensures that such clinics meet basic standards, and provide administrative oversight.

Any entity that meets the definition of a health care clinic must be licensed as a health care clinic. To be licensed, an entity must submit a completed application form to AHCA¹⁶ and must:

- Submit to a Level 2 background screening including owners and certain employees and officers
 of the entity;
- Provide a description or explanation of any exclusions, suspensions, or terminations of the applicant from the Medicare, Medicaid, or federal Clinical Laboratory Improvement Amendment programs;
- Demonstrate financial ability to operate by showing that the applicant's assets, credits, and projected revenues will meet or exceed projected liabilities and expense¹⁷ or provide a surety bond of at least \$500,000 payable to AHCA;¹⁸
- Provide proof of the applicant's legal right to occupy the property in which the clinic is located;
 and
- Provide proof of any required insurance.¹⁹

AHCA has 60 days after the receipt of the completed application for licensure to approve or deny the application. Licenses must be renewed biennially. There are currently 2,016 licensed health care clinics.²⁰

¹² Sections 458.347(4)(f), F.S., and 459.022(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, F.A.C., and 64B15-6.0038, F.A.C., prohibits PAs from prescribing; general, spinal or epidural anesthetics; radiographic contrast materials; and psychiatric mental health controlled substances for children younger than 18 years of age. It also restricts the prescribing of Schedule II controlled substances to a 7-day supply. However, the rules authorize physicians to delegate to PAs the authority to order controlled substances in hospitals and other facilities licensed under ch. 395, F.S. ¹³ Chapter 395, F.S., provides for the regulation and the licensure of hospitals and trauma centers, part II of ch. 400, F.S., provides for the regulation and licensure of nursing home facilities.

¹⁴ Sections 458.347(4) and 459.022(e), F.S.

¹⁵ Chapter 2003-411, Laws of Fla. PIP insurance is no fault auto insurance that provides certain benefits for individuals injured as a result of a motor vehicle accident. All motor vehicles registered in this state must have PIP insurance.

¹⁶ Section 408.806, F.S.

¹⁷ Section 408.8069, F.S. This also includes providing AHCA with financial statements, including balance sheet, income and expense statement, a statement of cash flow for the first 2 years of operation that provides evidence that the applicant has sufficient assets, credits, and projected revenues to cover liabilities and expenses, and a statement of the applicant's startup costs and sources of funds through the breakeven point.

¹⁸ Section 408.8069, F.S.

¹⁹ Section 408.810, F.S.

²⁰ E-mail correspondence with AHCA staff dated February 16, 2017, (on file with the Health Quality Subcommittee). **STORAGE NAME**: h0129a.HQS

Although all clinics must be licensed by AHCA, the Act creates a number of exceptions from the health care clinic licensure requirements.²¹ There are currently 10,238 entities with Certificates of Exemption under the Act.²²

Each clinic must appoint a medical or clinical director. A medical director must be a physician employed or under contract with a clinic and who maintains and unencumbered licensed as a allopathic physician, osteopathic physician, chiropractor, or podiatrist.²³ In lieu of a medical director, a health care clinic may appoint a clinical director if the clinic does not provide services that are regulated by one of the aforementioned physician practice acts. In those situations, a duly licensed health care practitioner may serve as clinic director as long as the services provided are not beyond the scope of the practitioner's license.

The medical or clinical director must agree in writing to accept the legal responsibility for the following activities on behalf of the clinic:

- Display signs that identify the medical or clinical director posted in a conspicuous location within the clinic readily visible to all patients;
- Ensure that all practitioners providing health care services or supplies to patients maintain a current active and unencumbered Florida license;
- Review any patient referral contracts or agreements executed by the clinic;
- Ensure that all health care practitioners at the clinic have active appropriate certification or licensure for the level of care being provided;
- Serve as the clinic records owner:
- Ensure compliance with the recordkeeping, office surgery, and adverse incident reporting requirements;
- Conduct systematic reviews of clinic billings to ensure that the billings are not fraudulent or unlawful;
- Not refer a patient to the clinic if the clinic performs magnetic resonance imaging, static radiographs, computed tomography, or positron emission tomography; and
- Ensure that the clinic publishes a schedule of charges for the medical services offered to patients.²⁴

If the health care clinic's medical director is a physician, it may provide any health care service or treatment that a physician is authorized to provide. However, if the health care clinic employs another health care practitioner as its clinic director, the health care services it may offer is limited to those services within the scope of practice of that health care practitioner's license. For example, if the clinic director is a licensed under ch. 463, F.S., as an optometrist, the health care clinic services would be limited to optometric services.

Effect of Proposed Changes

HB 129 authorizes ARNPs PAs to serve as health care clinic medical directors if employed or under contract with the clinic. To serve as a medical director, an ARNP must have an active and unencumbered license under ch. 464, F.S., and be certified under s. 464.012, F.S., and a PA must have an active and unencumbered license under ch. 458, F.S. or ch. 459, F.S.

The bill also authorizes ARNPs and PAs to sign, certify, stamp, verify, or endorse a document that requires the signature, certification, stamp, verification, or endorsement of a physician. This includes, among other things, signing a certificate to initiate an involuntary examination of a person under the Baker act, signing for the release of persons in receiving facilities under the Baker Act, or signing death certificates.

²¹ Section 400.9905(4), F.S.

²² Id.

²³ Section 400.9905(5), F.S.

²⁴ Section 400.9935, F.S.

²⁵ Section 400.9905 (5), F.S. **STORAGE NAME**: h0129a.HQS

The bill provides an effective date of July 1, 2017.

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Section 1: Amends s. 400.9905, F.S., relating to definitions.

Section 2: Amends s. 458.347, F.S., relating to physician assistants.

Section 3: Amends s. 459.022, F.S., relating to physician assistants.

Section 4: Amends s. 464.012, F.S., relating to certification of advanced nurse practitioners; fees; controlled substance prescribing.

Section 5: Provides an effective date of July 1, 2017.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

Not applicable. The bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

None.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

STORAGE NAME: h0129a.HQS PAGE: 6

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On February 22, 2016, the Health Quality Subcommittee adopted an amendment that authorized a physician assistant (PA) to serve as a medical director of a health care clinic. The amendment authorized a physician to delegate to a PA the authority to sign, certify, stamp, verify, or endorse any document that is required by law to be signed, certified, stamped, verified, or endorsed by a physician.

The bill was reported favorably as a committee substitute. The analysis is drafted to the committee substitute.

STORAGE NAME: h0129a.HQS PAGE: 7