2004 SUNRISE REVIEW

Colorado Department of Regulatory Agencies
Office of Policy, Research and Regulatory Reform

Surgical Assistants

October 15, 2004

STATE OF COLORADO

DEPARTMENT OF REGULATORY AGENCIES
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Bill Owens
Governor

October 15, 2004

Members of the Colorado General Assembly
c/o the Office of Legislative Legal Services
State Capitol Building
Denver, Colorado 80203

Dear Members of the General Assembly:

The Colorado Department of Regulatory Agencies has completed its evaluation of the sunrise application for regulation of surgical assistants and is pleased to submit this written report. The report is submitted pursuant to section 24-34-104.1, Colorado Revised Statutes, which provides that the Department of Regulatory Agencies shall conduct an analysis and evaluation of proposed regulation to determine whether the public needs, and would benefit from, the regulation.

The report discusses the question of whether there is a need for the regulation in order to protect the public from potential harm, whether regulation would serve to mitigate the potential harm, and whether the public can be adequately protected by other means in a more cost-effective manner.

Sincerely,

Tambor Williams

Tambor Williams
Executive Director

Table of Contents

Background

The Sunrise Process

Colorado law, section 24-34-104.1, Colorado Revised Statutes (C.R.S.), requires that individuals or groups proposing legislation to regulate any occupation or profession first submit information to the Department of Regulatory Agencies (DORA) for the purposes of a sunrise review. The intent of the law is to impose regulation on occupations and professions only when it is necessary to protect the public health, safety or welfare. DORA must prepare a report evaluating the justification for regulation based upon the criteria contained in the sunrise statute:

> (I) Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety, or welfare of the public, and whether the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
>
> (II) Whether the public needs, and can reasonably be expected to benefit from, an assurance of initial and continuing professional or occupational competence; and
>
> (III) Whether the public can be adequately protected by other means in a more cost-effective manner.

Any professional or occupational group or organization, any individual, or any other interested party may submit an application for the regulation of an unregulated occupation or profession. Applications must be accompanied by supporting signatures and must include a description of the proposed regulation and justification for such regulation. Applications received by July 1 must have a review completed by DORA by October 15 of the year following the year of submission.

Methodology

DORA has completed its evaluation of the proposal for regulation of surgical assistants. During the sunrise review process, DORA performed a literature search, contacted and interviewed representatives of the applicant, reviewed licensure laws in other states, surveyed ambulatory surgical centers and hospitals throughout Colorado, and interviewed other health care providers. Additionally, DORA contacted the Colorado Medical Society, Colorado Association of Health Plans, Colorado Health and Hospital Association, Federated Ambulatory Surgical Association, and the Association of periOperative Registered Nurses. In order to determine the number and types of complaints filed against surgical assistants in Colorado, DORA contacted the Colorado Board of Nursing, the Colorado Board of Medical Examiners, and the Colorado Department of Public Health and Environment.

Proposal for Regulation

The Colorado Association of Surgical Assistants (Applicant), which has 34 members, has submitted a sunrise application to the Department of Regulatory Agencies (DORA) for review in accordance with the provisions of section 24-34-104.1, Colorado Revised Statutes (C.R.S.). The application proposes licensure of surgical assistants as the appropriate level of regulation to protect the public. The Applicant states that surgery is inherently dangerous and that sufficient risk of physical harm or death due to intra-operative mistakes exists; therefore, only individuals who are properly educated, examined, and who fall under state authority in the form of occupational licensure should be allowed entry to the profession. The proposal does not exempt physician assistants, nurses, and other health care professionals who would be performing the duties of the surgical assistant as defined by statute, but would require that they become licensed as surgical assistants.

The following components would characterize the recommended licensure program:

- Licensing program administered by DORA;
- Continuing education requirements; and
- Establishment of qualifications for licensure that include:
    - Minimum education standards, including a two-year associates degree in a health science field such as surgical technology, nursing, physician assistant or equivalent.
    - Eligibility to take the examination administered by the Liaison Council on Certification for the Surgical Technologist, the National Surgical Assistants Association, or the American Board of Surgical Assistants.
    - Provisions to allow for the grandfathering of surgical assistants who have the equivalent of experience for education and who also have private certification.

The Applicant maintains that surgery is inherently and obviously dangerous, and yet at this time no minimal training or credentialing standards are in place in Colorado that would compel hospitals, surgical centers, or physicians to utilize only the services of properly credentialed individuals in the operative setting. Despite national educational standards and a voluntary national credential, they argue that too many operating room suites still utilize untrained surgical personnel.

Regarding public harm, the Applicant argues that the role of surgical assistants is such that the duties they perform place the public at increased risk for harm during surgery if minimal education standards and state oversight are not ensured. Surgery is a rapidly advancing field, and surgical assistants are now called on to use sophisticated electrosurgical, endoscopic, laser equipment, and gas beam coagulation equipment, as well as other technology. These processes require highly specialized knowledge and skill, acquired through education and experience.

Furthermore, the Applicant argues that the general public does not have the opportunity to evaluate the qualifications of surgical assistants and must depend upon the standards set by employers, which at this time vary from verification of education and holding a voluntary national credential in surgical assisting to no verification of skills or training at all.

Profile of the Profession

Members of a wide range of health professions perform the functions of surgical assistants, who may also be referred to as first assistants or assistants-at-surgery. These include:

- Physicians (postresidency)
- Physicians in residency
- Registered nurses, including those in surgical specialties, such as orthopedics or plastic surgical nurses
- Licensed practical/vocational nurses
- Nurse practitioners
- Clinical nurse specialists
- Certified registered nurse first assistants
- Surgical technologists
- Physician assistants
- Ophthalmic assistant/technicians
- Surgical assistants
- Orthopedic technologists
- Orthopedic physician assistants
- International medical graduates

Credentialed hospital employees serve as surgical assistants for a majority of the procedures for which the American College of Surgeons supports the concept that “ideally, the first assistant to the surgeon at the operating table should be a qualified surgeon or resident in a surgical education program that is approved by the appropriate residency review committee and accredited by the Accreditation Council for Graduate Medical Education.”

The U.S. Department of Labor's, *Occupational Outlook Handbook* does not classify surgical assistants or first assistants as an occupation, therefore there is no definition included in this resource. However, the American College of Surgeons defines surgical assistants as those who provide aid in exposure, hemostasis, closure, and other intra-operative technical functions that help the surgeon carry out a safe operation with optimal results.

Surgical assistants, who serve as members of the surgical team, 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 by reconnecting external tissue ("closing").[1] Additionally, surgical assistants should possess knowledge of sterility requirements, aseptic techniques, draping procedures, operating room equipment, drain placement and catheterization, and dressing techniques.

With experience, surgical assistants learn to anticipate the moves and needs of the surgeon as the operative procedure progresses. Surgical assistants function under the direction and supervision of the surgeon and in accordance with hospital policy and appropriate laws and regulations. They may work in multiple specialties and perform in a variety of surgical procedures.

The decision by a hospital or surgeon to use a surgical assistant depends on the complexity of the operation and medical condition of the patient. Physician associations, such as the American College of Surgeons and the American Society of General Surgeons, maintain that the surgeon should be responsible for determining if an assistant-at-surgery is needed, although some hospitals require the use of an assistant for certain surgical procedures.[2]

Education

There is no widely accepted set of uniform requirements for experience and education that the health professionals who serve as surgical assistants are required to meet and the health professions whose members serve as surgical assistants have varying educational requirements (see Table 1 on the following page). For example, a certified registered nurse first assistant must have a bachelor's degree and have completed a certification program, while a surgical technologist may have an associate's degree, military, or non-degree certificate. Furthermore, the certification programs developed by the various non-physician health professional groups whose members assist at surgery differ.

[1] *Medicare: Payment Changes are Needed for Assistants-at-Surgery*. United States General Accounting Office, Report to Congressional Committees, January 2004, p. 5.
[2] *Ibid*

Table 1
Education and State Licensure Requirements for Those Who May Assist at Surgery

Health Profession	General Education Requirements	Licensure Requirements in All States
Physician (postresidency)	Doctor of medicine or osteopathy	Yes
Physician in residency	Doctor of medicine or osteopathy	Yes
Registered nurse, including those in surgical specialties, such as orthopedics or plastic surgical nurses	Associate's or bachelor's degree in nursing or non-degree hospital diploma	Yes
Licensed practical/vocational nurse	1 year program	Yes
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	
Surgical technologist	Associate's degree, military or non-degree certificate	No
Physician assistant	Associate's or bachelor degree or non-degree certificate	Yes
Ophthalmic assistant/technician	Certificate programs or work experience	No
Surgical assistant	Bachelor's degree or non-degree certificate	No
Orthopedic physician assistant	Associate's degree, military or non-degree certificate, or 5 years of experience	No
International medical graduate	Non-U.S. degree in medicine	No

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

The Commission on Accreditation of Allied Health Education Programs (CAAHEP) is the largest programmatic/specialized accreditor in the health sciences field. In collaboration with its committees on accreditation, CAAHEP reviews and accredits more than 2,000 educational programs in 21 health science occupations, including surgical assistants, across the United States and Canada. Prior to 1994, accreditation in most of these disciplines was a function of a committee within the American Medical Association (AMA). When the AMA decided to relinquish accreditation of these programs to another entity, CAAHEP was created.

The Accreditation Review Committee on Education in Surgical Technology (ARC-ST) in cooperation with the Sub-Committee on Accreditation for Surgical Assisting (SASA) is the committee on accreditation that works directly with each surgical assisting educational program in the accreditation process. The ARC-ST/SASA performs a non-site evaluation to gather data on each program and then meets twice a year to make recommendations, which are then forwarded to CAAHEP.

The specialized accreditation of programs in surgical assisting began in 2002, with the implementation of standards of compliance that were developed by the collaborating organizations. The ARC-ST/SASA is composed of representatives from the American College of Surgeons, the Association of Surgical Technologists, and the National Surgical Assistant Association. CAAHEP, in conjunction with the ARC-ST, is recognized by the Council for Higher Education Accreditation, a non-governmental body that reviews and recognizes accrediting agencies.

CAAHEP currently accredits two programs for surgical assistants in the United States: Madisonville Community College in Madisonville, Kentucky and South Plains College in Lubbock, Texas.

In 2002, Madisonville Community College opened the first surgical assisting program in the nation to be accredited by CAAHEP. This program is one year in length and topics of study include surgical anatomy, surgical pharmacology, anesthesia, and principles of surgical assisting. Students are required to complete rotations in general surgery, neurosurgery, gynecology, orthopedics, and vascular and plastic surgery.

South Plains College, in cooperation with Texas Tech University Health Sciences Center in Lubbock, offers an advanced technical certificate program in surgical assisting. An applicant must be a certified surgical technologist, certified surgical assistant, certified first assistant, or certified operating room nurse and have current Cardiopulmonary Resuscitation or Basic Life Support certification. An applicant is required to have an associate degree or higher in an allied health field or the equivalent from an accredited institution. Classes are offered in surgical pharmacology, anesthesia, and advanced surgical technology. Additionally, a practicum is required in surgical assisting. Students rotate through general surgery, neurosurgery, pediatrics, orthopedics, plastic surgery, and ear nose and throat (ENT), and they work closely with physicians to achieve surgical assisting skills.

Though not accredited by CAAHEP, the East Virginia Medical School Department of Surgery has offered an educational program since 1981 to prepare candidates for a career to assist surgeons in the performance of surgical procedures. While prior medical and/or operating room experience is highly desired, it is not a prerequisite for acceptance into the Surgical Assistant Program. A baccalaureate degree is not required, but is strongly preferred. Candidates accepted into the program complete 22 months of training that includes classroom instruction in such topics as human physiology, gross anatomy, fundamentals of surgical skills, microbiology, and pharmacology. Second-year clinical rotations are conducted in regional tertiary facilities that provide students with experience in a wide range of surgical procedures.

Private Certification

The Liaison Council on Certification for the Surgical Technologist, the National Surgical Assistants Association, and the American Board of Surgical Assistants are national organizations that conduct voluntary certification programs for surgical assistants. All three organizations have developed examinations that measure a surgical assistant's education and knowledge and also have created codes of ethics for their respective organizations.

The Liaison Council on Certification for the Surgical Technologist (LCC-ST)

LCC-ST was originally established in 1974 as the certifying agency for surgical technologists. At this time, LCC-ST is solely responsible for all decisions regarding the eligibility for and granting, denial, renewal, maintenance, and revocation of LCC-ST certification of surgical technologists as well as first assistants.

LCC-ST's board of directors voted at its annual meeting to expand the eligibility requirements for the national certifying examination for first assistants. Previously, in order to be eligible for the examination, individuals were required to achieve certified surgical technologist status. Under the new requirements, which took effect January 1, 2004, individuals are eligible to take the certified first assistant (CFA) examination if they have advanced education in limited allied health fields that include associate and bachelor degrees as physician assistants, surgical technologists, or nurses. Surgeons with medical degrees (foreign and domestic) are also eligible to take the CFA examination.

The LCC-ST-administration of the CFA certifications has been reviewed and granted accreditation by the National Commission for Certifying Agencies (NCCA). The NCCA evaluates certifying agencies based upon a comprehensive set of criteria including the appropriateness of certification requirements to the occupation being certified, the validity and reliability of the certifying examinations, and the extent to which the public interest is protected. The LCC-ST is the only private certification entity for surgical assistants that is accredited by the NCCA.

National Surgical Assistants Association (NSAA)

In 1979, a group of surgical assistants formed the Virginia Association of Surgical Assistants (VASA) and created a job description and standards of practice for surgical assistants. The Eastern Virginia Medical School became the home for the surgical assistant program. With the assistance of the Department of Surgery at Norfolk General Hospital, a certification examination was developed. Membership in this organization grew to include members from throughout the United States. Thus, in 1983, VASA became NSAA.

In order to be eligible to take the certification examination, candidates are required to fulfill one of the following requirements: (1) graduate from an NSAA-approved surgical assisting program, (2) receive on the job training, (3) graduate from a foreign medical school, or (4) obtain U.S. military training in surgical assisting. The examination is given in three parts – written (more than 300 questions), oral, and practical. The examination candidate must pass all three parts to receive the "Certified Surgical Assistant" designation.

NSAA mandates continuing education for Certified Surgical Assistants throughout the country and recertification of the Certified Surgical Assistant credential, by the establishment of continuing medical education standards and verification.

The American Board of Surgical Assistants (ABSA)

The ABSA was founded in 1987 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. Individuals are eligible to take the ABSA Certification Examination for Surgical Assistants if they possess more than a basic surgical and anatomical knowledge, along with the manual and technical skills necessary to function effectively in the role of a surgical assistant. Eligibility criteria and requirements have been set by the American Board of Surgical Assistants, which has final authority regarding who may or may not sit for the examination. The examination evaluates candidate knowledge of surgical anatomy, procedures and techniques, diagnostic studies, emergency situations, regulations promulgated by the U.S. Occupational Safety and Health Administration, and general patient safety.

In order to be recertified as a surgical assistant, individuals must assist in this role as defined by the ABSA for a minimum of 400 procedures or 1,500 hours every two years.

Summary of Current Regulation

The Colorado Regulatory Environment

There are individuals with various experience and educational backgrounds who perform the functions of surgical assistants in Colorado, such as registered first assistant nurses, licensed practical nurses, physician assistants, certified surgical assistants, and other non-specified health care professionals. The Colorado Association of Surgical Assistants (Applicant) estimates that there are 350 surgical assistants currently practicing in Colorado.

Currently, there is no Colorado statute or local or county law that specifically requires licensure of surgical assistants. However, section 12-36-106(3)(l), Colorado Revised Statutes (C.R.S.), permits physicians to delegate the performance of medical services to unlicensed providers or to providers who may have a license but are not licensed to perform the service being delegated. The Board of Medical Examiners has promulgated Rule 800, which clarifies this general delegatory authority granted to physicians. Rule 800 clarifies the delegation and personal and responsible direction and supervision of medical services to a person who is not otherwise exempt pursuant to section 12-36-106, C.R.S., from holding a license to practice medicine. Under this rule, a physician agrees to provide the necessary direction and supervision of the delegatee and the delegating physician is accountable for the acts of the delegatee. Generally, personal and responsible direction and supervision requires that a delegating physician be on the premises and readily available. It is the responsibility of the physician to ensure that the delegatee has the necessary education, training, or experience to perform the delegated services.

In addition, there are practice prerogatives that have been outlined by hospital systems in Colorado. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a private organization that accredits health care organizations, including hospitals, requires hospitals to credential their staffs (i.e., establish requirements, such as licensure, certification, and experience for physicians and certain non-physician health professionals) and ensure that those requirements are utilized when personnel decisions are made. However, JCAHO does not recommend the type or length of education or experience necessary for credentialing hospital staffs that serve as surgical assistants.

Appendix A on page 22 illustrates the various education, training, supervision, and experience required of personnel who perform the functions of surgical assistants at the major hospital systems along Colorado's Front Range. These hospitals include: HealthONE, Exempla Healthcare, Centura Health, Denver Health Medical Center, and the University of Colorado Health Sciences Center.

HealthONE is the largest hospital system in Colorado and includes such hospitals as The Medical Center of Aurora, North Suburban Medical Center, Presbyterian/St. Luke's Medical Center, Rose Medical Center, Swedish Medical Center, Sky Ridge Medical Center, and Spalding Rehabilitation Hospital. Exempla Healthcare System encompasses Lutheran Medical Center and St. Joseph's Hospital. Centura Health Hospitals includes Avista Adventist Hospital, Littleton Adventist Hospital, Parker Adventist Hospital, Penrose-Saint Francis (Colorado Springs), Porter Adventist Hospital, St. Anthony Central, St. Anthony North, Saint Mary-Corwin Medical Center (Pueblo), and Summit and Granby Medical Centers.

The results of the review of the hospital systems reveal that the scopes of practice, supervision, education/training, and experience requirements are very similar. All the hospitals surveyed require that surgical assistants be under direct supervision of the surgeon during the surgical procedure. Additionally, they require either a license or a certification to perform the functions of a surgical assistant and a designated number of years of experience. In reply to the question whether there is a need for regulation of surgical assistants, the respondents articulated that there are processes in place to monitor and assess the ability of a surgical assistant and adding another layer of credentialing may be redundant. One major hospital facility commented that if those assisting in surgery were required to be certified surgical assistants, the health care industry would be adversely impacted especially in times of shortage.

Summary of Survey of Colorado Rural and Independent Hospital Facilities' Use of Surgical Assistants

Additionally, as part of this sunset review, a survey was developed and mailed to 23 independent and rural hospital facilities in Colorado. Complete survey results are found in Appendix B on page 24 of this report. The two page survey contained eight questions with a few containing sub-questions. Respondents were asked to answer questions concerning the use of surgical assistants; their scope of practice; and the education, training, and experience required to perform the functions of a surgical assistant. The final question inquired whether regulation of surgical assistants was needed and the reasons for or against regulation.

Of the 23 surveys mailed, 16 were completed and returned to the Department of Regulatory Agencies (DORA), representing an overall response rate of 70 percent. Ten hospital facilities (63 percent) noted that they were located in a rural environment while 6 (37 percent) were described as urban. Of the 16 respondents, only one facility indicated that it does not utilize surgical assistants.

Respondents were asked to identify the health professionals who perform the functions of surgical assistants. Fifteen facilities (94 percent) responded that they utilize physician assistants, 9 facilities (60 percent) employ certified surgical assistants, 11 facilities (73 percent) employ certified registered nurse first assistants, 10 facilities (67 percent) utilize both licensed physicians and Registered Nurses, and 6 (40 percent) employ surgical technologists. Non-certified surgical assistants (13 percent), international medical graduates (7 percent) and licensed practical nurses (0 percent) were the least frequently utilized individuals to perform surgical assisting functions.

DORA's survey also asked respondents to specify from a list of 17 activities, those in which surgical assistants engage at their respective facilities. The responses ranged from 100 percent participation in assisting in the retraction of tissues per surgeon's directive to 60 percent participation in preparing anterior cruciate ligament (ACL) grafts under a surgeon's supervision. Additionally, 93 percent of the surgical assistants assist in maintaining hemostasis and 80 percent assist in placement and suturing of surgical drains.

When questioned whether there is a need for the regulation of surgical assistants, 47 percent of respondents answered "yes" and 33 percent indicated "no." Generally, those who responded in the affirmative commented that there is such diversity in training and certification of surgical assistants that it needs to be standardized. Those who responded in the negative reported that it is the responsibility of the facilities to assure competence of the surgical assistants that they hire. Additionally, a comment from the rural hospitals stated that in a small rural county, it is prohibitive to hire "assistants" only.

Summary of Survey of Ambulatory Surgical Centers Use of Surgical Assistants

As part of this sunset review, a survey was developed and mailed to all 82 ambulatory surgical centers in Colorado. Complete survey results are attached as Appendix C beginning on page 27 of this report. The two page survey contained eight questions with a few containing sub-questions. Respondents were asked to answer questions concerning their use of surgical assistants; their scopes of practice; and the education, training, and experience required to perform the functions of a surgical assistant. The final question inquired whether regulation of surgical assistants was needed and the reasons for or against regulation.

Of the 82 surveys mailed, 52 were completed and returned to DORA, representing an overall response rate of 65 percent. The first finding worth noting from this survey is that 37 facilities (71 percent) utilize surgical assistants. One question posed on this survey asked respondents to identify the health professionals who perform as surgical assistants. Twenty-four facilities (65 percent) responded that they utilize certified surgical assistants, 26 facilities (70 percent) employ registered nurses, while 20 facilities (54 percent) utilize physician assistants. Other health care professionals utilized for surgical assistant functions include certified registered nurse first assistants (35 percent), licensed physicians (51 percent), non-certified surgical assistants (38 percent), and surgical technologists (35 percent).

DORA's survey also asked respondents to specify from a list of 17 activities, those in which surgical assistants engage at their respective facilities. The responses ranged from 84 percent participation in assisting in the retraction of tissues per surgeon's directive to a 24 percent rate of participation in urinary catheter placement. Additionally, 76 percent of the surgical assistants assist in maintaining hemostasis and 57 percent assist in placement and suturing of surgical drains.

When questioned whether there is a need for the regulation of surgical assistants, the responses were somewhat different than the responses from the rural and independent hospital facilities. Whereas the rural and independent hospitals responded in the affirmative at a rate of 47 percent and in the negative at a rate of 33 percent, ambulatory surgical center respondents replied in the affirmative at a rate of 59 percent and in the negative at a rate of 35 percent. Generally, those who responded in the affirmative commented that regulation lends itself to accountability and would provide a means of monitoring and tracking the surgical assistant. Those who responded in the negative remarked that it is the responsibility of the facilities to assure the competence of the assistants that they hire.

Third Party Reimbursement

Many of the practitioners involved in performing the surgical assistant functions are reimbursed either by insurance companies, patients, or in some cases by surgeons with whom they work. However, many surgical assistants are not eligible for third-party reimbursement for services rendered. There is nothing in Colorado state law that mandates reimbursement for services rendered by non-physician surgical assistants. The U.S. General Accounting Office (GAO) issued a report in 2004 entitled, *Medicare: Payment Changes are Needed for Assistants-at-Surgery*, which examines who serves as assistants-at-surgery, whether health professionals who perform the role must meet a uniform set of professional requirements, and whether Medicare's payment policies for assistants-at-surgery are consistent with the goals of the program and, if not, whether there are alternatives that would help attain those goals.

The GAO document reports that Medicare pays hospitals, physicians, and certain non-physician health professionals for assistant-at-surgery services through the hospital inpatient prospective payment system (PPS) and the Medicare physician fee schedule. Medicare makes a single payment to hospitals for all the services, including assistant-at-surgery services that a hospital provides to a beneficiary while an inpatient. Medicare also makes payments under the Medicare physician fee schedule for assistant-at-surgery services performed by physicians and members of certain non-physician health professions. These non-physician health professionals – primarily physician assistants, nurse practitioners, and clinical nurse specialists – are allowed to bill Medicare under the physician fee schedule.

The report found that since 1997, the number of assistant-at-surgery services performed by physicians and paid under the Medicare physician fee schedules has declined, while the number of such services performed by non-physician health professionals eligible to receive payment under the physician fee schedule has increased.

In conclusion, the report cited three flaws in Medicare's policies for paying assistants-at-surgery that prevent the payment system from meeting the program's goals of making appropriate payment for medically necessary services by qualified providers. First, decisions to use an assistant-at-surgery should not be influenced by payment; they should be based on medical necessity. Second, paying a health professional under the physician fee schedule to be an assistant-at-surgery, instead of including this payment in an all-inclusive payment, gives neither the hospital nor the surgeon an incentive to use an assistant only when one is medically necessary. Third, the distinctions between those health professionals eligible for payment as assistants-at-surgery under the physician fee schedule and those who are not eligible are not based on surgical education or experience as an assistant. Criteria for determining who should be paid as assistants-at-surgery under the physician fee schedule do not exist. The report recommends that Congress consider consolidating all Medicare payments for assistant-at-surgery services under the hospital inpatient PPS.[3]

Regulation in Other States

There are no widely accepted qualifications for the education and experience required to serve as surgical assistants. The health care professions whose members provide surgical assistant services have varying educational requirements. No state licenses all types of health professionals who perform the functions of surgical assistants. Furthermore, the certification programs developed by the various non-physician health professional groups whose members assist at surgery differ.

According to the Liaison Council on Certification for the Surgical Technologist, states employing the most certified first assistants are Texas, Florida, Ohio, Michigan, Indiana, Illinois, Tennessee, Kentucky, Colorado, and California. Regulation of surgical assistants currently exists in only three states: Illinois, Kentucky, and Texas. Of the three jurisdictions that regulate surgical assistants, one state has established a reimbursement and registration program for surgical assistants, one state instituted title protection, and one state has a licensing act.

The Texas State Board of Medical Examiners (Board) is the regulatory authority responsible for the licensure program of surgical assistants. The program establishes education, training, scope of practice, supervision, continuing education, and grounds for disciplinary action. Although there are qualifications for licensure, nothing in the rules and regulations is construed to require licensure as a surgical assistant for those individuals who are exempted from the regulation. The list of persons exempted is fairly inclusive and, in reality, creates a licensure program that is voluntary. Texas requirements for licensure are:

- Pass an independently evaluated examination approved by the Board;
- Hold at least an associate's degree from a two or four year institution of higher education;

[3] *Medicare: Payment Changes are Needed for Assistants-at-Surgery*. United States General Accounting Office, Report to Congressional Committees, January 2004, p. 22.

- Successfully complete an educational program in surgical assisting or a substantially equivalent educational program;
- Demonstrate to the Board the completion of full-time work experience in the U.S. under the direct supervision of a licensed physician consisting of at least 2,000 hours as a surgical assistant for the three years preceding the date of application; and
- Hold a current certification from a national certifying board approved by the Board.

Exemptions to licensure include:

- Students in surgical assistant education programs;
- Surgical assistants employed by the federal government;
- Persons acting under the delegated authority of a licensed physician;
- Licensed health care workers acting within the scope of their license;
- Registered nurses; and
- Licensed physician assistants.

The Illinois regulation of surgical assistants, which passed in 2003 and became effective on July 1, 2004, provides for reimbursement and title protection for surgical assistants. The purpose of the act is to set standards for qualification, education, training, and experience for those who voluntarily elect to hold the title of "registered surgical assistant." A "registered surgical assistant" is defined as a person who is certified by the National Surgical Assistant Association on the Certification of Surgical Assistants, the Liaison Council on Certification for the Surgical Technologist as a certified first assistant, or the American Board of Surgical Assisting; performs duties under direct supervision; and provides services only in a licensed hospital, ambulatory treatment center, or office of a licensed physician. The act does not prohibit persons otherwise licensed in Illinois from engaging in the practice for which they are licensed or require them to be registered as surgical assistants. These persons include, but are not limited to:

- Physicians, physician assistants, advanced practice registered nurses, or nurses performing surgery-related tasks within the scope of their licenses;
- Persons practicing as surgical assistants or surgical technologists as an employee of the U.S. government; and
- Persons assisting in surgery at an operating physician's discretion, including but not limited to medical students and residents.

Additionally, the law provides that hospitals, health systems or networks, ambulatory surgical treatment centers, and physician medical groups that provide surgery related services are not required to utilize registered surgical assistants.

The Kentucky Legislature passed a law requiring health insurance companies that provide coverage for surgical first assisting or intraoperative surgical care benefits or services to provide coverage for a certified surgical assistant who performs these services. The legislation also includes a list of tasks that certified surgical assistants may perform under the direction of the surgeon (positioning, preparing and draping the patient, observing the surgical site, retracting tissue and exposing the surgical field, assisting in incision closures, and wound dressings).

The Kentucky act defines "certified surgical assistant" as an unlicensed health care provider who is accountable to a physician or, in the physician's absence, to a registered nurse. It requires licensed health care facilities to: develop policies that establish the credentials, oversight, appointment, and reappointment of certified surgical assistants; and grant, renew, and revise surgical assistants' clinical privileges. Furthermore, the act provides that any health benefit plan providing coverage for surgical first assisting or intraoperative surgical care benefits or services shall be construed as providing coverage for a certified surgical assistant who performs those services.

Legislative Activity

In the past few years, several other states have introduced legislation regarding the regulation of surgical assistants, though none have resulted in subsequent laws. A summary of each is described below.

Arizona. The National Surgical Assistant Association (NSAA) proposed legislation in 2000 to regulate and certify all non-physician surgical assistants in the state of Arizona. The legislation aimed to create two scopes of practice: one for duties performed at the direction of a surgeon (positioning patients, prepping surgical sites) and another for duties performed under the direct supervision of a surgeon (retracting tissues and organs, maintaining hemostasis in a patient). The Arizona Nurses Association, the Arizona Physician Assistants Association, the Association of periOperative Registered Nurses, and the Arizona Medical Association opposed the legislation. The Arizona House of Representatives' Executive Committee voted against the proposed legislation.

Missouri. House Bill 1630, the "Registered Surgical Assistant and Registered Surgical Technologist Title Protection Act," was introduced into the Missouri House of Representatives in 2004. The bill defined a registered surgical assistant as a person who is not licensed to practice medicine and is certified by the National Surgical Assistants Association, the Liaison Council on Certification for the Surgical Technologist as a certified first assistant, or the American Board of Surgical Assistants. Furthermore, it provided exemptions for certain health care professionals acting within the scopes of their practice and established qualifications to be met prior to applying for registration.

Oklahoma. Senate Bill 734, the “Certified First Surgical Assistant Act,” was introduced in the Oklahoma State Legislature in 2003. The regulation of surgical assistants would have been created within the State Board of Medical Licensure and Supervision. The bill defined the scope of practice, outlined eligibility requirements, provided exemptions for certain health care professionals acting within the scopes of their practice, established qualifications, and provided authority for investigations and hearings.

Oregon. A bill to license surgical technologists and surgical assistants, Senate Bill 77, was introduced in the Oregon State Legislature in January 2003. The 2003 legislative session ended without passage of Senate Bill 77.

Virginia. A bill to certify surgical assistants was introduced in the Virginia General Assembly in 2001; however, the bill never made it out of the Committee on Health, Welfare, and Institutions. The bill defined certified surgical assistant, the scope of practice, and required that the Virginia Board of Medicine establish requirements for surgical assistant certification. This was a title protection bill, so only individuals with a certificate from the state to practice as a certified surgical assistant would have been able to use the title "certified surgical assistant."

Analysis and Recommendations

The sunrise criteria are very clear and specific regarding justification for the creation of a new regulatory program. The burden is upon the applicant to document through the application process that the occupation or profession being considered meets all three criteria.

Public Harm

The first sunrise criterion asks:

> Whether the unregulated practice of the occupation or profession clearly harms or endangers the health, safety or welfare of the public, and whether the potential for harm is easily recognizable and not remote or dependent on tenuous argument.

The Colorado Association of Surgical Assistants (Applicant) argues that surgical assistants work in a dangerous, high-stress environment, and often must deal with life or death patient emergencies. The role of surgical assistants is such that the duties they perform place the public at increased risk for harm during surgery if minimal education standards and responsibility are not ensured. However, the Applicant did not submit information demonstrating that harm to the public has occurred, or that the public was endangered by the threat of potential harm from the unregulated practice of surgical assistants. This sunrise review found no evidence of harm being caused to Colorado citizens by the unregulated practice of surgical assistants.

The report published by the U.S. General Accounting Office (GAO), entitled *Medicare: Payment Changes are Needed for Assistants-at-Surgery*, researched the quality of care provided by assistants-at-surgery. In February 2003, the authors of this report performed a literature search of the National Library of Medicine and found only six articles dealing with the quality of care provided by assistants-at-surgery. None of the six articles compared the quality of assistant-at-surgery services provided by one non-physician health profession group with that provided by another non-physician health profession group. Only one article actually dealt specifically with the influence of assistants on surgical outcomes.

The Department of Regulatory Agencies (DORA) investigated the types and numbers of complaints received by the Board of Nursing (BON), the Board of Medical Examiners (BME), and the Health Facilities Division of the Colorado Department of Public Health and Environment (CDPHE). A representative of the BON reported that there has only been one complaint in the past nine years concerning a licensee functioning as a surgical assistant. The program administrator within CDPHE responsible for the program that regulates ambulatory surgical centers reported that no surgical assistant has been found culpable in any investigation of death or any violation of generally accepted standard of care given to a patient. A representative of the BME stated there have been no complaints against physicians because of the actions of their surgical assistant. The only complaints

the BME has received have been against physician assistants performing the functions of surgical assistants and these complaints involve fee disputes. These fee disputes, which are outside the jurisdiction of the BME generally, involve a lack of communication between the patient and the hospital and/or physician regarding reimbursement to the physician assistant.

During the course of this review, some evidence was revealed pertaining to situations whereby consumers were directly billed for the services of surgical assistants. In all instances, the surgical assistants billed the patients for services performed because they were denied reimbursement from the health insurance company. These patients reported that they were never informed that there would be an extra charge, outside of the hospital and physician, for the particular surgery.

DORA contacted health insurance carriers to further understand the issue of reimbursement to surgical assistants. Insurance companies report that there is a list of permitted and non-permitted procedures whereby the use of a surgical assistant is warranted. If a surgeon elects to use a surgical assistant and the health insurance company has determined that this procedure is located on the non-permitted list, then the claim is denied. The permitted and non-permitted procedures are generally similar to those established by Medicare. There is an appeals process available to consumers that has been established by health insurance carriers.

During the 2004 legislative session, the Colorado General Assembly recognized that not all health care providers are cognizant of the terms of health insurance coverage for their patients. Therefore, the General Assembly determined that there was a need to disclose to consumers the scope of their health insurance coverage. House Bill 04-1177 determined that it is in the best interest of Colorado residents that health insurance carriers, health care providers, and health facilities provide timely notice concerning the incursion of additional charges not covered by their health benefit plans. Subsequently, during the summer of 2004, the State Insurance Commissioner, in collaboration with DORA's Division of Registrations, CDPHE, other state agencies, and interested parties convened public hearings to evaluate:

- Methods to improve disclosure to consumers of individual and group health insurance;
- When a person may be responsible for amounts in excess of the person's covered benefits from nonparticipating providers;
- What the carrier's responsibilities are for payment of health benefits covered under the person's health benefit plan; and
- The appropriate appeals process for insurers and health care providers to settle disputes.

On August 31, 2004, the Division of Insurance held a public hearing pursuant to House Bill 04-1177. Testimony was heard from consumers and from representatives from Colorado Association of Health Plans, Colorado Health & Hospital Association, Pediatrix Medical Group (neo-natologists), Colorado Society of Anesthesiologists, Colorado Association of Surgical Assistants, Colorado Chapter of American College of Emergency Physicians, and the Colorado Medical Society. Discussions included the issue of how payment should be made to providers who practice in a participating hospital but are not themselves under contract with a managed care plan. Present law (§ 10-16-704(3), C.R.S.), which was recently upheld in Colorado District Court, provides that any covered benefits provided in a network facility must be covered at the in-network benefit level. The in-network benefit to the consumer consists of co-payments or coinsurance only. Therefore, any balance billing must be handled by the insurer.

During this hearing, it was determined that a task force of interested parties would be formed and would convene before the second public hearing scheduled for October 5, 2004. At the hearing on October 5, reports were presented by the three subcommittees consisting of insurers, health care providers, hospitals, and consumers. Three areas of concern were identified for further discussion: notification, dispute resolution, and reasonable and customary charges for medical procedures. A third public hearing was scheduled for November 17, 2004 with the final report to be submitted to the General Assembly by February 5, 2005.

Need for Regulation

The second sunrise criterion asks:

> Whether the public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional or occupational competence.

Hospitals have very rigorous bylaws covering the credentialing of any allied health professional. Hospitals must meet the standards outlined in the bylaws because they are strictly enforced. If the hospital credentials someone who performs improperly while a surgeon is overseeing that individual, the surgeon's license is at stake. Surgical assistants function in a highly structured environment, even though the State of Colorado does not regulate them.

While some national physician and accreditation organizations say assistants-at-surgery should have to meet some requirements, there is no consensus about what those requirements should be. For example, the American College of Surgeons has stated that when surgeons or residents are unavailable to serve as assistants-at-surgery, a non-physician health professional should be allowed to perform the role if the practice privileges of such an individual is based upon verified credentials, reviewed and approved by the hospital credentialing committee, and within the defined limits of state law. Similarly, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), a private organization that accredits health care organizations, including hospitals, requires

hospitals to credential their staff (i.e., establish requirements such as licensure, certification and experience for physicians and certain non-physician health professionals) and ensure that those requirements are used when personnel decisions are made. However, JCAHO does not suggest the type or length of education or experience to be used in credentialing hospital staff who serve as assistants-at-surgery.

Many mechanisms are already in place to protect the public. During the sunrise process, DORA surveyed the major hospital systems in Colorado, independent urban and rural hospitals, and ambulatory surgical centers to determine their credentialing requirements for surgical assistants. As evidenced in the survey findings in Appendices A, B, and C beginning on page 22, anyone performing the functions of a surgical assistant is under the oversight of the medical staff and is generally required to be privately certified and have significant hours of experience.

Results of Regulation in Other States Do Not Support the Argument to Regulate in Colorado

When the number of states that regulate surgical assistants is reviewed, only three states have any type of regulation. The Applicant argues that surgical assistants in regulated states are held to higher standards of care than surgical assistants practicing in Colorado. However, DORA's review of these laws revealed that the lists of exemptions for registration or licensure in these states basically create voluntary programs. Thus, the experiences of other states do not indicate that Colorado would benefit from a regulatory program.

Alternatives to Regulation

The third sunrise criterion asks:

> Whether the public can be adequately protected by other means in a more cost-effective manner.

Cost-effective alternatives to regulation exist that protect the health, safety, and welfare of the public. As mentioned earlier in this report, Colorado statutes protect the public from incompetent or illegal medical practice and provide for physician oversight of delegated functions. Hospital systems and ambulatory surgical centers require credentialing, which generally includes education, certification, and experience for persons practicing as surgical assistants.

In addition to statutory remedies, the Liaison Council on Certification for the Surgical Technologist, the National Surgical Assistants Association, and the American Board of Surgical Assistants offer private credentialing and guidelines. The purpose of these certifications is to determine, by examination, that an individual has acquired both a theoretical and practical knowledge of surgical assisting. In addition, through the acquisition of continuing education credits or by re-examination, certified surgical assistants are required to stay current with changes in the medical field.

If regulation were to be imposed by the General Assembly, the cost of such regulation would be dependent upon a number of issues, such as:

- The establishment of a Board of Surgical Assistants or the amalgamation of surgical assistants within an existing board;
- The number of persons who function as surgical assistants in Colorado who would become licensed;
- The type of regulation imposed;
- The establishment of a new examination or usage of any or all of the three private credentialing examinations in existence;
- The requirements necessary to ensure initial or continuing competency; and
- Other matters to be considered by the Board such as processing complaints and rulemaking.

Conclusion

Given the data submitted and obtained during this review, and the fact that the unregulated practice of surgical assistants has not resulted in significant harm to Colorado consumers, this sunrise review contends that regulation is not necessary. The Applicant failed to submit compelling evidence of public harm that satisfies the burden of proving that regulation is necessary to protect the public health, safety, or welfare.

Although, as previously reported in this review, there are potential incidences of financial harm affecting Colorado consumers, the passage of House Bill 04-1177, partly in response to this problem, addressed this issue in public hearings held during the summer of 2004. These hearings addressed improved disclosure of information regarding a consumer's health insurance policy, the health insurance carrier's responsibilities for payment of health benefits, and the appropriate appeals process to settle disputes.

Regulating the surgical assistant functions that may be performed by so many different disciplines is very difficult. Many of these health care professionals already have mechanisms in place that require education, experience, and examination and also have processes that address standard of care issues.

Licensing inadvertently creates or fosters professional monopolies because licensing has traditionally defined who can or cannot provide certain services and perform certain functions. This produces a system that fails to recognize overlapping skills and competencies.

Recommendation – The General Assembly should not regulate the practice of surgical assistants.

Appendix A – Review of Requirements for Surgical Assistants in Front Range Colorado Major Hospital Systems

KEY

AST	Association of Surgical Technologists
BON	Colorado State Board of Nursing
CAAHEP	Commission on Accreditation of Allied Health Education Programs
CAHEA	Committee on Allied Health Education and Accreditation
CBPN	Certification Board of periOperative Nursing
CNOR	Certified Nurse Operating Room
CRNFA	Certified Registered Nurse First Assistant
CST/CFA	Certified Surgical Technologist/Certified First Assistant
LCC ST	Liaison Council on Certification for the Surgical Technologist
LRN	Licensed Registered Nurse
NLN	National League of Nursing
NSAA	National Surgical Assistants Association

Hospital System	Scope of Practice	Supervision	Education/Training	Certification Includes the Following	Experience
HealthONE	Preparing supplies Scrubbing/gowning/gloving Creating sterile field Draping Wound dressing Handling of specimens Handling of instruments Handling of equipment	Under personal and responsible direction and supervision of a licensed surgeon on staff	Graduation from school of surgical technology approved by CAAHEP and Certified by the NSAA or Graduation from a school of registered nursing approved by the BON and CNOR certification and completion of a First Assistant Program approved by CBPN or Qualified to practice medicine but is not qualified to be licensed to practice in Colorado	Current basic life support Current CST/CFA certification or Licensed as a registered nurse and current CNOR certification as well as certification as a CRNFA or certified first assistant	Verification of previous employment and three (3) professional references
Centura Health Hospitals	Preparing supplies Scrubbing/gowning/gloving Creating sterile field Draping Wound dressing Handling of specimens Handling of instruments Handling of equipment	Medical staff members supervise surgical assistants whether hired by hospital or independently contracted	Licensed as a physician assistant in the state of Colorado or certified surgical technologist and/or certified by LCC-ST or successfully completed an acceptable surgical assistant program or LRN with not less than three (3) years experience or CRNFA or CNOR certification or academically trained surgical assistant with not less than three (3) years experience	See Education/Training column	Functioned as a surgical assistant within the previous three (3) years, or have appropriate supervision for first six (6) cases

Hospital System	Scope of Practice	Supervision	Education/Training	Certification Includes the Following	Experience
Exempla Healthcare	Applying, adjusting, modifying, or removing splints, casts, or braces Performing dressing changes May not perform any task delegated by the supervising physician that is not authorized by medical staff bylaws, and rules	Physician must physically remain in the operating room suites while the surgical assistant is performing the delegated tasks Physician is responsible for the integrity of the surgical assistant's credentials and patient care quality	Completion of a surgical technologist program accredited by AST or Completion of a nursing program accredited by the NLN or Completion of a physician assistant program accredited by CAHEA or Completion of a foreign or domestic medical school program	See Education/Training column	Minimum requirements include three (3) months of didactic instruction or clinical preceptorship in an accredited education setting and six (6) months experience as a surgical assistant
Denver Health Medical Center	Draping Wound dressing Urinary catheter placement Patient positioning Scrubbing/gowning/gloving Assisting with CPR Preparing ACL graft Handling of specimens Handling of instruments Handling of equipment Assisting in retracting tissues	Licensed physician	Physician assistant training with first assistant training as part of the educational program	None	Physician assistant training with first assistant training as part of the experiential program
University of Colorado Health Sciences Center (UCHSC)	UCHSC utilizes several different types of professionals who assist during surgery and the scope of practice varies depending on the profession	Direct supervision by the surgeon during surgery	Varies depending on the profession	Personnel are not specifically certified as first assistants but rather are licensed in their professions	N/A

Appendix B - Survey of Colorado Rural and Independent Hospitals' Use of Surgical Assistants

The American College of Surgeons defines a surgical assistant as "one who provides aid in exposure, hemostasis, closure, and other intraoperative technical functions that help the surgeon carry out a safe operation with optimal results." Surgical assistants are also called "assistants-at-surgery" or "first assistants."

1. Please choose the option that best describes your geographic location:
Rural **6 (63%)** Urban **4 (37%)**

2. Is your facility Medicare certified? Yes **10 (100%)** No **0**

3. Who retains the services of the surgical assistants? Please check all that apply.
Physicians **6 (75%)** Facility **6 (50%)** Other_____

Has a surgical assistant ever been utilized at your facility? **Yes 15 (94%) No 1 (6%)** If you responded "yes," please proceed with the survey and submit in the envelope provided. If you responded "no," please stop, and submit the survey in the envelope provided.

If the answer to Question #3 is the "facility," what percentage is employees and what percentage is independent contractors?

4 facilities responded 100% employees
2 facilities responded 100% contractors
1 facility responded 50% employees - 50% contractors
1 facility responded 20% employees - 80% contractors
2 facilities responded 10% employees - 90% contractors

4. Please indicate which health professionals assist at surgery (performing as surgical assistants) in your facility. Check all that apply:

10 (67%) Licensed Physician
10 (67%) Registered Nurse
11 (73%) Certified Registered Nurse First Assistant
0 Licensed Practical Nurse
3 (20%) Nurse Practitioner
13 (87%) Physician Assistant
9 (60%) Certified Surgical Assistant
2 (13%) Non-certified Surgical Assistant
6 (40%) Surgical Technologist
1 (7%) International Medical Graduate
Other (please specify): **3rd year medical student, Certified Nurse Midwife,**

5. Is your facility accredited by either of the following organizations? Check all that apply.

14 (93%) Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
0 Healthcare Facilities Accreditation Program (HFAP)
If your facility is accredited by another entity, please specify: **American Osteopathic Association, American College of Trauma Surgeons**

6. What requirements/credentialing have been established in your facility to perform the functions of a surgical assistant? Please respond to questions a-e below.

a. Scope of Practice In which activities may surgical assistants engage? (Please check all that apply):

8 (53%) Prepare supplies
12 (80%) Creating sterile field
15 (100%) Draping
15 (100%) Wound dressing
10 (67%) Urinary catheter placement
15 (100%) Patient positioning
14 (93%) Scrubbing/gowning/gloving
10 (67%) Assists with CPR
12 (80%) Wound closure
9 (60%) Prepare ACL graft as directed by physician
14 (93%) Handling of specimens
14 (93%) Handling of instruments
14 (93%) Handling of equipment
12 (80%) Assist in placement and suturing of surgical drains
14 (93%) Assists in maintaining hemostasis
12 (80%) Use of eletrocautery mono and bipolar
15 (100%) Assist in retracting tissues per surgeon's directive
Other (please specify): **Vein graft harvesting**

b. Supervision Who supervises the surgical assistant? Please check all that apply.

15 (100%) Licensed physician
_____ Licensed practical nurse
____Other (please specify)_____
4 (27%) Registered nurse
_____Nurse practitioner

c. Education/Training What are the education/training requirements for surgical assistants?

Summary of responses

- **Physician assistant with specific training as a first assistant**
- **Certified first assistant by examination**
- **120 assisting hours and 10 proctored cases**
- **Advanced training as a certified first assistant or certified registered nurse first assistant**
- **All surgical assistants are certified**

d. Experience What experience is required for surgical assistants?

Summary of responses

- **Minimum of one year of full time experience as a first assistant in an acute care general hospital**
- **Past certified surgical technologist experience or military training and credentialing**
- **50 cases per year**
- **At least 5 years as a scrub, circulator or both**
- **Operating room experience**

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e. Private Certification Does your facility require private certification for surgical assistants?

Yes **4 (27%)** No **10 (67%)**

If the response is yes, please check all that are accepted.

3 (20%) Liaison Council on Certification for the Surgical Technologist and First Assistants (LCC-ST)
4 (27%) National Surgical Assistants Association (NSAA)
3 (20%) American Board of Surgical Assistants (ABSA)
____Other(please specify)_____

7. Does your facility assist the surgical assistants in third-party reimbursement efforts?

Yes **0** No **11 (73%)**

8. Do you believe that there is a need for the regulation of surgical assistants? Yes **7 (47%)** No **5 (33%)**

Please explain:

Summary of Explanations Given for the "Yes" Response for Regulation of Surgical Assistants

- **There is such diversity in training and certification of surgical assistants that it needs to be standardized. Most surgical assistants are employed by the physician and therefore credentialed on their sponsorship.**
- **It would help ensure competency and provide disciplinary support similar to that for physicians.**

Summary of Explanations Given for the "No" Response for Regulation of Surgical Assistants

- **Perhaps this is necessary if a facility does not have systems in place to govern this practice. The practice in our institution is that if anyone is performing surgery or assisting the surgeon in a first assistant role, they are required to be credentialed through our Medical Staff Office. This Office ensures that the individual has the appropriate certification. Additionally, there is an oversight surgeon.**
- **In a small rural county it is prohibitive to hire "assistants" only. The physician chooses the type of assistants that he/she needs.**
- **The protection of the public exists through hiring, credentialing and quality review and performance evaluations that are already in place. The additional layer of state bureaucracy is wholly unnecessary.**

Appendix C - Survey of Ambulatory Surgical Centers' Use of Surgical Assistants

The American College of Surgeons defines a surgical assistant as "one who provides aid in exposure, hemostasis, closure, and other intraoperative technical functions that help the surgeon carry out a safe operation with optimal results." Surgical assistants are also called "assistants-at-surgery" or "first assistants."

1. Please choose the option that best describes your facility:
Free Standing **27 (52%)** Affiliated with a Clinic **3 (6%)** Joint Venture **10 (19%)**
Affiliated with a Hospital **0** Physician Owned **20 (38%)** Hospital Owned **2 (4%)**
Affiliated with a Physician Office **5 (10%)**

2. Is your facility a member of the Federal Ambulatory Surgery Association? Yes **27 (52%)** No **23 (44%)**

3. Is your facility Medicare certified? Yes **47 (90%)** No **4 (8%)**

4. How many years has your facility been in operation? **Average of 7 years (years in operation ranged from 4 months to 20 years.)**

Has a surgical assistant ever been utilized at your facility? **Yes 37 (71%) No 15 (29%)** If you responded "yes," please proceed with the survey and submit in the envelope provided. If you responded "no," please stop, and submit the survey in the envelope provided.

5. Who retains the services of the surgical assistants? Please check all that apply.
Physicians **28 (76%)** Facility **18 (49%)**
Other_____

If the answer to Question #5 is the "facility," what percentage is employees and what percentage is independent contractors?

11 facilities responded 100% employees
2 facilities responded 10% employees - 90% contractors
1 facility responded 80% employees - 20% contractors
1 facility responded 75% employees - 25% contractors
1 facility responded 70% employees - 30% contractors
1 facility responded 100% contractors

6.Please indicate which health professionals assist at surgery (performing as surgical assistants) in your facility. Check all that apply:

19 (51%) Licensed Physician
26 (70%) Registered Nurse
13 (35%) Certified Registered Nurse First Assistant
5 (14%) Licensed Practical Nurse
2 (5%) Nurse Practitioner
20 (54%) Physician Assistant
24 (65%) Certified Surgical Assistant
14 (38%) Non-certified Surgical Assistant
13 (35%) Surgical Technologist
2 (5%) International Medical Graduate
Other (please specify **Medical students, certified medical assistants**

7. Is your facility accredited by any of the following organizations? Please check all that apply.

9 (24) Joint Commission on Accreditation of Healthcare Organizations (JCAHO)
12 (32%) Accreditation Association for Ambulatory Healthcare (AAAHC)
0 American Association for Accreditation of Ambulatory Plastic Surgery Facilities (AAAAPSF)
0 Healthcare Facilities Accreditation Program (HFAP)

8. What requirements/credentialing have been established in your facility to perform the functions of a surgical assistant? Please respond to questions a-e below.

a. Scope of Practice In which activities may surgical assistants engage? (Please check all that apply):

25 (68%) Prepare supplies
33 (89%) Creating sterile field
34 (92%) Draping
27 (73%) Wound dressing
23 (62%) Wound Closure
9 (24%) Urinary catheter placement
28 (76%) Patient positioning
35 (95%) Scrubbing/gowning/gloving
17 (46%) Assists with CPR
14 (46%) Prepare ACL graft as directed by physician
27 (73%) Handling of specimens
31 (84%) Handling of instruments
29 (78%) Handling of equipment
31 (84%) Assist in retracting tissues per surgeon's directive
21 (57%) Assist in placement and suturing of surgical drains
28 (76%) Assists in maintaining hemostasis
18 (49%) Use of eletrocautery mono and bipolar

Other (please specify) **Administration of local anesthetics; tourniquet application; intra-articular injections**

b. Supervision Who supervises the surgical assistant? Please check all that apply.

34 (92%) Licensed Physician
0 Licensed practical nurse
12 (32%) Registered nurse
0 Nurse practitioner
____Other (please specify)_____

c. Education/Training What are the education/training requirements for surgical assistants?

Summary of responses

- **Basic background in surgical procedures**
- **RN or LPN and past operating room experience**
- **Completed a certified course as a surgical assistant**
- **Successful completion of surgical technologist education**
- **Demonstration of skills**
- **State licensure for physician assistants and registered nurses; certification for surgical techs**
- **Needs to be appropriate to the specialty of surgery**
- **High school diploma**
- **Certified surgical assistant, at a minimum**
- **Successful completion of externship**
- **Completion of school approved by Commission on Accreditation of Allied Health Programs and completion of first assistant program offered by LCC-ST or certification by NSAA.**

d. Experience What experience is required for surgical assistants?

Summary of responses

- **Knowledge specifically in eye surgery assistance**
- **Needs to be appropriate to the specialty of surgery**
- **1-2 years direct experience**
- **We are willing to train though some experience is preferable**
- **Several years of clinical experience**
- **350 cases within the past 4 years**

- **Require letters of recommendations from supervising physicians**

e. Private Certification Does your facility require private certification for surgical assistants?
Yes **9 (24%)** No **25 (68%)**
If the response is yes, please check all that are accepted.
7 (19%) Liaison Council on Certification for the Surgical Technologist and First Assistants (LCC-ST)
8 (22%) National Surgical Assistants Association (NSAA)
6 (16%) American Board of Surgical Assistants (ABSA)
Other(please specify) **certified registered nurse first assistant; Association of Surgical Technologists**

9. Does your facility require continuing education or annual assessment for surgical assistants?
Yes **15 (41%)** No **17 (46%)**

10. Does the facility assist the surgical assistants in third-party reimbursement efforts?
Yes **3 (8%)** No **30 (81%)**

11. Do you believe that there is a need for the regulation of surgical assistants?
Yes **22 (59%)** No **13 (35%)**

Please explain

Summary of Explanations Given for the "Yes" Response for Regulation of Surgical Assistants

- **Surgical assistants should be regulated so that their practice is based on a formal performance function and not according to the physician's requirements.**
- **Patient safety being of primary concern; regulation is one component of assuring safe, competent delivery of care. Regulation lends itself to accountability and would provide a means of monitoring and tracking the surgical assistant.**
- **Problems arise when physicians or administrators fail to provide adequate training and scope of service.**
- **While the surgeon takes responsibility for surgical assistant's action, the wide variety of training and experience that support someone calling themselves a surgical assistant make it difficult to assure skill in the operating room.**
- **As with all quality of patient care, there needs to be efforts taken to make professionals competent practitioners. Regulation of the scope of practice of professionals helps to assure that quality of patient care is being delivered and also gives credit and notoriety to professionals.**
- **Some surgeons want to bring in totally untrained people from their offices to assist in surgery.**

Summary of Explanations Given for the "No" Response for Regulation of Surgical Assistants

- **In eye surgery they have very little involvement with the actual procedure.**
- **The scope of practice for surgical assistants will vary among specialties.**
- **They are currently only allowed to work under the direct supervision of a licensed physician.**
- **Regulatory oversight by other agencies (in our case JCAHO) ensures our organization's compliance with rules, regulations, and safety standards. Another layer of regulation is not needed.**
- **They are under the supervision of physicians who are ultimately responsible for any part of the procedure.**
- **Facilities may set their minimum standards of conduct and enforce as well as the surgeon accepting responsibility for allied health privileges.**
- **It is the responsibility of the facility to assure competence of the assistants that they hire.**