

## HOUSE OF REPRESENTATIVES STAFF ANALYSIS

**BILL #:** CS/HB 425 Surgical Technology

**SPONSOR(S):** Health & Human Services Quality Subcommittee; Renuart

**TIED BILLS:** **IDEN./SIM. BILLS:** SB 362

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health & Human Services Quality Subcommittee	13 Y, 0 N, As CS	Holt	Calamas
2) Rulemaking & Regulation Subcommittee			
3) Health Care Appropriations Subcommittee			
4) Health & Human Services Committee			

### SUMMARY ANALYSIS

The American College of Surgeons defines “surgical assistants” as those who provide or aid in exposure, hemostasis, closure and other operative technical functions that help the surgeon carry out a safe operation with optimal results. Surgical technologists may function as members of the surgical team in the role of scrub person or with specialized training in the role of surgical first assistant (or assistant-at-surgery). Currently, the state of Florida does not regulate surgical technologists.

The bill amends s. 395.0191, F.S., restricting who a hospital may employ to perform surgical technology in an operating room to a person who has completed a nationally accredited program for surgical technologists. A hospital is directed to establish policies and procedures for the employment of persons who may perform surgical technology functions in an operating room. The person must hold the credential of certified surgical technologist within 6 months from the date of hire. The bill provides exemptions and requires AHCA to accept inspections or surveys conducted by national organizations as documentation of compliance.

The bill has no fiscal impact on the state or local governments.

The bill takes effect July 1, 2012.

# FULL ANALYSIS

## I. SUBSTANTIVE ANALYSIS

### A. EFFECT OF PROPOSED CHANGES:

#### Background

##### 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.<sup>1</sup>

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).<sup>2</sup>

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.<sup>3</sup>

There are numerous health practitioners who collaborate to create a surgical team:<sup>4</sup>

#### An overview of the surgical team

Role	Who Performs	Who Manages	Tasks
<b>Sterile</b>			
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
<b>Non-sterile</b>			
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

<sup>1</sup> 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](http://www.facs.org/fellows_info/statements/st-11.html) (last viewed January 25, 2012).

<sup>2</sup> *Id.*

<sup>3</sup> *Id.*

<sup>4</sup> Study into the Need to Regulate: Surgical Assistants & Surgical Technologist in the Commonwealth of Virginia, July 2010, available at: [www.dhp.state.va.us/.../SurgicalAssistant\\_TechnologistReportFinal](http://www.dhp.state.va.us/.../SurgicalAssistant_TechnologistReportFinal) (last viewed January 26, 2012)

## State Regulations

Hospitals, ambulatory surgical centers, 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 2006<sup>5</sup>, the Legislature required hospitals to comply with the requirements of the Centers for Medicare and Medicaid Services, Conditions of Participation (CoPs) for Hospitals, as they apply to registered nurses who perform circulating duties in the operating room.<sup>6</sup> Section 395.0191(1)(d), F.S., also provides that a circulating nurse 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:<sup>7</sup>

- Hospitals must have an organized nursing service that provides 24-hour nursing services. The services must be furnished or supervised by a registered nurse.<sup>8</sup>
- The operating room must be supervised by an experienced registered nurse or a doctor of medicine or osteopathy.<sup>9</sup>
- Licensed practical nurses (LPNs) and surgical technologists may serve as “scrub nurses” under the supervision of a registered nurse.<sup>10</sup>
- Qualified registered nurses may perform circulating duties in the operating room.
- LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately<sup>11</sup> available to respond to emergencies.<sup>12</sup>

## 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 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

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<sup>5</sup> Ch. 2006-37, L.O.F.

<sup>6</sup> Section 395.0191(1)(d), F.S.

<sup>7</sup> The Health Care Financing Administration, Survey Protocol, *available at*: [http://new.cms.hhs.gov/manuals/downloads/som107ap\\_a\\_hospitals.pdf](http://new.cms.hhs.gov/manuals/downloads/som107ap_a_hospitals.pdf) (last viewed January 10, 2006).

<sup>8</sup> 42 CFR Part 482.23

<sup>9</sup> 42 CFR Part 482.51(a)(1)

<sup>10</sup> 42 CFR Part 482.51(a)(2)

<sup>11</sup> 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.

<sup>12</sup> 42 CFR Part 482.51 (a)(3)

scrub person. With additional education and training, some surgical technologists function in the role of surgical first assistant.<sup>13</sup>

The use of non-physician practitioners and unlicensed persons as assistant-at-surgery is increasing due to a:<sup>14</sup>

- A restriction on resident duty hours promulgated by the Accreditation Council on Graduate Medical Education (ACGME) in 2003,
- Changing reimbursement strategies by Centers for Medicare and Medicaid Services (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.

### Certifying Bodies

Currently, there is a wide range of non-physician allied health professionals trained as surgical assistants or technologists in a variety of programs. According to the Department of Labor, most employers prefer to hire surgical assistants or technologists who are certified. Surgical assistants or technologists may obtain voluntary professional certification by graduating from an accredited program and passing a national certification examination.<sup>15</sup>

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 15 months for a diploma or certificate to two years for an associate's degree.<sup>16</sup>

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.<sup>17</sup> Currently, there are 36 accredited CAAHEP programs located in Florida that offer an associate's degree, certificate, or diploma in surgical technology.<sup>18</sup>

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 surgical technologists and surgical first assistants accredited by the National Commission for Certifying Agencies in the nation.<sup>19</sup>

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<sup>13</sup> American College of Surgeons, Statement on Surgical Technology Training and Certification, available at: [http://www.facs.org/fellows\\_info/statements/st-47.html](http://www.facs.org/fellows_info/statements/st-47.html) (last viewed January 25, 2012).

<sup>14</sup> Study into the Need to Regulate: Surgical Assistants & Surgical Technologist in the Commonwealth of Virginia, July 2010, available at: [www.dhp.state.va.us/.../SurgicalAssistant\\_TechnologistReportFinal](http://www.dhp.state.va.us/.../SurgicalAssistant_TechnologistReportFinal) (last viewed January 26, 2012)

<sup>15</sup> American College of Surgeons, Statement on Surgical Technology Training and Certification, available at: [http://www.facs.org/fellows\\_info/statements/st-47.html](http://www.facs.org/fellows_info/statements/st-47.html) (last viewed January 25, 2012).

<sup>16</sup> *Id.*  
<sup>17</sup> Commission on Accreditation for Allied Health Education Programs, available at: <http://www.caahep.org/> (last viewed January 25, 2012).

<sup>18</sup> Commission on Accreditation for Allied Health Education Programs, available at: <http://www.caahep.org/Find-An-Accredited-Program/#> (last viewed January 25, 2012).

<sup>19</sup> National Board of Surgical Technology and Surgical Assisting, About, available at: <http://nbstsa.org/about/index.html> (last viewed January 26, 2012).

## Education and Regulation in Other States

According to a study conducted by the U.S. General Accounting Office (GAO) in 2004,<sup>20</sup> there is no widely accepted set of uniform requirements for experience and education that the health professionals who serve as assistance-at-surgery or surgical first assistants are required to meet. The health professionals whose members provide assistants-at-surgery services have varying educational requirements. No state licenses all the health professionals who serve as assistants-at-surgery, and the states that issue health professional licenses typically require the completion of broad-based institutional health care education, rather than qualifying health professionals based on education or experience as an assistant. Furthermore, the certification programs developed by the various non-physician health professional groups whose members assist-at-surgery differ. The GAO found that there was insufficient information about the quality of care provided by assistants-at-surgery generally, or by a specific type of health professional, to assess the adequacy of the requirements for members of a particular profession to perform the role.

Based on the findings in the GAO study, in January 2004 only one state, Texas, had a specific assistant-at-surgery license. Even though Texas licenses assistants-at-surgery, a license is not required to serve as an assistant-at-surgery. According to the proponents of the bill several other states now regulate surgical technologists: Colorado, Illinois, Indiana, South Carolina, Tennessee, Texas, and Washington.<sup>21</sup> Currently, the state of Florida does not regulate surgical technologists.

### Surgical Education, Experience Requirements, and Licensure Requirements for Surgical First Assistants

Health Profession	General Education Requirements	Licensure Requirements in All States	Example of Surgical Experience Requirements
<b>Physician</b>			
Physicians (post-residency)	Doctor of medicine or osteopathy	Yes	
Physician in residency	Doctor of medicine or osteopathy	Yes	
<b>Nurse</b>			
Registered nurse, including surgical specialties * (*A variety of surgery-related certifications are available for nurses. Some of these are for surgical specialties. Orthopedic nurse certified requires 1,000 hours of experience as an orthopedic nurse. Certified plastic surgical nursing requires 2 years experience in plastic surgery. Both certifications include operating room experience, but neither requires OR experience.)	Associate's or bachelor's degree in nursing or non-degree hospital diploma	Yes	Requirements vary by certification program, but surgical experience is not required for certain surgical-related certifications
Nurse practitioner	Master's of science in nursing or non-degree certificate	Yes	
Clinical nurse specialist	Master's of science in nursing	Yes	
Certified registered nurse first assistant	Bachelor's degree and certification program with 2-3 surgical classes	Yes	2,400 hours of operating room experience in the scrub or circulating role and 2,000 hours as assistant-at-surgery
Licensed practical nurse	1-year program	Yes	
<b>Other health professions</b>			

<sup>20</sup> United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.

<sup>21</sup> 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 & Human Service Quality Subcommittee staff.

Surgical technologist	Associate's degree, military or non-degree certificate	No	2 years of surgical experience
Physician assistant	Associate's or bachelor's degree or non-degree certificate	Yes	
Ophthalmic assistant/technician	Certificate programs or work experience	No	18 months of surgical experience
Surgical assistant	Bachelor's degree or non-degree certificate	No	2-3 years of surgical assistant experience, depending upon certification program
Orthopedic physician assistant	Associate's degree, military or non-degree certificate, or 5 years of experience	No	1 year surgical experience
International medical graduate	Non-U.S. degree in medicine	No	

Source: 2004 GAO Report Medicare Payments for Assistants-at-Surgery

### Medicare Reimbursement of Surgical Assistants

According to a GAO report on Medicare costs in 2004,<sup>22</sup> surgical assistants have a wide range of educational training and expertise, and different levels of professional requirements that do not justify the same level of reimbursement by Medicare. Generally, the health care industry looks to Medicare and as a basis for reimbursement and payment structure.

As reported by the GAO, Medicare pays for assistant-at-surgery services through both the hospital inpatient prospective payment system (PPS) and the physician fee schedule, and the hospital payments for surgical care are not adjusted when an assistant receives payment under the physician fee schedule. The majority of assistants-at-surgery are employed by hospitals, where the inpatient hospital PPS pays for their services.<sup>23</sup> Generally, the amount Medicare pays under the physician fee schedule is based on the resources needed to perform a service, the physician's time and skill, practice expenses, that include the cost of staff (which may include a surgical tech), equipment, supplies, and the cost of liability insurance.<sup>24</sup>

Depending on the procedure performed, and the qualifications and training of the provider assisting in surgery, the services may be billable to Medicare. Medicare reimburses only assistants-at-surgery who are licensed personnel (such as physicians, clinical nurse specialists, nurse practitioner, and physician assistant) and does not reimburse for surgical assistants included under the physician fee schedule that are non-physicians. Non-physician assistants-at-surgery include certified registered nurse first assistant, orthopedic physician assistants, licensed practical nurses, or certified surgical technologists.<sup>25</sup> These non-physician assistants-at-surgery are usually paid by the hospital from the inpatient PPS or by the surgeon who pays them from the physician fee schedule (also referred to as the surgeons global fee).<sup>26</sup>

### **Effect of Proposed Changes**

The bill requires a hospital to establish policies and procedures for the employment of persons who may perform surgical technology functions in an operating room. The hospital may only consider a person who has successfully completed a nationally accredited program for surgical technologist. The person must hold the credential of certified surgical technologist within 6 months from the date of hire. Persons that are currently employed by a specific hospital or hospital system are exempt from this requirement as long as they maintain employment. Persons licensed under chapters 458 (MDs), 459 (DOs), and 464 (nurses), F.S., and interns or residents on a surgical rotation are exempt.

<sup>22</sup> United States General Accounting Office, Report to Congressional Committees. January 2004. Medicare: Payment Changes are Needed for Assistants-at-Surgery. GAO 04-97.

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> *Id.*

<sup>26</sup> *Id.*

AHCA is required to accept, in lieu of its own periodic inspection, a survey or inspection conducted by an accrediting organization as documentation of compliance, as long as the hospital does not hold a provisional license.

**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 October 1, 2012.

**II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT**

**A. FISCAL IMPACT ON STATE GOVERNMENT:**

1. Revenues:

None identified.

2. Expenditures:

None identified.

**B. FISCAL IMPACT ON LOCAL GOVERNMENTS:**

1. Revenues:

None identified.

2. Expenditures:

None identified.

**C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:**

None identified.

**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:**

No additional rule making is necessary to implement the provisions of the bill.

**C. DRAFTING ISSUES OR OTHER COMMENTS:**

None.

#### **IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES**

On January 31, 2012, the Health & Human Services Quality Subcommittee adopted a strike-all amendment and reported the bill favorably as a committee substitute. The strike-all:

- Removes the regulatory scheme created in ch. 468, F.S., mandating the certification of surgical technologists in Florida;
- Requires hospitals to establish policies and procedures for employing individuals who perform surgical technology;
- Provides hospitals may only hire a person who has completed a nationally accredited surgical technology program;
- Requires the person to hold the credential of certified surgical technologist within 6 months from the date of hire;
- Provides an exemption for current hospital employees, as long as employment is maintained;
- Provides an exemption to MDs, DOs, PAs, nurses and interns or residents on a surgical rotation; and
- Requires AHCA to accept, in lieu of its own periodic inspections, a survey or inspection conducted by an accrediting organization as documentation of compliance.

This analysis is drafted to the committee substitute.