

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government/Promote Personal Responsibility—The bill increases the regulation of physician office practice settings and creates a designation of “outside a physician office practice” with specific regulations.

Safeguard Individual Liberty—Patient safety may improve with increased supervision of advanced registered nurse practitioners and physician assistants.

B. EFFECT OF PROPOSED CHANGES:

Current Situation

According to the Department of Health, there are approximately 3,000 physician assistants (PAs), 9,500 advanced registered nurse practitioners (ARNPs) and 33,000 allopathic and osteopathic physicians with active Florida licenses. PAs practice under the indirect supervision of an allopathic or osteopathic physician. ARNPs practice under a protocol of general supervision with a supervising allopathic or osteopathic physician. A physician may supervise up to four PAs at any one time. There is no limit on the number of ARNPs that a physician may supervise at any one time. ARNPs and PAs may practice without the supervising physician being on the premises.

Physician Assistants

Physician assistants are licensed to conduct physical exams, diagnose and treat illnesses, order and interpret tests, counsel on preventive health care, and assist in surgery with physician supervision. This includes filling out prescriptions under the physician’s authority. PAs practice in the areas of primary care medicine (family medicine, internal medicine, pediatrics, and obstetrics and gynecology), as well as surgery and surgical subspecialties.

Because of the close working relationship PAs have with physicians, PAs are trained in intensive master-level programs designed to complement physician training based on the medical model, and accredited by the Accreditation Review Commission on Education for the Physician Assistant. The average PA program curriculum is approximately 26 months long. Education consists of classroom and laboratory instruction in the basic medical and behavioral sciences (such as anatomy, pharmacology, pathophysiology, clinical medicine and physical diagnosis), followed by clinical rotations in internal medicine, family medicine, surgery, pediatrics, obstetrics and gynecology, emergency medicine and geriatric medicine.

Upon graduation, PAs take a national certification examination developed by the National Commission on Certification of Physician Assistants in conjunction with the National Board of Medical Examiners. To maintain their national certification, PAs must log 100 hours of continuing medical education every two years and sit for a recertification examination every six years.

Sections 458.347(3) and 459.022(3), Florida Statutes, require that a physician may not supervise more than four licensed physician assistants at any one time. Each physician or group of physicians supervising a licensed physician assistant must be qualified in the medical areas performed by the physician assistant and are responsible and liable for the performance and acts and omissions of the physician assistant. In addition, 64B8-30.012, Florida Administrative Code, relating to physician assistant performance, requires:

- A supervising physician shall delegate only tasks and procedures to the physician assistant which are within the supervising physician’s scope of practice.

- The decision to permit the physician assistant 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.
- Prescribing, dispensing, or compounding medicinal drugs and final diagnosis are not permitted to be delegated to a PA, except where expressly authorized by statute.
- All tasks and procedures performed by the physician assistant must be documented in the appropriate medical record.
- During the initial six months of supervision of each physician assistant, all documentation in a medical chart must be reviewed, signed and dated by a supervising physician within seven days.
- After the initial six months of supervision, a supervising physician must review, sign and date all documentation in medical charts by a physician assistant, within 30 days.

Advanced Registered Nurse Practitioners

Advanced registered nurse practitioners are registered nurses with advanced master-level¹ training and clinical experience that enables them to diagnose and manage most common and many chronic illnesses, either independently or as part of a health care team. Training includes an intensive preceptorship under the direct supervision of a physician or an experienced nurse practitioner.

ARNPs are primary care providers who practice in ambulatory, acute and long-term care settings, including: neonatology; nurse-midwifery; pediatrics; school health; family and adult health; women's health; mental health; home care and geriatrics. ARNPs provide some care previously offered only by physicians, including the ability to prescribe medications under conditions of a protocol established with a physician.

Section 464.003(c), Florida Statute, provides that the ARNPs may, in addition to nursing diagnosis and nursing treatment, perform medical diagnosis and treatment, prescription, and operation identified and approved by a joint committee appointed by the Board of Nursing and the Board of Medicine. Approved acts must be performed under general supervision and protocols established with a medical doctor, osteopathic physician, or dentist licensed under chapter 458, 459 or 466, Florida Statutes. The protocols must identify the medical acts to be performed and the conditions for their performance.

In addition, 64B8-35.002, Florida Administrative Code, relating to Standards for Protocols requires:

- An ARNP shall only perform medical acts of diagnosis, treatment, and operation pursuant to a protocol between the ARNP and a Florida-licensed medical doctor, osteopathic physician, or dentist.
- General supervision by the physician or dentist is required unless rules set a different level of supervision for a particular act.
- The number of persons to be supervised shall be limited to insure that an acceptable standard of medical care is rendered, based on risk to patient, experience, setting and availability of the physician or dentist.
- A Collaborative Practice Agreement is required that identifies the duties of the ARNP and the physician or dentist, and the management areas for which the ARNP is responsible, including:
 - (a) Conditions for which therapies may be initiated.
 - (b) Treatments that may be initiated by the ARNP, depending on patient condition and judgment of the ARNP.
 - (c) Drug therapies that the ARNP may prescribe, initiate, monitor, alter or order.
- The protocol agreement between the ARNP and physician is required to be filed annually with the department, and kept at the site of practice of each party to the protocol.

¹ Florida does not require ARNPs to have a master's degree but most ARNP programs are masters programs.

House Bill 1009 CS

House Bill 1009 CS amends section 458.348, Florida Statutes, and creates section 459.025, Florida Statute, to define the term "physician office practice setting" and provides increased restrictions on supervision of advanced registered nurse practitioners (ARNPs) and physician assistants (PAs) who practice outside the physician office practice setting.

The bill defines "physician office practice setting" as a business location where the physician delivers medical services, that is not a hospital, ambulatory surgical center, abortion clinic or other medical facility licensed by the Department of Health or Agency for Health Care Administration, the Department of Corrections, a successor agency, or certified rural health clinic. The bill requires the physician to be physically present in the office at least 40 hours during every 21 consecutive calendar days to maintain its designation as a physician office practice setting.

If a physician is not present in the office practice setting 40 hours during every 21 consecutive calendar days, the business will be considered an "outside a physician office practice," and the office will not be considered a physician practice setting. The definition of physician office practice setting does not depend on whether or not the business is physician owned.

The bill establishes requirements for supervision of ARNPs and PAs who practice outside the physician office practice setting of the supervising physician. The supervising physician must:

- Maintain no more than four supervisory relationships at any one time.
- Provide indirect supervision as defined by the Board of Medicine.²
- Ensure that the ARNP or PA has been practicing within the medical specialty area for a minimum of four years before providing care outside the supervising physician's office practice setting.
- Delegate only tasks and procedures within the physician's practice and medical specialty area.
- Ensure that the ARNP or PA wears identification that clearly identifies that they are an ARNP or PA to the patient.
- Document consultation, occurring a minimum of every 21 calendar days, with the ARNP or PA, during which patient files and care plans are managed by the ARNP or PA during the preceding 21 calendar days are evaluated.
- Maintain a valid active Florida license and a valid federal controlled substance registry number.

The bill amends section 459.025, Florida Statutes, to conform supervision requirements for ARNPs, PAs, emergency personnel, and electrologists providing laser hair removal, to provisions in chapter 458, the Medical Practice Act.

The bill also provides an exemption from the above requirements for nursing homes, licensed under part II of chapter 400, Florida Statutes; an assisted living facility, licensed under part III of chapter 400, Florida Statutes; a continuing care facility, licensed under chapter 651, Florida Statutes; or a retirement community consisting of independent living units and either licensed nursing home or assisted living facility. ARNPs and PAs providing services to persons enrolled in a program designed to maintain elders or persons with disabilities in a home or community based setting are also exempt.

The effective date of the bill is upon becoming law.

² Rule 64B8-2.001(1)(b), F.A.C., provides the following definition: "indirect supervision" shall require only that the supervising licensee practice at a location within close physical proximity of the practice location of the supervised licensee and that the supervising licensee must be readily available for consultation as needed. "Close proximity" shall be within 20 miles or 30 minutes unless otherwise authorized by the Board of Medicine.

**Comparison of Regulation and Supervision of
Advanced Registered Nurse Practitioner and Physician Assistant
Practice in Florida**

Advanced Registered Nurse Practitioners	Physician Assistants
Statutory Authority	
<ul style="list-style-type: none"> Nurse Practice Act, Ch. 464, F.S. 	<ul style="list-style-type: none"> Medical Practice Act, Ch. 458, F.S. Osteopathic Medical Practice Act, Ch. 459, F.S.
Rules	
<ul style="list-style-type: none"> 64B8-35, F.A.C. In addition to the practice of nursing, ARNPs may perform acts of medical diagnosis, treatment, prescription and prevention, as approved by the Joint Committee of Board of Medicine and Board of Nursing. The Board of Nursing develops rules approved by the Joint Committee. 	<ul style="list-style-type: none"> 64B8-30, F.A.C. All proposed rules must be approved by the Board of Medicine and the Board of Osteopathic Medicine.
Supervision	
<ul style="list-style-type: none"> General supervision under protocols filed with department. 	<ul style="list-style-type: none"> Direct supervision means in the building, on-site with the PA. Indirect supervision means easy access by phone, beeper, etc.
<ul style="list-style-type: none"> May be supervised by Allopathic and osteopathic physicians, and dentists licensed under Ch. 458, 459, and 466, F.S. 	<ul style="list-style-type: none"> May be supervised by Allopathic and osteopathic physicians licensed under Ch. 458 and 459, F.S.
<ul style="list-style-type: none"> Protocols filed annually with the Department of Health. Protocols may include description of the nature of the practice, description of duties and management areas of the ARNP and duties of the physician. 	<ul style="list-style-type: none"> Protocols only required for County Health Departments. Most PAs work under a protocol of indirect supervision (see Board of Medicine definition, 64B8-2.001(1)(b), F.A.C.).
<ul style="list-style-type: none"> No restriction on number of ARNPs per physician. 	<ul style="list-style-type: none"> Physician may supervise only up to four PAs simultaneously.
Scope of Practice	
<ul style="list-style-type: none"> Practice in specialty area. Scope of practice may be limited by the supervising physician. 	<ul style="list-style-type: none"> PAs may be delegated tasks and procedures within scope of practice of supervising physician. Direct or indirect supervision required.

B. SECTION DIRECTORY:

Section 1. Amends s. 458.348, F. S., relating to formal supervisory relationships to define the term "physician office practice setting" and provide increased restrictions.

Section 2. Creates s. 459.025, F. S., delineating formal supervisory relationships; defining the term "physician office practice setting;" and providing increased restrictions.

Section 3. Provides an effective date.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The provisions of the bill restrict the total number of ARNPs and PAs who may be supervised by a physician at any one time to four. The Department of Health estimates that this restriction may limit the access to health care services in remote areas.

The specification that physician offices are not considered physician office practice settings when the physician is not present may limit physician use of ARNPs and PAs in their practices. Patient safety may improve with more physician supervision of ARNPs and PAs.

D. FISCAL COMMENTS:

According to DOH, the bill may increase the enforcement demands on the department by requiring the monitoring of the amount of time a physician is present in the office, and monitoring the level of supervision of ARNPs and PAs by the physician.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take an action requiring the expenditure of funds. This bill does not reduce the percentage of a state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

Rulemaking authority is provided by the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill amends provisions in chapters 458 and 459, Florida Statutes, relating to physicians. The bill does not address the supervisory relationships of dentists, licensed under chapter 466, Florida Statutes, who can supervise ARNPs.

Proponents of the bill provided committee staff with information supporting the physician office requirements in the bill. Proponents assert that currently patients are being examined, diagnosed and treated, without physician contact or oversight. Proponents have also asserted that the bill prevents potential patient safety issues by creating minimum safety standards required of physicians that choose to enter into supervisory relationships with ARNPs and PAs.

Opponents of the bill provided committee staff with information that the bill places barriers on the practice of nursing and will drive ARNPs out of Florida. Opponents argue that current protocols for ARNPs (general supervision) and PAs (indirect supervision) provide sufficient patient safety.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On March 30, 2005, the Health Care Regulation Committee adopted five amendments.

- **Amendment 1.** Adds Department of Corrections and certified rural health clinics to the list of entities not required to comply with provisions of the bill.
- **Amendment 2.** Removes the word consecutive. ARNPs and PAs practicing “outside of the office practice setting” must have four years of experience in their specialty, but the experience does not need to be consecutive.
- **Amendment 3.** Deletes language that would have expanded the Board of Medicine’s rule authority without clear legislative direction. The amendment removes the unconstitutional delegation of rulemaking authority.
- **Amendment 4.** Inserts language to state that allopathic physician supervision standards in this bill do not apply to nursing homes, continuing care facilities, retirement communities, independent living units, and programs providing services to the disabled in home and community based settings.
- **Amendment 5.** Inserts language (same as amendment four) to state that osteopathic physician supervision standards in this bill do not apply to nursing homes, continuing care facilities, retirement communities, independent living units, and programs providing services to the disabled in home and community based settings.

On April 11, 2005, the Health Care Appropriations Committee adopted a strike-all amendment as described below:

- Changes language describing what constitutes a physician office practice setting.
- Changes the number of supervisory relationships a physician maintains with any combination of ARNPs or PAs outside the physician office practice setting at any one time from two to four.
- Adds language requiring ARNPs and PAs to wear identification that clearly identifies to the patient that he or she is an ARNP or PA.
- Adds language requiring that physicians in a supervisory relationship with an ARNP or PA document consultation within every 21 calendar days during which patient file and care plans managed by the ARNP or PA during the preceding 21 calendar days are evaluated.
- Adds language requiring the Board of Medicine take into account existing rules and procedures performed by ARNPs and PAs under indirect supervision.
- Adds language specifying that any licensee failing to comply is in violation, which constitutes grounds for denial of license or disciplinary action.
- Creates language (same as all above) relating to osteopathic physicians.

The analysis is drafted to the committee substitute.