Department of Regulatory Agencies

Office of Policy, Research and Regulatory Reform

2010 Sunrise Review: Surgical Technologists

January 25, 2010

Consumer Protection

Dora
Department of Regulatory Agencies

Executive Director's Office
Barbara J. Kelley
Executive Director

Bill Ritter, Jr.
Governor

January 25, 2010

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 mission of the Department of Regulatory Agencies (DORA) is consumer protection. As a part of the Executive Director's Office within DORA, the Office of Policy, Research and Regulatory Reform seeks to fulfill its statutorily mandated responsibility to conduct sunrise reviews with a focus on protecting the health, safety and welfare of all Coloradans.

DORA has completed its evaluation of the sunrise application for regulation of surgical technologists 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 DORA 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 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,

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Executive Director

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Consumer Protection

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Background

Consistent, flexible, and fair regulatory oversight assures consumers, professionals and businesses an equitable playing field. All Coloradans share a long-term, common interest in a fair marketplace where consumers are protected. Regulation, if done appropriately, should protect consumers. If consumers are not better protected and competition is hindered, then regulation may not be the answer.

As regulatory programs relate to individual professionals, such programs typically entail the establishment of minimum standards for initial entry and continued participation in a given profession or occupation. This serves to protect the public from incompetent practitioners. Similarly, such programs provide a vehicle for limiting or removing from practice those practitioners deemed to have harmed the public.

From a practitioner perspective, regulation can lead to increased prestige and higher income. Accordingly, regulatory programs are often championed by those who will be the subject of regulation.

On the other hand, by erecting barriers to entry into a given profession or occupation, even when justified, regulation can serve to restrict the supply of practitioners. This not only limits consumer choice, but can also lead to an increase in the cost of services.

There are also several levels of regulation.

Licensure

Licensure is the most restrictive form of regulation, yet it provides the greatest level of public protection. Licensing programs typically involve the completion of a prescribed educational program (usually college level or higher) and the passage of an examination that is designed to measure a minimal level of competency. These types of programs usually entail title protection – only those individuals who are properly licensed may use a particular title(s) – and practice exclusivity – only those individuals who are properly licensed may engage in the particular practice. While these requirements can be viewed as barriers to entry, they also afford the highest level of consumer protection in that they ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Certification

Certification programs offer a level of consumer protection similar to licensing programs, but the barriers to entry are generally lower. The required educational program may be more vocational in nature, but the required examination should still measure a minimal level of competency. Additionally, certification programs typically involve a non-governmental entity that establishes the training requirements and owns and administers the examination. State certification is made conditional upon the individual practitioner obtaining and maintaining the relevant private credential. These types of programs also usually entail title protection and practice exclusivity.

While the aforementioned requirements can still be viewed as barriers to entry, they afford a level of consumer protection that is lower than a licensing program. They ensure that only those who are deemed competent may practice and the public is alerted to those who may practice by the title(s) used.

Registration

Registration programs can serve to protect the public with minimal barriers to entry. A typical registration program involves an individual satisfying certain prescribed requirements – typically non-practice related items, such as insurance or the use of a disclosure form – and the state, in turn, placing that individual on the pertinent registry. These types of programs can entail title protection and practice exclusivity. Since the barriers to entry in registration programs are relatively low, registration programs are generally best suited to those professions and occupations where the risk of public harm is relatively low, but nevertheless present. In short, registration programs serve to notify the state of which individuals are engaging in the relevant practice and to notify the public of those who may practice by the title(s) used.

Title Protection

Finally, title protection programs represent one of the lowest levels of regulation. Only those who satisfy certain prescribed requirements may use the relevant prescribed title(s). Practitioners need not register or otherwise notify the state that they are engaging in the relevant practice, and practice exclusivity does not attach. In other words, anyone may engage in the particular practice, but only those who satisfy the prescribed requirements may use the enumerated title(s). This serves to indirectly ensure a minimal level of competency – depending upon the prescribed preconditions for use of the protected title(s) – and the public is alerted to the qualifications of those who may use the particular title(s).

Licensing, certification and registration programs also typically involve some kind of mechanism for removing individuals from practice when such individuals engage in enumerated proscribed activities. This is generally not the case with title protection programs.

Regulation of Businesses

Regulatory programs involving businesses are typically in place to enhance public safety, as with a salon or pharmacy. These programs also help to ensure financial solvency and reliability of continued service for consumers, such as with a public utility, a bank or an insurance company.

Activities can involve auditing of certain capital, bookkeeping and other recordkeeping requirements, such as filing quarterly financial statements with the regulator. Other programs may require onsite examinations of financial records, safety features or service records.

Although these programs are intended to enhance public protection and reliability of service for consumers, costs of compliance are a factor. These administrative costs, if too burdensome, may be passed on to consumers.

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:[1]

> (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.

Methodology

DORA has completed its evaluation of the proposal for regulation of surgical technologists. During the sunrise review process, DORA performed a literature search, contacted and interviewed the applicant, reviewed laws in other states, and interviewed representatives of local and national professional and industry associations. In order to determine the number and types of complaints filed against surgical technologists in Colorado, DORA contacted representatives of the Colorado Department of Public Health and Environment's Health Facilities and Emergency Medical Services Division and The Joint Commission.

[1] § 24-34-104.1(4)(b), C.R.S.

Profile of the Profession

According to the U.S. Bureau of Labor Statistics, surgical technologists (ST), also known as surgical technicians and surgical techs, are members of operating room teams, along with surgeons, anesthesiologists, and circulating nurses, who perform several functions in and around the operating room. STs assist in surgical operations under the supervision of the surgeons, registered nurses, or other licensed personnel. A circulating ST is the "unsterile" member of the surgical team who may:

- Interview the patient before surgery;
- Prepare the patient;
- Help with anesthesia;
- Obtain and open packages for the "sterile" members of the surgical team to remove the sterile contents during the procedure; and
- Keep a written account of the surgical procedure.

Prior to an operation, STs may help prepare the operating room by setting up surgical instruments and equipment, sterile drapes, and sterile solutions. They may assemble surgical equipment and check it to ensure proper functioning. STs may get patients ready for surgery by washing, shaving, and disinfecting incision sites; transporting them to the operating room; helping to position them on the operating table; and covering them with sterile surgical drapes. Also, they may check charts and help the surgical team put on sterile gowns and gloves.

During surgery, STs may observe patients' vital signs or pass instruments and other sterile supplies to surgeons and surgical assistants. They may hold retractors, cut sutures, and help count sponges, needles, supplies, and instruments.

STs may help prepare, care for, and dispose of specimens taken for laboratory analysis and help apply dressings. Some operate sterilizers, lights, or suction machines, and help operate diagnostic equipment.

After an operation, STs may help transfer patients to the recovery room and clean and restock the operating room.

STs with specialized education or training also may act in the role of the surgical first assistant or circulator. The surgical first assistant, as defined by the American College of Surgeons (ACS), provides aid in exposure, homeostasis (controlling blood flow and stopping or preventing hemorrhage), and other technical functions under the surgeon's direction that help the surgeon carry out a safe operation.[2]

[2] Bureau of Labor Statistics, U.S. Department of Labor. *Occupational Outlook Handbook*. Retrieved December 16, 2009 from http://www.bls.gov/oco/ocos106.htm

In short, the functions performed by an ST are dictated, in large part, by the training and experience of the individual ST, the policies of the facility employing that ST, and the functions delegated to the ST by the licensed personnel in the operating room.

Education and Certification

While only five states require ST training, there are programs, typically in a community or junior college-like setting, for those who desire formal training. Colorado is home to five educational programs that are accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and another program accredited by the Accrediting Commission of Career Schools and Colleges (ACCSC).

Of the five CAAHEP-accredited programs, one is at a public institution, Aims Community College, and four are at private institutions, Everest College, ConCorde Career College, and Colorado Technical University, which has a program at both its Pueblo and Denver campuses. The Department of Regulatory Agencies (DORA) staff repeatedly contacted the ACCSC-accredited program at Anthem College in Aurora, but DORA was unable to obtain information about its program.

The CAAHEP-accredited programs are associate degree programs with very similar curricula. To graduate, students must successfully complete both general education and major-specific classes. The requirements common to all of the programs are classes in surgical technology, anatomy and physiology, medical terminology, surgical technique, pharmacology, and infection control, and completion of an internship.

The cost of an ST education in Colorado varies from $5,212, for an in-district student at Aims Community College, to an average of approximately $32,000 at the other four schools for which DORA was able to obtain information.

After completing the entire course of study, a student becomes eligible to take the certification examination offered by the National Board of Surgical Technology and Surgical Assisting (NBSTSA), though there are other certifying organizations.

The NBSTSA certification examination costs $290 for first time takers and $499 for those renewing a certification by examination.

An NBSTSA certificate is valid for four years and can be renewed by either retaking the examination or acquiring 60 continuing education credits. In addition to graduates of CAAHEP-accredited schools, ST graduates of Accrediting Bureau of Health Education Schools (ABHES) are eligible for the NBSTSA certification examination. [3] However, there are no ABHES-accredited schools in Colorado.

[3] National Board of Surgical Technology and Surgical Assisting. *Eligibility and Fees*. Retrieved December 22, 2009 from http://www.nbstsa.org/certifyingexam/eligibility.html

The National Center for Competency Testing (NCCT) also certifies STs and allows an individual to sit for its certifying examination without fulfilling an educational requirement, although the NCCT certification is also accessible to applicants who completed an approved program and have requisite experience. For those who choose the non-educational route, NCCT allows an ST with at least seven years validated surgical experience within the 10 years prior to the examination, to test.[4]

The NCCT certification test ranges from $90 to $195, depending on the pre-examination qualifications of the applicant.

To maintain an NCCT certification, an ST must complete a minimum of 14 clock hours of approved continuing education.[5]

Based on data supplied by the Association of Surgical Technologists (AST), 50 percent of all STs nationwide are certified; in Colorado, 604 of 1,530 employed STs (39 percent) are certified in some manner.

[4] National Center for Competency Testing. *Tech in Surgery*. Retrieved December 28, 2009 from http://www.ncctinc.com/documents/TS-C(NCCT).pdf
[5] National Center for Competency Testing, *Certification…Step by Step*.

Proposal for Regulation

Family Voices of Colorado (Applicant) 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. The application identifies either licensure or certification for surgical technologists (STs) as the appropriate level of regulation to protect the public.

The Applicant claims that because surgery is inherently dangerous and the risk of physical harm or death due to intra-operative mistakes is so high, only properly educated and examined individuals should be allowed to practice.

The Applicant acknowledges that many STs have been practicing successfully in Colorado for many years, but asserts the need exists to create standardization for the occupation. It also maintains that the general public does not the have the opportunity to evaluate ST qualifications and must depend on varying standards set by employers.

Additionally, the Applicant states that the state cannot prevent an individual ST from practicing after the ST has proven to be "erroneous, incompetent, unqualified, or guilty of negligent error." However, no data to support any claims of malpractice in this mode is presented with the application.

The Applicant lists eight competencies that STs should proficiently demonstrate:

- Knowledge and practice of basic concepts;
- The application of the principles of asepsis in a knowledgeable manner that provides for optimal patient care in the operating room;
- Basic surgical case preparation skills;
- The ability to perform the role of first scrub on all basic surgical cases;
- Responsible behavior as a health care professional;
- The ability to recognize basic instrument sets (major, minor, and plastic);
- The ability to position patients with confidence and ease; and
- The ability to function effectively as a member of a surgical team.

The Applicant states, "the National Board of Surgical Technology and Surgical Assisting (NBSTSA) is solely responsible for all decisions regarding certification – from determining eligibility to maintaining, denying, granting and reviewing the designation." However, the Applicant offers no suggestion as to how the certification should apply to Colorado state regulation or any grounds for revocation of a license or certificate should a regulatory program be implemented.

Summary of Current Regulation

The Colorado Regulatory Environment

Although surgical technologists (STs) are not regulated in Colorado, most of the employers for which they work are regulated. All hospitals and ambulatory surgical centers are licensed by the Colorado Department of Public Health and Environment (CDPHE).[6]

CDPHE, through the State Board of Health, has promulgated rules that require hospitals to have policies that identify the scope of the services to be provided by various personnel, the lines of authority and accountability, and the qualifications of the personnel performing those services.[7]

Similarly, ambulatory surgical centers must maintain written job descriptions for all personnel, including each position's title, authority, specific responsibilities and minimum qualifications.[8]

In short, then, it is incumbent upon the facility employing STs to ensure that the people it employs as such are qualified and perform within certain, predetermined parameters.

Additionally, licensed facilities are routinely surveyed for compliance with a variety of laws, and as part of that survey process, personnel files are reviewed to ensure that the particular facility is complying with its own policies.

For facilities that are accredited by The Joint Commission,[9] these surveys are conducted every three years by The Joint Commission.

For facilities that are not so accredited, CDPHE surveys hospitals at least every five years and ambulatory surgical centers at least every three years.

Finally, all licensed facilities are required to report certain occurrences to CDPHE promptly:[10]

- Abuse, physical;
- Abuse, sexual;
- Abuse, verbal;
- Brain injuries;

[6] § 25-3-101(1), C.R.S.
[7] Health Facilities and Emergency Medical Services Division Standards for Hospitals and Health Facilities, Chapter IV, Rule 7.101(1).
[8] Health Facilities and Emergency Medical Services Division Standards for Hospitals and Health Facilities, Chapter XX, Rule VI(C).
[9] The Joint Commission is an independent, not-for-profit organization that accredits healthcare organizations. It seeks to improve healthcare delivery and emphasizes the provision of safe and effective care.
[10] *Occurrence Reporting Manual*, Health Facilities and Emergency Medical Services Division (November 2009).

- Burns and burn charts;
- Death;
- Diverted drugs;
- Life-threatening complications of anesthesia;
- Life-threatening transfusion errors or reactions;
- Malfunction or misuse of equipment;
- Misappropriations of resident/patient property;
- Missing persons;
- Neglect; and
- Spinal cord injuries.

Regulation in Other States

As of December 2009, at least six states regulated STs: Indiana, Illinois, South Carolina, Tennessee, Texas, and Washington. According to information provided to the Department of Regulatory Agencies (DORA) by the Association of Surgical Technologists (AST), legislation is pending in seven other states.

Of the states that regulate, Washington has the least rigorous parameters. An ST, defined as,

> …a person, regardless of title, who is supervised in the surgical setting under the delegation of authority of a health care practitioner acting within the scope of his or her license and under the laws of this state(,)[11]

must register with the Department of Health. Once an ST has registered, he or she is granted title protection.[12] In other words, no one may refer to him- or herself as an ST without being registered. It is the responsibility of the ST to register, not an employer to verify a registration. If a person fails to register, he or she violates the statute. Registrant discipline is administered under the state's Uniform Disciplinary Act.[13] This statute regulates healthcare professionals and enables regulators to discipline a registrant for, among other things, unprofessional conduct,[14] thus indicating the existence of professional standards.

[11] Washington Rev. Code § 18.215.010 (3).
[12] Illinois and Indiana also confer title protection to certified surgical technicians.
[13] Washington Rev. Code § 18.130.
[14] Washington Rev. Code § 18.130.080.

The remaining regulating states have similar regulatory guidelines to one another. Indiana, South Carolina, Texas, and Tennessee have, in effect, adopted the same statutory definition for the ST occupation. The following statute comes from Tennessee Code section 68-57-105 and delineates who is an ST and scope of practice:

> For the purposes of this chapter, "surgical technologist" means one who works under supervision to facilitate the safe and effective conduct of invasive surgical procedures. This individual is usually employed by a hospital, medical office, or surgical center and supervised during the surgical procedure according to institutional policy and procedure to assist in providing a safe operating room environment that maximizes patient safety by performing certain tasks, including, but not limited to:
>
> (1) Preparation of the operating room and the sterile field for surgical procedures by preparing sterile supplies, instruments, and equipment using sterile technique;
> (2) Preparation of the operating room for surgical procedures by ensuring that surgical equipment is functioning properly and safely; and
> (3) Passing instruments, equipment or supplies to a surgeon, sponging or suctioning an operative site, preparing and cutting suture material, holding retractors, transferring but not administering fluids or drugs, assisting in counting sponges, needles, supplies, and instruments, and performing other similar tasks as directed during a surgical procedure.

These states, plus Illinois, require all STs to be certified by the National Board of Surgical Technology and Surgical Assisting (NBSTSA).[15] Though maintaining a NBSTSA certificate requires that an ST complete 60 hours of continuing education every four years, the Indiana and South Carolina laws specifically mandate 15 hours of continuing education annually. In addition to certification, Illinois' law necessitates ST registration. Considering all six of the regulating states, three hold the individual responsible for statutory compliance: Indiana, Illinois, and Washington, and three hold the employing facility responsible for statutory compliance: South Carolina, Tennessee, and Texas.

There are two types of general exemptions in the ST laws. Indiana, South Carolina, and Texas allow a facility to employ non-certified STs but only if there are not enough certified STs to meet the facility's demand. All of the states that require certification, except Illinois, exempt STs from the certification requirement for those individuals employed as STs prior to enactment of the state's ST law. Texas also has a specific exemption for people whose main function is sterilization of surgical supplies, instruments, equipment, or operating rooms.[16]

[15] Texas also allows certification by the National Center for Competency Testing or other certification program approved by the Department of State Health Services. Source: Texas Surgical Technology Law § 259.002.(a)(1).
[16] Texas Surgical Technology Law § 259.005.(2).

Analysis and Recommendations

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.

In other words, has the lack of regulation resulted in harm to the public? Given that surgical technologists (STs) work in the healthcare arena and come into physical contact with patients, harm can legitimately be considered to be physical harm.

In order to determine if the public is being harmed by the lack of regulation of STs, staff of the Department of Regulatory Agencies (DORA) asks all sunrise applicants, including Family Voices of Colorado (Applicant) to submit specific examples of harm.

The Applicant submitted a single example of harm involving an ST. In this well-known case, an ST had previously worked in hospitals in New York, where she was discharged for poor performance due to having a bad attitude, problems labeling specimens and problems keeping track of instruments,[17] and in Texas.

She began working at a Denver area hospital in October 2008. At some time prior to her start date, the ST was given a drug test and a physical evaluation. The drug test came back clean, but there were some indications that the ST suffered from Hepatitis C.[18] It was suggested she seek medical attention for the Hepatitis C, but such status did not disqualify her from employment. It appears that the ST did not seek the suggested medical treatment and it is unclear whether she in fact knew she had Hepatitis C.

Part of this ST's job involved retrieving Fentanyl, a highly addictive pain medication, and delivering it to the operating room. Over the next several months, this ST diverted Fentanyl by removing some of the drug from its vials with needles she had previously used to inject herself with previously diverted drugs, and replacing the diverted Fentanyl with a saline solution.[19]

[17] Greg Griffin and Michael Booth, "Rose surgery tech previously fired in N.Y.," *The Denver Post*, July 17, 2009. Retrieved on July 17, 2009, from www.denverpost.com/ci_12856817

[18] Hepatitis C is a viral infection of the liver. In time, it can lead to permanent liver damage as well as cirrhosis, liver cancer and liver failure. It is spread by contact with an infected person's blood. Source: WebMD. *Hepatitis C Guide.* Downloaded on December 28, 2009, from www.webmd.com/hepatitis/hepc-guide/hepatitis-c-topic-overview

[19] Michael Booth and Allison Sherry, "Hospital, officials look to fix lapses," *The Denver Post*, July 16, 2009. Retrieved on July 16, 2009, from www.denverpost.com/ci_12847488

By April 2009, the ST's employer became aware of the drug diversion and terminated her employment. The employing hospital informed the Colorado Department of Public Health and Environment (CDPHE) that it had terminated an unnamed employee for drug diversion. This was in keeping with standard practice and nothing exceptionally unusual was noted.[20]

The hospital also notified law enforcement of the situation.[21]

By May, the ST had secured employment at an ambulatory surgical center in Colorado Springs, where she again diverted pain medications. She worked there until June 2009, at which time the details of her actions became more widely known.

In the end, this ST not only deprived approximately 5,700 (4,700 in Denver and 1,000 in Colorado Springs)[22] of needed pain medications, but she also may have exposed them to Hepatitis C. According to CDPHE, at least 15 individuals contracted Hepatitis C as a direct result of this ST's actions.

Although drug diversion by hospital employees may not be rare, occurring at least 22 times in the last three years in Colorado hospitals, this case represents only the fourth time, nationally, that a hospital employee's drug use has resulted in the spread of Hepatitis.[23]

In an attempt to identify additional instances of harm, DORA staff asked for such examples during interviews with interested parties and stakeholders, and DORA staff conducted an Internet search. No additional specific instances of harm could be identified.

Nonetheless, many stakeholders maintained the position that STs, in general, are in a position to cause harm. This is due, in large part, to the fact that surgery itself is an inherently dangerous undertaking. Therefore, this line of reasoning concludes, everyone in the operating room is in a position to cause harm to the patient.

Furthermore, STs may participate in at least three distinct activities that can have a direct impact on patient care. First, an ST may be responsible for setting up and maintaining the sterile field in the operating room. If this is not done correctly, infection, and the related complications, can result.

[20] TheDenverChannel.com. *Parker Worked At Audubon While Under Investigation At Rose*. Retrieved on December 23, 2009, from www.thedenverchannel.com/print/20008580/detail.html
[21] TheDenverChannel.com. *Parker Worked At Audubon While Under Investigation At Rose*. Retrieved on December 23, 2009, from www.thedenverchannel.com/print/20008580/detail.html
[22] Michael Booth and Allison Sherry, "Hospital, officials look to fix lapses," *The Denver Post*, July 16, 2009. Retrieved on July 16, 2009, from www.denverpost.com/ci_12847488
[23] Jennifer Brown and Michael Booth, "Colorado hospitals fight inner demons," *The Denver Post*, July 12, 2009. Retrieved on July 16, 2009, from www.denverpost.com/ci_12818540

Second, an ST may be responsible for what is commonly referred to as "the count." This means that the ST counts the supplies that are to be used during the surgery before the surgery begins, and then ensures that all are accounted for at the conclusion of the surgery. This process helps to decrease the likelihood that something was left inside the patient that should not have been.

Finally, an ST may participate in the "time out" period before surgery begins. During this process, the surgical team verifies the identity of the patient, the surgical procedure to be performed and the surgical site.

While these functions are certainly important, they pose only a general risk of harm. Indeed, DORA staff was unable to identify any specific instances in which an ST harmed a patient as a result of these activities.

Recall that CDPHE licenses many of the facilities in which STs work. Either CDPHE or The Joint Commission routinely surveys these facilities for compliance with their own employment policies and CDPHE receives mandatory occurrence reports.

Although The Joint Commission would not divulge any information regarding problems with STs, CDPHE reported that no surveys have revealed problems with STs.

Additionally, CDPHE staff searched occurrence reports for the last five years, and that search revealed only one report involving harm to patients – the ST from Denver and Colorado Springs highlighted above.

This leaves just the one specific example of harm – the ST who engaged in criminal conduct by diverting drugs and exposing patients to Hepatitis C in Denver and Colorado Springs.

While this example is certainly illustrative of deplorable conduct, it is less clear that any kind of regulatory structure could have prevented this ST from harming these patients.

Regulation is an inherently weak response to criminal activity. The deterrent value of administrative discipline pales in comparison to the possibility of imprisonment. If jail time is insufficient to deter someone from diverting drugs, the threat of losing a license to practice certainly will not stop that person.

Additionally, regulation is ineffective at preventing intentional conduct. Regulation, such as a licensing or certification program, serves to ensure a minimal level of competency in order to help reduce the occurrence of negligence.

Therefore, it is reasonable to conclude that the licensing program proposed by the Applicant would not have prevented this situation from occurring.

On the other hand, however, even a minimal regulatory system, such as a registration program, could have provided the Denver employer a vehicle through which to file a complaint against the person, thereby, at a minimum, starting the administrative investigatory process, rather than simply complying with its general duty to report the drug diversion to CDPHE and law enforcement.

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.

In short, the second criterion asks whether the harm, as identified in the analysis of the first sunrise criterion, is attributable to competency.

Given the single instance of harm, there is little basis to conclude that competency is a problem with STs.

Therefore, it is reasonable to conclude that the public cannot reasonably expect to benefit from an assurance of initial or continuing competence of STs.

Alternatives to Regulation

The third sunrise criterion asks:

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

Although the Applicant has proposed certifying or licensing STs, the third sunrise criterion demands that alternative regulatory structures be explored. Several options merit discussion.

The least restrictive form of regulation is a registration system. Generally, these types of structures have few if any entry requirements, but they allow the state to know who is working in a particular field and they enable the state to bar someone from working in that field.

Given that the single instance of harm in this sunrise review was based on intentional criminal conduct, as opposed to competency, a registration system may be viable. A structure tailored specifically to the harm identified herein, for example, could require STs to undergo criminal history background checks as a prerequisite to registration. Similarly, grounds for registration revocation could include actions such as being convicted of a crime, diverting drugs, or directly causing harm to patients.

However, this alternative offers little more protection than the current, employer-based system where employers can obtain similar pre-employment information by simply conducting thorough reference checks on employees before hiring them and where the employer is ultimately responsible and liable for the conduct of its employees.

Additionally, with no competency-based pre-requisites to register, these types of systems are inherently reactive in nature and due process still attaches. As a result, any complaints regarding registrants must still be investigated and follow the provisions of the Administrative Procedure Act.

The next higher level of regulation, certification, is remarkably similar to licensing. Under this scenario, the state could require STs to be certified by a single, or one of the several, national certifying organizations.

From a consumer protection perspective, this alternative is more beneficial than a registration system because it provides some objective determination of competency.

However, certification is not justified here because there is no evidence that the STs working in Colorado are incompetent. Indeed, with only 39 percent of the state's STs certified and the lack of evidence demonstrating competency as an issue, this alternative, too, is unjustified.

Another option would be to impose a credentialing requirement on the employers of STs. This would require hospitals, surgical centers and other employers to ensure that the STs they employ are certified either by a single, or one of the several, national certifying organizations.

Again, though, this appears to be unjustified given that employers are already responsible for determining the competency of their employees and, based on the lack of evidence to the contrary, competency does not appear to be an issue with respect to STs.

Given the low rate of patient harm attributable to STs, any level of regulation will be costly. Even a credentialing system would require facilities, which include small and rural hospitals that are already struggling to maintain quality staffs, to either pay for their current non-certified staff to become certified or to terminate non-certified staff and recruit certified STs.

If there were sufficient evidence of harm, this could be justified. But in the absence of specific widespread instances of harm caused by incompetent STs, it is unjustified.

Although alternatives to licensure exist, none are justified given the harm identified during the course of this sunrise review.

Finally, the marketplace appears to be taking a proactive stance on this issue. The Colorado Hospital Association has created a 75-member task force to study a variety of safety issues and to share best practices. The goal of this task force is to develop proposals to improve safety and procedures related to medication. These proposals are expected sometime in mid- to late-2010. Therefore, it is reasonable to conclude that if there are systemic problems, the hospitals, as the employers of STs, and thus ultimately liable for the acts of those STs, will identify any problems and correct them through this process.

Conclusion

The incident of the ST in Denver and Colorado Springs justifiably invokes an emotional desire to regulate the entire occupation. However, even a broad application of the sunrise criteria excludes a logical justification for regulation.

First, STs work in supervised settings. When they work in a physician's office, the physician is responsible for their conduct. When they work in hospitals or surgical centers, not only is the employer responsible, but the surgeon, too, is responsible.

STs perform functions that are difficult to define as a scope of practice. Their duties are dictated, in large part, by the training and experience of the individual ST, the policies of the facility employing that ST, and the functions delegated to the ST by the licensed personnel in the operating room.

Indeed, one of the earliest justifications for regulating professions was the tenet that consumers are either unable to determine the qualifications of the professionals they hire, or it is inefficient to expect them to do so. Therefore, the state steps in to establish minimal qualifications so that the public can be assured of a minimal level of competency.

With respect to STs, however, the patient plays no role in selecting the ST. Rather, the hospital or surgical center, in most cases, performs this function by employing and determining the competency of the ST. These facilities are highly sophisticated employers and are capable of determining the qualifications and competencies of their staffs.

The absence of competency-related harm perpetrated by STs strongly suggests that employers are doing a satisfactory job of performing this function. This conclusion is bolstered by the fact that only 39 percent of STs in Colorado are certified, yet there is no evidence of widespread competency-related harm.

Additionally, many hospitals and surgical centers are accredited by The Joint Commission, which requires facilities in states that do not regulate a particular occupation to develop their own standards and policies regarding the employment of such individuals. As part of its survey and re-accreditation process, The Joint Commission ensures that facilities comply with their own policies.

Further, CDPHE surveys facilities that are not accredited by The Joint Commission and has found no evidence that STs are harming patients.

In the final analysis, the sunrise criteria dictate that absent evidence of widespread harm caused by STs, regulation is unjustified.

Recommendation – Do not regulate surgical technologists.