

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Health Care Committee

BILL: SB 2634

SPONSOR: Senator Haridopolos

SUBJECT: Medical Practice

DATE: April 22, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	Pre-meeting
2.	_____	_____	HA	_____
3.	_____	_____	_____	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

The bill defines “physician office practice setting” and requires medical and osteopathic physicians who supervise an advanced registered nurse practitioner or physician assistant in a setting outside of the “physician office practice setting” to meet additional requirements.

The bill requires an osteopathic physician who enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic, which relationship or orders contemplate the performance of medical acts, or when an osteopathic physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts identified and approved by the joint committee under section 464.003(3)(c), F.S., or acts within the framework of an established protocol between the physician and an advanced registered nurse practitioner that are outlined in the nurse practice act, to submit notice to the Board of Osteopathic Medicine. The bill adds an osteopathic physician member to the joint committee.

Under the bill, all osteopathic physician protocols relating to electrolysis or electrology using laser or light-based hair removal or reduction by persons other than osteopathic physicians must require the person performing such service to be appropriately trained and work only under the direct supervision and responsibility of a Florida-licensed osteopathic physician.

This bill amends section 458.348 and 464.003, Florida Statutes, and creates section 459.025, Florida Statutes, and an undesignated section.

II. Present Situation:

Practice of Medicine

Chapter 458, F.S., the medical practice act, provides for the regulation of medical physicians by the Board of Medicine within the Department of Health. Section 458.305, F.S., defines the “practice of medicine” to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition. Section 458.303, F.S., provides exceptions to the “practice of medicine” for: other duly licensed health care practitioners acting within their scope of practice authorized by statute; licensed out-of-state physicians when meeting in consultation with Florida licensed physicians; medical officers of the United States Armed Forces and of the United States Public Health Service; medical residents; persons furnishing emergency medical assistance; the domestic administration of recognized family remedies; the practice of the religious tenets of any church in Florida; and any person or manufacturer who, without the use of drugs or medicine, mechanically fits or sells lenses, artificial eyes or limbs, or other apparatus or appliances, or is engaged in the mechanical examination of the eyes for the purpose of constructing or adjusting spectacles, eyeglasses, or lenses.

The medical practice act provides criminal penalties for any person who performs acts comparable to the definition of the “practice of medicine” who is not licensed or otherwise exempt from the medical licensure requirements. Under section 458.327(1), F.S., any person who practices medicine or attempts to do so, without being licensed or otherwise exempt from the licensure requirements, is subject to a third-degree felony punishable by imprisonment of up to 5 years and a fine up to \$5,000. Subsection (2) of section 458.327, F.S., subjects any person who leads the public to believe that person is licensed as a medical doctor, or is engaged in the licensed practice of medicine, without holding a valid active license to practice medicine, to a first-degree misdemeanor punishable by imprisonment of up to 1 year and a fine up to \$1,000.

Section 458.331, F.S., specifies grounds for which a medical physician may be subject to disciplinary action by the board. Paragraph 458.331(1)(w), F.S., provides that a medical physician may be subject to discipline for delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, or licensure to perform them.

Paragraph 458.331(1)(v), F.S., specifies that a physician may be disciplined for practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities which the licensed physician knows or has reason to know that he or she is not competent to perform. Paragraph 458.331(1)(v), F.S., also authorizes the board to establish by rule standards of practice and standards of care for particular practice settings, including, but not limited to, education and training, equipment and supplies, medications including anesthetics, *assistance of and delegation to other personnel*, transfer agreements, sterilization, records, performance of complex or multiple procedures.

Subsection 458.303(2), F.S., provides that nothing in various enumerated provisions within the medical practice act shall be construed to prohibit any service rendered by a registered nurse or a licensed practical nurse, if such service is rendered under the direct supervision and control of a

licensed medical physician who provides specific direction for any service to be performed and gives final approval to all services performed.

In *Ortiz v. Board of Medicine*, the Fourth District Court of Appeal held that subsection 458.303(2), F.S., provides a limitation on the Board of Medicine's rulemaking authority.¹ The court ruled that the medical practice act did not allow the board, by rule, to place restrictions on what professional services a medical physician could delegate to a registered nurse or licensed practical nurse to perform under the physician's supervision. In *Ortiz*, a certified registered nurse anesthetist sought judicial review of the Division of Administrative Hearings' rejection of a challenge to an administrative rule adopted by the Board of Medicine, which required a surgeon in an outpatient facility to have a licensed anesthesiologist present to supervise the administration of anesthesia for Level III surgery.² The Board of Medicine adopted a rule to establish standards of care for physicians performing surgery in an office setting pursuant to specific statutory authority in paragraph 458.331(1)(v), F.S.³

Under the office surgery rule, the board had established various levels of surgery and determined that in a Level III surgery, an anesthesiologist who must be a licensed medical physician or osteopathic physician, other than the surgeon, must provide direct supervision of the administration and maintenance of the anesthesia. The court noted that the parties to the action agreed that patient safety was not the issue in the proceeding and the court cited the findings of an administrative law judge in another proceeding who found that there was no evidence to indicate that there was any significant difference in patient outcomes whether anesthesia was administered by a certified registered nurse anesthetist or an anesthesiologist.

Section 120.52, F.S., provides that an administrative rule is invalid when the agency exceeds its grant of rulemaking authority, which must be cited specifically by the agency, or if the rule enlarges, modifies, or contravenes the specific provision of law implemented. In *Ortiz*, the court reasoned that where rulemaking authority is granted in one law, it may not be read to negate any restriction on rulemaking authority that is specified in another law. The court reasoned that by reading paragraph 458.331(1)(v), F.S., together with section 458.303, F.S., which relates to a limitation on the board's rulemaking authority, "the Legislature has circumscribed the Board's rulemaking authority."⁴

The Fourth District Court of Appeal held that the Board of Medicine had invalidly exercised its delegated authority. The court found that although the Board of Medicine had rulemaking authority to develop standards of practice for particular practice settings under sections 458.303 and 458.331(1)(v), F.S., subsection 458.303(2), F.S., prevented the use of the board's rulemaking authority to prohibit provision of services by a registered nurse when supervised by a licensed physician, and the rule would indirectly prohibit nurses from providing services when supervised by licensed physicians, by subjecting surgeons to discipline for violating the standard of practice covered by the administrative rule.

¹ See *Ortiz v. Department of Health, Board of Medicine*, 882 So.2d 402 (4th DCA 2004).

² *Id.*

³ See Rule 64B8-9.009, Florida Administrative Code.

⁴ See *Ortiz*, at 406.

The Practice of Osteopathic Medicine

Chapter 459, F.S., the osteopathic medical practice act, similarly provides for the regulation of osteopathic physicians by the Board of Osteopathic Medicine in the Department of Health. Section 459.003, F.S., defines the “practice of osteopathic medicine” to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition, which practice is based in part upon educational standards and requirements which emphasize the importance of the musculoskeletal structure and manipulative therapy in the maintenance and restoration of health. Chapter 459, F.S., contains provisions relating to the definition of practice, exceptions to the licensure requirements, discipline of licensed osteopathic physicians, and criminal violations for unlicensed persons, which are comparable to those in the medical practice act.

Physician Assistants and Advanced Registered Nurse Practitioners

Sections 458.347 and 459.022, F.S., provide requirements for the regulation of physician assistants by the Council on Physician Assistants, the Board of Medicine and the Board of Osteopathic Medicine under the Department of Health. Physician assistants perform medical services delegated by the supervising medical or osteopathic physician under indirect supervision. A physician may not supervise more than four currently licensed physician assistants at any one time.⁵

Section 464.012, F.S., provides certification requirements for advanced registered nurse practitioners by the Board of Nursing. Advanced registered nurse practitioners perform medical acts of medical diagnosis and treatment, prescription, and operation under the general supervision of a medical or osteopathic physician as outlined in a protocol filed with the appropriate boards of the supervising physician and the supervised advanced register nurse practitioner. Advanced registered nurse practitioners are independent practitioners who may perform all duties of a registered nurse and advanced level nursing in accordance with established protocols, including managing selected medical problems, monitoring and altering drug therapies, initiating appropriate therapies for certain conditions, performing physical examinations, ordering and evaluating diagnostic tests, ordering physical and occupational therapy, and initiating and monitoring therapies for certain uncomplicated acute illnesses. There are no statutory limitations on the number of advanced registered nurse practitioners with whom a physician may establish protocols.

Indirect supervision and general supervision do not require that the supervising physician be physically within the same office suite as the person being supervised. Section 458.348, F.S., requires a medical physician who enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic, which relationship or orders contemplate the performance of medical acts, or when a medical physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts identified and approved by the joint committee under section 464.003(3)(c), F.S., or acts within the framework of an established protocol between the physician and an advanced

⁵ See s. 458.347(3), F.S., and s. 459.022(3), F.S.

registered nurse practitioner that are outlined in the nurse practice act, to submit notice to the Board of Medicine.

Part I, chapter 464, F.S., requires the Board of Nursing to adopt rules authorizing advanced registered nurse practitioners to perform acts of medical diagnosis and treatment, prescription, and operation, which are identified and approved by a joint committee. The joint committee is composed of three members appointed by the Board of Nursing, two of whom must be advanced registered nurse practitioners; three members appointed by the Board of Medicine, two of whom must have had work experience with advanced registered nurse practitioners; and the Secretary of Health or the secretary's designee. The Board of Nursing must adopt rules authorizing the performance of any such acts approved by the joint committee.

Advanced registered nurse practitioners may perform medical acts under the general supervision of a medical physician, osteopathic physician, or dentist within the framework of standing protocols, which identify the medical acts to be performed, and the conditions for their performance. The Board of Nursing and the Board of Medicine have filed identical administrative rules setting forth standards for the protocols⁶, which establish obligations on medical physicians, osteopathic physicians, and dentists who enter into protocol relationships with advanced registered nurse practitioners. The Board of Osteopathic Medicine and the Board of Dentistry who have regulatory jurisdiction over osteopathic physicians and dentists, respectively, are not required to adopt administrative rules regarding the standards for advanced registered nurse practitioner protocols. Although advanced registered nurse practitioners may prescribe medications in accordance with a protocol, they cannot prescribe controlled substances.

Medical Assistants

Section 458.3485, F.S., authorizes medical assistants to assist in all aspects of medical practice under the direct supervision and responsibility of a medical physician. Medical assistants are unlicensed persons who may perform specified tasks under the direct supervision and responsibility of a licensed physician, including the performance of clinical procedures. Section 458.303(2), F.S., provides that nothing in the medical practice act or any other law may be construed to prohibit any service rendered by a medical assistant in accordance with section 458.3485, F.S.

Physician Office Surgery Adverse Incident Reporting

Licensed medical physicians may perform surgery in their medical offices, ambulatory surgical centers, or hospitals. Sections 458.351 and 459.026, F.S., require any medical physician, osteopathic physician, or physician assistant to notify the Department of Health of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under chapter 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. The sections require any medical physician, osteopathic physician, or physician assistant to notify the department in writing and by certified mail of the adverse incident within 15 days

⁶ See Rules 64B-4.010 and 64B-35.002, Florida Administrative Code.

after the adverse incident occurred. The notice must be postmarked within 15 days after the adverse incident occurred.

“Adverse incident” is defined under sections 458.351 and 459.026, F.S., to mean an event over which the physician or physician assistant could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries: death of a patient; brain or spinal damage to a patient; performance of a surgical procedure on the wrong patient; any condition that required the transfer of a patient to a hospital licensed under chapter 395, F.S., from an ambulatory surgical center licensed under chapter 395, F.S., or from any facility or any office maintained by a physician for the practice of medicine which is not licensed under chapter 395, F.S., or performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure. Under the definition of adverse incident, a medical physician, osteopathic physician, or physician assistant must provide notice of patient injuries only if they result in death, brain or spinal damage, permanent disfigurement, fracture or dislocation of bones or joints, a limitation of neurological, physical or sensory function, or any condition that required the transfer of the patient. The Department of Health must review each adverse incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action, and provides that the procedures for handling disciplinary complaints under section 456.073, F.S., apply.

III. Effect of Proposed Changes:

Section 1. Amends section 458.348, F.S., to define the term “physician office practice setting” to mean a business location where a physician delivers medical services regardless of whether or not the business is owned by a physician. A physician office practice setting includes a location where medical services are performed other than at a hospital, an ambulatory surgical center, an abortion clinic, or any other medical facility licensed by the Department of Health, the Agency for Health Care Administration, or a successor agency. A business location is a physician office practice setting if a physician is physically present in the business location during the provision of care greater than 33 percent of the hours of operation in which medical care is provided. A business location that does not meet this requirement must be considered outside a physician office practice setting during all hours when a physician is not physically present, irrespective of the ownership or business name of the site.

A physician who is in a supervisory relationship with an advanced registered nurse practitioner or a physician assistant who is practicing outside a physician office practice setting of the supervising physician must:

- Maintain a valid and unrestricted active Florida license to practice medicine and a valid federal controlled substance registry number under chapter 893, F.S., which relates to controlled substances;
- Provide indirect supervision as defined by the Board of Medicine to the advanced registered nurse practitioner or physician assistant;
- Notwithstanding the number of supervisory relationships authorized in section 458.347(3), F.S., for physicians over physician assistants, maintain no more than two

supervisory relationships with any combination of advanced registered nurse practitioners or physician assistants in the out-of-office practice setting at any one time;

- Delegate only tasks and procedures to the advanced registered nurse practitioner or physician assistant which are within the supervising physician's practice and medical specialty area;
- Ensure that the advanced registered nurse practitioner or physician assistant has been actively practicing within the medical specialty area for a minimum of 4 consecutive years prior to providing care in a practice setting outside the physician office practice setting of the supervising physician; and
- Ensure that the advanced registered nurse practitioner or physician assistant under supervision clearly identifies to the patient that he or she is an advanced registered nurse practitioner or a physician assistant.

The Board of Medicine may adopt rules to administer this section. Such rules may impose stricter standards than those found in this section for specific medical specialties, to ensure the health and safety of patients.

Section 2. Creates section 459.025, F.S., to require an osteopathic physician who enters into a formal supervisory relationship or standing orders with an emergency medical technician or paramedic, which relationship or orders contemplate the performance of medical acts, or when an osteopathic physician enters into an established protocol with an advanced registered nurse practitioner, which protocol contemplates the performance of medical acts identified and approved by the joint committee under section 464.003(3)(c), F.S., or acts within the framework of an established protocol between the physician and an advanced registered nurse practitioner that are outlined in the nurse practice act, to submit notice to the Board of Osteopathic Medicine. The notice must contain a statement as provided in the section and must be filed within 30 days of entering into the relationship, orders, or protocol. The osteopathic physician must provide notice within 30 days after the osteopathic physician has terminated any such relationship, orders, or protocol.

All protocols relating to electrolysis or electrology using laser or light-based hair removal or reduction by persons other than osteopathic physicians must require the person performing such service to be appropriately trained and work only under the direct supervision and responsibility of a Florida-licensed osteopathic physician.

The section defines the term "physician office practice setting" to mean a business location where a physician delivers medical services regardless of whether or not the business is owned by a physician. A physician office practice setting includes a location where medical services are performed other than at a hospital, an ambulatory surgical center, an abortion clinic, or any other medical facility licensed by the Department of Health, the Agency for Health Care Administration, or a successor agency. A business location is a physician office practice setting if a physician is physically present in the business location during the provision of care greater than 33 percent of the hours of operation in which medical care is provided. A business location that does not meet this requirement must be considered outside a physician office practice setting during all hours when a physician is not physically present, irrespective of the ownership or business name of the site.

A physician who is in a supervisory relationship with an advanced registered nurse practitioner or a physician assistant who is practicing outside a physician office practice setting of the supervising physician must:

- Maintain a valid and unrestricted active Florida license to practice osteopathic medicine and a valid federal controlled substance registry number under chapter 893, F.S., which relates to controlled substances;
- Provide indirect supervision as defined by the Board of Medicine to the advanced registered nurse practitioner or physician assistant;
- Notwithstanding the number of supervisory relationships authorized in section 459.022(3), F.S., for physicians over physician assistants, maintain no more than two supervisory relationships with any combination of advanced registered nurse practitioners or physician assistants in the out-of-office practice setting at any one time;
- Delegate only tasks and procedures to the advanced registered nurse practitioner or physician assistant which are within the supervising physician's practice and medical specialty area;
- Ensure that the advanced registered nurse practitioner or physician assistant has been actively practicing within the medical specialty area for a minimum of 4 consecutive years prior to providing care in a practice setting outside the physician office practice setting of the supervising physician; and
- Ensure that the advanced registered nurse practitioner or physician assistant under supervision clearly identifies to the patient that he or she is an advanced registered nurse practitioner or a physician assistant.

The Board of Osteopathic Medicine may adopt rules to administer this section. Such rules may impose stricter standards than those found in this section for specific medical specialties, to ensure the health and safety of patients.

Section 3. Amends section 464.003, F.S., to revise the definition of “advanced or specialized nursing practice” to change the composition of the joint committee that identifies and approves the acts of medical diagnosis and treatment, prescription, and operation that an advanced registered nurse practitioner may perform pursuant to Board of Nursing rules. The bill adds a member appointed by the Board of Osteopathic Medicine to the joint committee.

Section 4. Provides an effective date upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

To the extent that the bill authorizes the Board of Medicine and the Board of Osteopathic Medicine, respectively, to adopt rules that may impose stricter standards for supervision of advanced registered nurse practitioners or physician assistants than those found in the bill for specific medical specialties, to ensure the health and safety of patients, it raises the question of whether this provides adequate limitations and safeguards so that the Legislature's delegation to the boards is not a violation of Section 3, Article II of the Florida Constitution. The bill does not expressly provide sufficient limitation on the board's authority to so.⁷

The bill defines "physician office practice setting" to mean a business location where a physician delivers medical services regardless of whether or not the business is owned by a physician. The bill imposes additional requirements on medical or osteopathic physicians who supervise advanced registered nurse practitioners or physician assistants in settings other than a "physician office practice setting" as defined in the bill. The bill may impair existing contracts between supervising physicians, advanced registered nurse practitioners, and physician assistants to provide medical services. There is no express constitutional prohibition against retroactive noncriminal statutes; however, retroactive application of statutes that impair the obligations of contracts or vested rights is invalid. Section 10, Article I of the United States Constitution and Section 10, Article I of the Florida Constitution both prohibit state laws impairing the obligations of contracts.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The role of an advanced registered nurse practitioner or physician assistant who practices outside of a physician office practice setting as defined under the bill will be restricted. A practice that includes satellite offices with an advanced registered nurse practitioner or physician assistant or that uses telemedicine to treat patients may close under the bill and reduce access to medical services.

⁷ See *Askew v. Cross Key Waterways*, 372 So.2d 913, at 921 (Fla.1978). See also *Bush v. Schiavo*, 885 So.2d 321, at 332 (Fla.2004) in which the Florida Supreme Court cites *Askew* and notes that the nondelegation doctrine requires that "fundamental and primary policy decisions ... be made by members of the legislature who are elected to perform those tasks, and [that the] the administration of legislative programs must be pursuant to some minimal standards and guidelines ascertainable by reference to the enactment establishing the program."

C. Government Sector Impact:

The Department of Health reports that the bill's requirements will increase its enforcement activities and notes that the increase is indeterminate.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires osteopathic physicians who do not practice in a "physician office practice setting" and who supervise advanced registered nurse practitioners in such settings to provide indirect supervision as defined by the "Board of Medicine" rather than the Board of Osteopathic Medicine. Additionally, section 2 of the bill inconsistently uses the term "physician" rather than "osteopathic physician." For purposes of chapter 459, F.S., the osteopathic medicine practice act, section 459.003, F.S., defines "osteopathic physician" to mean a person who is licensed to practice osteopathic medicine in Florida but does not define "physician."

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
