

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 1044

INTRODUCER: Senators Fasano and Alexander

SUBJECT: Surgical First Assistants

DATE: March 20, 2006

REVISED: _____

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

I. Summary:

The bill provides for the licensure of certified surgical first assistants under the regulatory jurisdiction of the Board of Medicine (board). For purposes of the licensure of these practitioners, “certified surgical first assistant” means a person who provides primary surgical assistance to the primary surgeon during a surgical procedure, is listed on the operative record as the first assistant, and meets the qualifications for licensure. “Direct supervision” means supervision by a delegating physician who is physically present and who personally directs delegated acts and remains immediately available to personally respond to any emergency until the patient is released from the operating room or the physician’s care. Each supervising physician using a certified surgical first assistant may be liable for acts or omissions of the certified surgical first assistant acting under the physician’s supervision and control.

To be licensed in Florida, certified surgical first assistants must hold and maintain certification from one of three recognized certifying agencies and pay the appropriate licensure fees. The bill specifies requirements for reciprocity so that certified surgical first assistants licensed in other states may practice in Florida.

The bill specifies that a health insurance policy, plan, or contract that provides for payment for surgical first assistant services must be construed to provide payment to a certified surgical first assistant or the employer of the assistant if reimbursement for an assisting physician is covered and the certified surgical first assistant is used as a substitute. The bill provides that an insurer is not required to provide payment to a certified surgical first assistant directly if the certified surgical first assistant is paid or will be paid for a surgical procedure by the health care facility at which the surgical procedure is performed.

The bill expands the list of surgical first assistants who may receive direct reimbursement from an insurer to include a physician assistant. Currently only registered nurse first assistants and employers of registered nurse first assistants and physician assistants may direct bill.

This bill creates s. 458.3465, Florida Statutes.

This bill amends s. 627.419, Florida Statutes.

II. Present Situation:

Professions Assisting in Surgeries

According to the National Surgical Assistant Association, surgical teams typically consist of anesthesia personnel: the surgeon; a surgical assistant (another physician or an allied health professional non-physician surgical assistant); the peri-operative nurse; and the instrument specialist. Certified surgical assistants are specially trained and tested to assist a physician performing surgery.

According to a recent U.S. Government Accounting Office (GAO) report regarding Medicare reimbursement for these services¹, there is a wide range of health professionals who serve as surgical assistants including, physicians, residents in training for licensure or board certification, international medical graduates, nurses, and several unlicensed health professionals. The report provides the following description of the role of the surgical assistant in the operating room:

Assistants-at-surgery, who serve as members of surgical teams, perform tasks under the direction of surgeons and aid them in conducting operations. These tasks may include making initial incisions (“opening”), exposing the surgical site (“retracting”), stemming blood flow (“hemostasis”), surgically removing veins and arteries to be used as bypass grafts (“harvesting”), reconnecting tissue (“suturing”), and completing the operation and reconnecting external tissue (“closing”). Some of these tasks, like retraction, are relatively simple, while others, such as harvesting, are more complex. An assistant-at-surgery may perform one or more simple or complex tasks during an operation.

Tasks performed by others on the surgical team differ from those performed by assistants-at-surgery. Scrub staffs work within the sterile field—the area within the operating room that is kept free from harmful microorganisms—passing instruments, sponges, and other items directly to the surgeon and assistant-at-surgery who work within the sterile field. Circulators work outside the sterile field, responding to the needs of team members within the sterile field. Anesthesiologists, or anesthetists, who administer and monitor anesthesia, painkillers, and other drugs, are also present during an operation.²

¹ United States General Accounting Office, January 2004. *Medicare Payment Changes Are Needed for Assistants-at-Surgery*, GAO 04-97.

² *Ibid.* p. 5.

Section 395.0197(1)(b) 3., F.S., prohibits unlicensed persons from assisting or participating in any surgical procedure unless the facility has authorized the person to do so following a competency assessment. Assistance or participation must be done under the direct and immediate supervision of a licensed physician and must not be an activity that may only be performed by a licensed health care practitioner. Under s. 766.110, F.S., all health care facilities in Florida, including hospitals and ambulatory surgical centers have a duty to assure comprehensive risk management and the competence of their medical staff and personnel through careful selection and review, and are liable for a failure to exercise due care in fulfilling these duties. These duties include among other specified items, a requirement to adopt written procedures for the selection of staff members and a periodic review of the medical care and treatment rendered to patients by each member of the medical staff.

Certified Surgical First Assistants

Certified surgical first assistants are health professionals who are specially trained and certified to assist in surgeries. The American College of Surgeons describes surgical first assistants as persons who provide aid in exposure, hemostasis, closure and other operative technical functions that help the surgeon carry out a safe operation with optimal results. Surgical first assistants must possess knowledge of sterility requirements, aseptic techniques, draping procedures, operating room equipment, drain placement and catheterization, and dressing techniques.

Surgical first assistants are not subject to licensure by the State of Florida. Texas, Illinois, and Kentucky have established a license category for licensed surgical assistants.³ Effective July 1, 2004, Illinois implemented a registration requirement for surgical assistants.⁴

Surgical first assistants or technologists may obtain voluntary professional certification by graduating from an accredited program and passing a national certification examination. To qualify to take the exam, candidates follow one of three paths. They complete an accredited training program, undergo a 2-year hospital on-the-job training program, or acquire 7 years of experience working in the field. The three professional organizations that certify surgical assistants are:

- The American Board of Surgical Assistants, which administers a national certification examination for surgical assistants. The examination covers all surgical disciplines and areas of preoperative medicine. It evaluates knowledge of surgical anatomy, procedures and techniques, diagnostic studies, emergencies, and general patient safety.
- The National Surgical Assistant Association, which establishes practice standards and develops a certification examination with the assistance of the Department of Surgery at Norfolk General Hospital.

³ Illinois establishes qualifications and provides for title protection for those who seek to use certain protected titles limited to these practitioners.

⁴ United States General Accounting Office, January 2004. Medicare Payment Changes Are Needed for Assistants-at-Surgery." GAO 04-97. p. 15. Also, see Kentucky Revised Statutes 311.866, et seq.

- The Liaison Council on Certification for the Surgical Technologist, which was established in 1974 as the certifying agency for surgical technologists, determines the eligibility for the granting and revocation of certification of surgical technologists and first assistants.

Insurance Reimbursement of Surgical Assistants

Generally, insurance plans state that they cover medically necessary services provided by doctors of medicine and osteopathy. Some plans are not specific in terms of listing each type of health care practitioner who may provide services under the plan.

Presently, s. 627.419(6), F.S., requires any health insurance policy, health care services plan, or other contract that provides for payment for surgical first assisting services to provide payment to a registered nurse first assistant or employers of a physician assistant or nurse first assistant who provides surgical assistance within the scope of their license. The provision applies only if reimbursement for an assisting physician, licensed under ch. 458 or ch. 459, F.S., would be covered, and the physician assistant or registered nurse first assistant is used as a substitute.

Sunrise Act

The Sunrise Act, codified in s. 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The act requires that all legislation proposing regulation of a previously unregulated profession or occupation be reviewed by the Legislature based on a showing of the following: (1) that substantial risk of harm to the public is a risk of no regulation which is recognizable and not remote; (2) that the skills the profession requires are specialized and readily measurable; (3) that other forms of regulation do not or cannot adequately protect the public; and (4) that the overall cost-effectiveness and economic impact of the proposed regulation is favorable. The act requires proponents of regulation of a previously unregulated profession to provide the agency that is proposed to have jurisdiction over the regulation and the legislative committees of reference information concerning the effect of proposed legislation to initially regulate a previously unregulated profession on the agency's resources to implement and enforce the regulation.

Proponents of the regulation of certified surgical first assistants did not provide any documentation of the nature and extent of harm to the public caused by the unregulated practice of surgical first assisting. Proponents assert that there is no documented harm to the public by the practice of surgical first assisting. In response to a Sunrise questionnaire, the proponents of the proposed regulation indicated that there is an inherent risk of physical harm in surgery and that a wide range of health care professionals, with varying educational and professional experience, performs the function of surgical first assisting. Proponents estimate that approximately 430 practitioners who reside in Florida hold membership in national organizations, but the proponents were unable to provide an estimate of the number of persons who would be subject to the proposed regulation in Florida.

Practice of Medicine and Osteopathic 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 (DOH). 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.

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. Subsection 458.303(2), F.S., also provides that nothing in the medical practice act or any other chapter shall be construed to prohibit any service rendered by a medical assistant in accordance with the provisions of s. 458.3485, F.S. Section 458.3485, F.S., provides that a medical assistant is a professional multiskilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician.

Similarly, ch. 459, F.S., provides for the practice of osteopathic medicine.

Subsection 459.002(2), F.S., provides that nothing in the osteopathic medical practice act shall be construed to prohibit any service rendered by any person if such service is rendered under the direct supervision and control of a licensed osteopathic physician who must be available when needed, must provide specific directions for any service to be performed, and must give final approval to all services performed.

III. Effect of Proposed Changes:

Section 1. Creates s. 458.3465, F.S., to establish licensure requirements for certified surgical first assistants.

Subsection (1) provides definitions for the following terms.

- “Board” is defined to mean the Board of Medicine. “Certified surgical first assistant” means a person who provides primary surgical assistance to the primary surgeon during a surgical procedure, is listed on the operative record as the first assistant, and meets the qualifications for licensure.
- “Continuing medical education,” means courses recognized and approved by the board and several specified national medical organizations.

- “Direct supervision” means supervision by a delegating physician who is physically present and who personally directs delegated acts and remains immediately available to personally respond to any emergency until the patient is released from the operating room or the physician’s care and has been transferred to the care and responsibility of another physician.
- “Surgical assisting,” means providing aid under direct supervision in exposure, hemostasis, closures, and other intraoperative technical functions that assist a physician in performing a safe operation with optimal results for the patient.

Subsection (2) requires the physician or group of physicians who supervise a certified surgical first assistant must be qualified in the medical areas in which the certified surgical first assistant is to perform and may be individually or collectively responsible and liable for the performance and the acts and omissions of the certified surgical first assistant.

Subsection (3) authorizes a certified surgical first assistant to perform duties limited to the scope of certification in surgical assisting functions while under the direct supervision of a physician. The scope of practice of a certified surgical first assistant is limited to surgical assisting and tasks delegated by the supervising physician. A certified surgical first assistant may only perform his or her duties in a medical clinic, hospital, ambulatory surgical center, or similar medical institution.

Subsection (4) specifies that a physician or hospital is not required to contract with a certified surgical first assistant. A health maintenance organization or health benefit plan may not require a physician, hospital, clinic, or ambulatory surgery center to contract with a certified surgical first assistant as a condition of payment to a certified surgical first assistant. The employment arrangement of a certified surgical first assistant may not be limited in any way by rule of the Board of Medicine or by statute.

Subsection (5) requires a person seeking to become licensed as a certified surgical first assistant to apply to the board. The board must issue a license to any person that the board has determined has met the following requirements:

- Is at least 18 years of age;
- Holds and maintains certification from one of the following recognized certifying agencies (the Liaison Council on Certification for the Surgical Technologist, the National Surgical Assistant Association, the American Board of Surgical Assistants);
- Has completed an application and paid a fee no greater than \$750 as set by the board. The application for licensure must include a certificate from one of the recognized certifying agencies and a sworn statement of any prior felony convictions and any previous revocation or denials of licensure or certification.

Certified surgical first assistant licenses must be renewed every 2 years. A renewal applicant must pay a renewal fee no greater than \$1,000 as set by the board. Licensed certified surgical first assistants must biennially complete 40 hours of continuing medical education or must hold a

current certificate issued by a recognized certifying agency. The board may discipline or impose applicable penalties on a certified surgical first assistant or the supervising physician if has violated, either ch. 458, F.S., the medical practice act, or ch. 456, F.S., the general regulatory provisions for health care professions licensed by DOH.

A certified surgical first assistant's license does not authorize the licensee to engage in the practice of medicine or professional nursing. A certified surgical first assistant's license is not required of a registered nurse, an advanced registered nurse practitioner, a registered nurse first assistant, or a physician assistant as a condition of employment.

Subsection (6) requires DOH to allow reciprocity to certified surgical first assistants who are determined by the board to be licensed in other states, who are in good standing with their state of licensure and their certifying agency, have paid appropriate licensure fees, and have complied with all other requirements of the board.

Subsection (7) establishes requirements for reactivation of inactive or delinquent status licenses.

Subsection (8) specifies that any person who has not been licensed by the board and approved by the department and who holds her or himself out as a licensed certified surgical first assistant or who uses any other term indicating or implying that he or she is a licensed certified surgical first assistant commits a third degree felony punishable by a fine of up to \$5,000 and imprisonment of up to 5 years.

Subsection (9) authorizes the board to deny, suspend, or revoke a certified surgical first assistant license if the board determines that the certified surgical first assistant has violated the medical practice act.

Subsection (10) grants the board rulemaking authority to administer the regulation of certified surgical first assistants.

Subsection (11) specifies that each supervising physician using a certified surgical first assistant may be liable for acts or omissions of the certified surgical first assistant acting under the physician's supervision and control.

Subsection (12) specifies that any fees collected by the Board of Medicine pursuant to the regulation of certified surgical first assistants must be used for the licensure and regulation of such practitioners.

Section 2. Amends s. 627.419, F.S., to specify that, notwithstanding any other law, when a health insurance policy, health care services plan, or other contract provides for payment for surgical first assistant services, the policy, plan or contract must be construed to provide payment to the certified surgical first assistant or the employer of the assistant. This provision applies only if reimbursement for an assisting physician is covered and the certified surgical first assistant is used as a substitute. None of the provisions in s. 627.419(6)(b), F.S., would require an insurer to provide payment to the certified surgical first assistant directly if the certified surgical first assistant is paid or will be paid for a surgical procedure by the health care facility at which the surgical procedure is performed. The intent of this provision is to prevent duplicative payments

to the certified surgical first assistant. The section defines “certified surgical first assistant” to mean a person who is a licensed health care provider who is directly accountable to a Florida-licensed medical or osteopathic physician and who is certified by the National Surgical Assistant Association, the Liaison Council on Certification for the Surgical Technologist, or the American Board of Surgical Assistants.

The bill expands the lists of entities that may receive direct reimbursement from an insurer to include a physician assistant. Currently only registered nurse first assistants and employers of registered nurse first assistants and physician assistants may direct bill.

Section 3. Provides an effective date of July 1, 2006.

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 Art. VII, s. 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 Art. I, s. 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 Art. III, Subsection 19(f) of the Florida Constitution.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

Licensure applicants must pay a licensure application fee no greater than \$750 and a renewal fee no greater than \$1,000 as set by the Board of Medicine.

B. Private Sector Impact:

Surgeons have been unable to bill third-party payors for the services of a surgical assistant unless the assistant was licensed as a physician assistant or a nurse. Under the bill, they will be able to bill for services of a certified surgical first assistant under certain conditions.

C. Government Sector Impact:

The Department of Health estimates that it will need five positions to implement the bill and will incur expenditures of \$191,514 offset by revenue equal to \$152,500 (assuming 500 applicants who pay an initial licensure fee of \$200, application fee of \$100, and \$5 unlicensed activity fee) in FY 2006-07 and expenditures equal to \$187,619 offset by

revenue equal to \$15,250 (assuming 50 applicants who pay an initial licensure fee of \$200, application fee of \$100 and \$5 unlicensed activity fee) in FY 2007-08. The department notes that a licensed profession with a small licensee base often operates in a deficit and that, based on the number of estimated licensees; this profession is expected to operate in a deficit.

This bill creates a criminal offense for a person who has not been licensed by DOH and approved by the Board of Medicine and who holds her or himself out as a licensed certified surgical first assistant or who uses any other term indicating or implying that he or she is a licensed certified surgical first assistant. The penalty for the offense is a third-degree felony punishable by a fine of up to \$5,000 and imprisonment of up to five years. Consequently, the bill could have an impact on the courts, county jails and state prison system. Pursuant to s. 921.002(4)(b), F.S., the Criminal Justice Estimating Conference is charged with reviewing the potential impact of newly created crimes on the state prison system. The conference has not reviewed this bill's prison bed impact. Staff anticipates that the conference will conclude that this bill's impact will be insignificant.

VI. Technical Deficiencies:

The Department of Health issues licenses to health care practitioners and persons apply to the department for licensure who meet specified statutory criteria. On page 4, line 14 of the bill, the term "board" should be corrected to refer to "department."

On page 6, line 8, the term "board" should be corrected to refer to "department" and the term "department" should be corrected to refer to "board."

The Department of Health collects fees and does other administrative acts in the regulation of professions. On page 6, lines 25-28, the bill provides that any fees collected by the Board of Medicine pursuant to the regulation of certified surgical first assistants must be used for the licensure and regulation of such practitioners. The term "board" should be corrected to refer to "department."

VII. Related Issues:

The bill specifies that any person who has not been licensed by the board and approved by the department and who holds her or himself out as a licensed certified surgical first assistant or who uses any other term indicating or implying that she or he is a licensed certified surgical first assistant commits a third degree felony punishable by a fine of up to \$5,000 and imprisonment of up to 5 years. Under the bill, any person who performs acts comparable to "surgical assisting" or who holds her or himself out as a licensed certified surgical first assistant or who uses any other term indicating or implying that she or he is a licensed certified surgical first assistant commits a third-degree felony. The bill specifies that a certified surgical first assistant's license is not required of a registered nurse, an advanced registered nurse practitioner, a registered nurse first assistant, or a physician assistant *as a condition of employment*. It is unclear in the bill whether nurses, physician assistants, and other persons who perform surgical assisting will need to be licensed as a "licensed certified surgical first assistant" or otherwise be exempt from the licensure requirements.

The bill provides for reciprocity. Generally, current Florida regulations provide for endorsement provisions that allow DOH to license a person who holds a license to practice as a health care practitioner in another jurisdiction if at the time of licensure in that other jurisdiction the licensure standards were equivalent to or more stringent than those in Florida. Reciprocity would allow a practitioner to practice surgical first assisting without having to meet minimum licensure standards established under Florida law.

Chapter 456, F.S., provides the general regulatory provisions for health care professions within the Division of Medical Quality Assurance in DOH. The organization of the Department of Health is created in s. 20.43, F.S., including the Division of Medical Quality Assurance, which is responsible for various boards and professions, established within the division. Section 20.43, F.S., needs to be amended to reflect the regulation of certified surgical first assistants by the department within the division.

The bill specifies that the employment arrangement of a certified surgical first assistant may not be limited in any way by rule of the board or by statute. In effect, this would arguably prevent the Board of Medicine from adopting rules to ensure compliance with the supervision of certified surgical first assistants by a physician or for enforcement of discipline for applicable violations by supervising physicians.

VIII. Summary of Amendments:

None.

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