

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 281 Surgical Assistants and Surgical Technologists

SPONSOR(S): Health Quality Subcommittee; Gaetz

TIED BILLS: **IDEN./SIM. BILLS:** SB 360

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N, As CS	Holt	O'Callaghan
2) Health Care Appropriations Subcommittee			
3) Health & Human Services Committee			

SUMMARY ANALYSIS

The bill amends s. 395.0191, F.S., to prohibit facilities from employing or contracting with a person to perform the duties of a surgical assistant unless the person is a certified surgical technologist or certified surgical assistant. The bill provides an exemption such that a facility may not contract or employ a person unless he or she is:

- Employed or contracted to perform the duties of a surgical assistants or surgical technologists anytime between January 1, 2013 to July 1, 2013;
- A health care practitioner as defined in ch. 456, F.S., or a student if the duties performed fall within the scope of his or her training and practice; or
- A person enrolled in an accredited surgical technology or surgical assisting training program as of July 1, 2013. However, the person may practice for only one year after completion of the accredited training program.

The bill defines the following terms: certified surgical assistant, certified surgical technologist, surgeon, surgical assistant, and surgical technologist.

The bill appears to have no fiscal impact on local governments.

The bill provides an effective date of July 1, 2013.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Present Situation

Surgery

Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is a part of the practice of medicine.¹

Surgery is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician).²

All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel.³

There are numerous health practitioners who collaborate to create a surgical team:⁴

An overview of the surgical team

Role	Who Performs	Who Manages	Tasks
Sterile			
Surgeon	Surgeon, Dentist, Podiatrist	Surgeon	Perform surgery, manage procedure
Assistant at Surgery	Surgeon, Physician, Physician Assistant, Resident, Registered Nurse, Surgical Assistant, Surgical Technologist, Licensed Practical Nurse	Surgeon	Provide exposure, control bleeding, close wounds, apply dressing
Scrub Person	Surgical Technologist, Registered Nurse, Licensed Practical Nurse	Circulating Nurse/Surgeon	Maintain sterile field, pass and count instruments, prepare supplies
Non-sterile			
Anesthesia Provider	Anesthesiologist, Certified Registered Nurse Anesthetists, Dentist, Physician, Physician Assistant Anesthesiologist Assistant	Anesthesia Provider	Provide and maintain anesthesia, maintain vitals
Circulator	Registered Nurse	Circulating Nurse	Patient advocate, patient comfort, manage team members, maintain sterile field, emergency assistance

Source: Study into the Need to Regulate, Surgical Assistants & Surgical Technologists in the Commonwealth of Virginia, July 2010.

¹ American College of Surgeons, Statement on Surgery Using Lasers, Pulsed Light, Radiofrequency Devices, or Other Techniques, available at: http://www.facs.org/fellows_info/statements/st-11.html (last viewed March 24, 2013).

² *Id.*

³ *Id.*

⁴ Study into the Need to Regulate: Surgical Assistants & Surgical Technologist in the Commonwealth of Virginia, July 2010, available at: www.dhp.virginia.gov (last viewed March 24, 2013).

State Regulations

Hospitals, ambulatory surgical centers, and other medical businesses such as physician offices where surgical procedures are performed may choose to employ persons as surgical assistants, surgical technologists, scrub techs or similarly titled positions to assist with surgical procedures. No state licensure exists for these individuals.

Hospitals, ambulatory surgical centers, and mobile surgical facilities are regulated by the Agency for Health Care Administration (AHCA) under ch. 395, F.S.

Section 395.1055(1)(a), F.S., requires AHCA to adopt rules to ensure that sufficient numbers and qualified types of personnel and occupational disciplines are on duty and available at all times in a licensed facility to provide necessary and adequate care and safety.

Section 395.0197(1)(b) 3., F.S., prohibits unlicensed persons from assisting or participating in any surgical procedure unless the licensed 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.

In 2006⁵, the Legislature required hospitals to comply with the requirements of the Centers for Medicare and Medicaid Services (CMS), Conditions of Participation (CoPs) for Hospitals, as they apply to registered nurses who perform circulating duties in the operating room.⁶ Section 395.0191(1)(d), F.S., also provides that a circulating nurse must be in the operating room for the duration of a surgical procedure.

The CMS regulations provide that hospitals must be in compliance with the federal requirements which are set forth in the Medicare Conditions of Participation, 42 CFR Part 482, in order to receive Medicare or Medicaid payments. The CoPs state that:

- Hospitals must have an organized nursing service that provides 24-hour nursing services. The services must be furnished or supervised by a registered nurse.⁷
- The operating room must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.⁸
- Licensed practical nurses (LPNs) and surgical technologists may serve as “scrub nurses” under the supervision of a registered nurse.⁹
- Qualified registered nurses may perform circulating duties in the operating room.¹⁰
- LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately¹¹ available to respond to emergencies.¹²

Surgical Assistants

American College of Surgeons defines “surgical assistants” as those who provide aid in exposure, hemostasis, closure and other operative technical functions that help the surgeon carry out a safe operation with optimal results. Some of the specific tasks include: making initial incisions (opening), exposing the surgical site (retracting), stemming blood flow (hemostasis), reconnecting tissue (suturing) and completing the operation by reconnecting external tissue (closing). Additionally, surgical assistants

⁵ Ch. 2006-37, L.O.F.

⁶ Section 395.0191(1)(d), F.S.

⁷ 42 CFR Part 482.23.

⁸ 42 CFR Part 482.51(a)(1).

⁹ 42 CFR Part 482.51(a)(2).

¹⁰ 42 CFR Part 482.51(a)(3).

¹¹ According to CMS, the supervising RN would not be considered immediately available if the RN was located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical tech.

¹² 42 CFR Part 482.51 (a)(3).

should possess knowledge of sterility requirements, aseptic techniques, draping procedures, operating room equipment, drain placement and cauterization, and dressing techniques.

Surgical technologists are individuals with specialized education who function as members of the surgical team in the role of “scrub person.” With additional education and training, some surgical technologists function in the role of surgical first assistant.¹³

The use of non-physician practitioners and unlicensed persons in surgery as an assistant-at-surgery is increasing due to:¹⁴

- A restriction on resident duty hours promulgated by the Accreditation Council on Graduate Medical Education (ACGME) in 2003,
- Changing reimbursement strategies by CMS and other third-party payers,
- Increased demands on physician and surgeon time, and
- The availability of skilled and experienced unlicensed personnel, particularly those trained in the military.

According to the U.S. Department of Labor’s Bureau of Labor Statistics’ *2012-13 Occupational Outlook Handbook*, there were approximately 93,600 surgical technologist jobs in the United States. The median annual income of surgical technologists in 2010 was \$39,920, or \$19.19 per hour.¹⁵

According to the Association of Surgical Assistants, a surgical assistant can’t enroll in Medicare, and can’t be paid by Medicare as an assistant-at-surgery. Medicare will pay for assistants-at-surgery only when the person reporting the service is a physician or the person bears the designation of physician assistant, nurse practitioner, nurse midwife, or clinical nurse specialist. If the person who assists at surgery is a surgical technologist or bears any title other than those listed, the service is not payable by Medicare.¹⁶

Educational Training

Currently, there is a wide range of non-physician health professionals trained as surgical assistants or technologists in a variety of programs. According to the U.S. Department of Labor, most employers prefer to hire surgical assistants or technologists who are certified. Surgical assistants or technologists may obtain certification by graduating from an accredited program and passing a national certification examination.¹⁷

Accredited programs may be offered in community and junior colleges, vocational and technical schools, the military, universities, and structured hospital programs in surgical technology. The accredited programs vary from nine to fifteen months for a diploma or certificate to two years for an associate’s degree.¹⁸

The Commission on Accreditation for Allied Health Education Programs (CAAHEP) is the largest programmatic accreditor in the health sciences field. In collaboration with its Committees on Accreditation, CAAHEP reviews and accredits over 2000 educational programs in 23 health science occupations.¹⁹ Currently, there are 35 accredited CAAHEP programs located in Florida that offer an

¹³ American College of Surgeons, Statement on Surgical Technology Training and Certification, available at: http://www.facs.org/fellows_info/statements/st-47.html (last viewed March, 2013).

¹⁴ *Supra* fn 4.

¹⁵ U.S. Department of Labor, Occupational Handbook, Surgical Technologists, available at: <http://www.bls.gov/ooh/Healthcare/Surgical-technologists.htm> (last viewed March 22, 2013).

¹⁶ Association of Surgical Assistants, ASA Statement on Medicare Reimbursement, available at: http://www.surgicalassistant.org/wp-content/uploads/ASA_Statement_Medicare_Reimbursement_5.27.doc (last viewed March 22, 2013).

¹⁷ *Supra* fn 13.

¹⁸ *Id.*

¹⁹ Commission on Accreditation for Allied Health Education Programs, available at: <http://www.caahep.org/> (last viewed March 22, 2013).

associate's degree, certificate, or diploma in surgical technology.²⁰ According to the CAAHEP, there is one school located in Florida that offers a diploma or associate's degree in surgical assisting.²¹

Certifying Bodies

There are at least four national organizations offering certification credentials to qualifying surgical technologists or surgical assistants. The organizations are: the American Board of Surgical Assistants, the National Board of Surgical Technology and Surgical Assisting, the National Surgical Assistant Association and the American Surgical Assistants.

The American Board of Surgical Assistants (ABSA), was founded in 1987, by Paul F. Weeks, M.D. as a national credentialing organization, for surgical assistants. The ABSA administers a national certification examination, for surgical assistants, covering all surgical disciplines and all areas of perioperative medicine.²²

The National Board of Surgical Technology and Surgical Assisting (NBSTSA), was established in 1974 as the certifying agency for surgical technologists. NBSTSA is solely responsible for all decisions regarding certification; from determining eligibility to maintaining, denying, granting and renewing the designation. The NBSTSA is the only examination program for certifying surgical technologists (CST) and surgical first assistants (CSFA) accredited by the National Commission for Certifying Agencies in the nation.²³

The National Surgical Assistant Association (NSAA) was created in 1979, when a group of Surgical Assistants banded together to form the Virginia Association of Surgical Assistants, created a job description for surgical assistants, and established standards of practice. This group saw a need for surgical assistants and the need for education. The Eastern Virginia Medical School then became the home for the surgical assistant program. In 1983, the Virginia Association of Surgical Assistants became the National Surgical Assistant Association.²⁴

The American Surgical Assistants was formed in 1999 in Houston, Texas from the merger of two of the leading surgical assistant companies in the industry. In June of 2005, American Surgical Assistants became the first surgical assistant professional services company in the country to be awarded the certification of The Joint Commission, the highest recognition in the industry. American Surgical Assistants has continued to grow over the years, with a current staff of over 150 surgical assistants.²⁵

Professional Regulation and the Florida Sunrise Act

There are three different types or levels of regulation:²⁶

1. Licensure is the most restrictive form of state regulation. Under licensure laws, it is illegal for a person to practice a profession without first meeting all of the standards imposed by the state.
2. Certification grants title protection to those who meet training and other standards. Those who do not meet certification standards cannot use the title, but can still perform the services.

²⁰ Commission on Accreditation for Allied Health Education Programs, available at: <http://www.caahep.org/Find-An-Accredited-Program/#> (last viewed March 22, 2013).

²¹ *Id.*

²² American Board of Surgical Assistants, "The ABSA," available at: <http://www.absa.net/> (last viewed March 22, 2013).

²³ National Board of Surgical Technology and Surgical Assisting, "About NBSTSA," available at: <http://nbstsa.org/about/index.html> (last viewed March 22, 2013).

²⁴ National Surgical Assistant Association, "About NSAA," <http://nsaa.net/about.php> (last visited March 22, 2013).

²⁵ American Surgical Assistants, "About Us," available at: <http://www.americansurgicalassistants.com/about-us/> (last viewed March 22, 2013).

²⁶ Schmitt, K. & Shimberg, B. (1996). *Demystifying Occupational and Professional Regulation: Answers to Questions You May Have Been Afraid to Ask. Council on Licensure, Enforcement, and Regulation.*

3. Registration is the least restrictive form of regulation, and usually only requires individuals to file their name, address, and qualifications with a government agency before practicing the occupation.

Section 456.003, F.S., specifies that health care professions must be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions are required to be regulated when:

- Their unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation;
- The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation; and
- Less restrictive means of regulation are not available.

Section 11.62, F.S., the Sunrise Act, provides legislative intent regarding the regulation of new professions and occupations:²⁷

- No profession or occupation is subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage and that the police power of the state must be exercised only to the extent necessary for that purpose; and
- No profession or occupation is regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation or adversely affects the availability of the professional or occupational services to the public.

In determining whether to regulate a profession or occupation, section 11.62(3), F.S., requires the Legislature to consider the following:

- Whether the unregulated practice of the profession or occupation will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote;
- Whether the practice of the profession or occupation requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements would reasonably assure initial and continuing professional or occupational ability;
- Whether the regulation will have an unreasonable effect on job creation or job retention in the state or will place unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a given profession or occupation to find employment;
- Whether the public is or can be effectively protected by other means; and
- Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, will be favorable.

The Sunrise Act requires proponents of the regulation to submit information documenting the need for the proposed regulation. In 2010, the Florida State Assembly of the Association of Surgical Technologist completed a sunrise questionnaire and estimated that fewer than 5,980 surgical technologists (also known by other terms such as operating room technician, “scrub nurse,” and surgical technician) would be affected by creating a mandatory regulatory scheme.²⁸

Generally, regulatory provisions include the following components: oversight conducted by a governing board or council, penalties allowing for enforcement, licensure by endorsement, title protection, defined supervisory relationships, identified delegable tasks, grounds for disciplinary action, and initial and renewal licensure fees.

²⁷ Section 11.62(2), F.S.

²⁸ Sunrise Questionnaire: Surgical Technology Regulation, prepared by the Florida State Assembly of the Association of Surgical Technologist, September 10, 2010, on file with the Health Quality Subcommittee staff.

Since 2010, there have been several bills filed proposing ways to regulate the surgical profession.

Health Care Professions

Chapter 456, F.S., governs the core licensure requirements for health care professions and facilities regulated by the Department of Health.

Section 456.001(4), F.S., defines “health care practitioner” to mean any person licensed under: ch. 457, F.S., (acupuncture); ch. 458, F.S., (medicine); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathic medicine); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry and dental hygiene); ch. 467, F.S., (midwifery); parts I, II, III, V, X, XIII, and XIV of ch. 468, F.S., (speech-language pathology and audiology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrology or electrolysis); ch. 480, F.S., (massage therapy); parts III and IV of ch. 483, F.S., (clinical laboratory personnel or medical physics); ch. 484, F.S., (opticianry and hearing aid specialists); ch. 486, F.S., (physical therapy); ch. 490, F.S., (psychology); and ch. 491, F.S. (psychotherapy).

Effect of Proposed Changes

The bill amends s. 395.0191, F.S., to prohibit facilities from employing or contracting with a person to perform the duties of a surgical assistant unless the person is a certified surgical technologist or certified surgical assistant.

The bill defines “certified surgical assistant” to mean a surgical assistant who maintains a valid and active certification issued by: the American Board of Surgical Assistants, the National Board of Surgical Technology and Surgical Assisting, or the National Surgical Assistant Association.

The bill defines “certified surgical technologist” to mean a surgical technologist who maintains a valid and active certification issued by the National Board Surgical Technology and Surgical Assisting.

The bill provides an exemption, such that, a facility may contract or employ a person who doesn’t possess a valid and active certification, if:

- The person is employed or contracted to perform the duties of a surgical assistant or surgical technologist anytime between January 1, 2013 to July 1, 2013;
- The person is a health care practitioner as defined in ch. 456, F.S., or a student if the duties performed fall within the scope of his or her training and practice; or
- The person is enrolled in an accredited surgical technology or surgical assisting training program as of July 1, 2013. The person may practice for one year following the date of completion of the accredited training program.

The bill defines “surgical technologist” to mean a person who assists and practices under the supervision of a surgeon to ensure that the operating room environment is safe, that proper equipment is available, and that the operative procedure is conducted efficiently. The bill states that surgical technologist duties include: maintaining sterility during surgical procedures, handling and ensuring the availability of necessary equipment and supplies, and maintaining visibility of the operative site.

The bill defines “surgical assistant” to mean a person who provides aid, under the supervision of the surgeon, with exposure, hemostasis, closures, and other intraoperative technical functions that assist the surgeon in performing technical functions that assist the surgeon in performing a safe operation with optimal results for the patient.

The bill defines "surgeon" to mean a health care practitioner licensed under ch. 456, F.S., whose scope of practice includes performing surgery and who is listed as the primary surgeon in the operative record.

B. SECTION DIRECTORY:

Section 1. Amends s. 395.0191, F.S., relating to staff membership and clinical privileges.

Section 2. Provides an effective date of July 1, 2013.

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:

The bill appears to have an indeterminate, but likely insignificant, fiscal impact on hospitals because the majority of hospitals hire certified or licensed personnel.²⁹

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:

The AHCA has sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

On line 45, the bill uses the term facility, which is an undefined term within the definition section of ch. 395.002, F.S. However, s. 395.002(16), F.S., defines the term "licensed facility" to mean a hospital, ambulatory surgical center, or mobile surgical facility licensed by AHCA.

²⁹ Per telephone conversation with staff representing the Florida Hospital Association.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES

On March 27, 2013, the Health Quality Subcommittee adopted an amendment and reported the bill favorably as a committee substitute. The amendment:

- Places the language of the bill into s. 395.0191, F.S., which negates the need to: define agency and health care facility and provide rulemaking authority.
- Adds definitions for certified surgical assistant, certified surgical technologist, and surgeon.
- Amends the definitions of surgical assistant and surgical technologist.
- Broadens the exemption to the employment and contracting prohibition of surgical assistants and technologists who are not certified, to allow for the employment or contracting of any health care practitioner as defined in ch. 456, F.S., or a student, if the duties performed fall within the scope of the practitioner's or student's practice.
- Deletes the requirement for the Agency for Health Care Administration to inspect accrediting documents to ensure compliance with the employment and contract requirements.
- Deletes the requirement that insurance providers pay for services provided by surgical assistants.

This analysis is drafted to the committee substitute as passed by the Health Quality Subcommittee