

**THE VIRGINIA BOARD OF HEALTH PROFESSIONS
THE VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS**

**Study into the Need to Regulate Perfusionists in the
Commonwealth of Virginia**

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**Virginia Board of Health Professions
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AUTHORITY

At its February 14, 2012 meeting, the Regulatory Research Committee of the Board of Health Professions considered a request to review the need to regulate perfusionists in the Commonwealth of Virginia. At this meeting, the RRC requested staff seek additional information regarding the risk of harm and the urgency of conducting this review. After receiving additional information at its May 8, 2012 meeting, the Regulatory Research Committee voted to conduct the review, but to wait until the fall to begin the study due to its current workload. At its Sept. 17, 2012 meeting, the RRC adopted a work plan and began work on the study. The study was conducted pursuant to the following authority:

Section 54.1-2510 assigns certain powers and duties to the Board of Health Professions. Among them are the power and duty:

7. To advise the Governor, the General Assembly and the Director on matters relating to the regulation or deregulation of health care professions and occupations;

12. To examine scope of practice conflicts involving regulated and unregulated professions and advise the health regulatory boards and the General Assembly of the nature and degree of such conflicts;

Pursuant to these powers and duties, the Board of Health Professions and its Regulatory Research Committee has conducted a sunrise review into the need to regulate perfusionists in the Commonwealth of Virginia.

THE CRITERIA AND THEIR APPLICATION

The Board of Health Professions has adopted the following criteria and guidelines for their application for evaluating the need to regulate health professions. These criteria were initially adopted in 1991, and readopted in 1998. Additional information and background on the criteria are available in the Board of Health Professions Guidance Document 75-2 *Appropriate Criteria in Determining the Need for Regulation of Any Health Care Occupations or Professions*, revised February 1998 available on the Board's website: http://www.dhp.virginia.gov/bhp/bhp_guidelines.htm

CRITERIA FOR EVALUATING THE NEED FOR REGULATION

CRITERION ONE: RISK FOR HARM TO THE CONSUMER

The unregulated practice of the health occupation will harm or endanger the public health, safety or welfare. The harm is recognizable and not remote or dependent on tenuous argument. The harm results from: (a) practices inherent in the occupation, (b) characteristics of the clients served, (c) the setting or supervisory arrangements for the delivery of health services, or (d) from any combination of these factors.

CRITERION TWO: SPECIALIZED SKILLS AND TRAINING

The practice of the health occupation requires specialized education and training, and the public needs to have benefits by assurance of initial and continuing occupational competence.

CRITERION THREE: AUTONOMOUS PRACTICE

The functions and responsibilities of the practitioner require independent judgment and the members of the occupational group practice autonomously.

CRITERION FOUR: SCOPE OF PRACTICE

The scope of practice is distinguishable from other licensed, certified and registered occupations, in spite of possible overlapping of professional duties, methods of examination, instrumentation, or therapeutic modalities.

CRITERION FIVE: ECONOMIC IMPACT

The economic costs to the public of regulating the occupational group are justified. These costs result from restriction of the supply of practitioner, and the cost of operation of regulatory boards and agencies.

CRITERION SIX: ALTERNATIVES TO REGULATION

There are no alternatives to State regulation of the occupation which adequately protect the public. Inspections and injunctions, disclosure requirements, and the strengthening of consumer protection laws and regulations are examples of methods of addressing the risk for public harm that do not require regulation of the occupation or profession.

CRITERION SEVEN: LEAST RESTRICTIVE REGULATION

When it is determined that the State regulation of the occupation or profession is necessary, the least restrictive level of occupational regulation consistent with public protection will be recommended to the Governor, the General Assembly and the Director of the Department of Health Professions

APPLICATION OF THE CRITERIA

In the process of evaluating the need for regulation, the Board's seven criteria are applied differently, depending upon the level of regulation which appears most appropriate for the occupational group. The following outline delineates the characteristics of licensure, certification, and registration (the three most commonly used methods of regulation) and specifies the criteria applicable to each level.

Licensure. Licensure confers a monopoly upon a specific profession whose practice is well defined. It is the most restrictive level of occupational regulation. It generally involves the delineation in statute of a scope of practice which is reserved to a select group based upon their possession of unique, identifiable, minimal competencies for safe practice. In this sense, state licensure typically endows a particular occupation or profession with a monopoly in a specified scope of practice.

RISK: High potential, attributable to the nature of the practice.

SKILL & TRAINING: Highly specialized accredited post-secondary education required; clinical proficiency is certified by an accredited body.

AUTONOMY: Practices independently with a high degree of autonomy; little or no direct supervision.

SCOPE OF PRACTICE: Definable in enforceable legal terms.

COST: High

APPLICATION OF THE CRITERIA: When applying for licensure, the profession must demonstrate that Criteria 1 - 6 are met.

Statutory Certification. Certification by the state is also known as "title protection." No scope of practice is reserved to a particular group, but only those individuals who meet certification standards (defined in terms of education and minimum competencies which can be measured) may title or call themselves by the protected title.

RISK: Moderate potential, attributable to the nature of the practice, client vulnerability, or practice setting and level of supervision.

SKILL & TRAINING: Specialized; can be differentiated from ordinary work. Candidate must complete education or experience requirements that are certified by a recognized accrediting body.

AUTONOMY: Variable; some independent decision-making; majority of practice actions directed or supervised by others.

SCOPE OF PRACTICE: Definable, but not stipulated in law.

COST: Variable, depending upon level of restriction of supply of practitioners.

APPLICATION OF CRITERIA: When applying for statutory certification, a group must satisfy Criterion 1, 2, 4, 5 and 6.

Registration. Registration requires only that an individual file his name, location, and possibly background information with the State. No entry standard is typically established for a registration program.

RISK: Low potential, but consumers need to know that redress is possible.

SKILL & TRAINING: Variable, but can be differentiated for ordinary work and labor.

AUTONOMY: Variable.

APPLICATION OF CRITERIA: When applying for registration Criteria 1,4,5 and 6 must be met.

EXECUTIVE SUMMARY

MAJOR FINDINGS OF THE STUDY

- 1. Perfusionists operate the heart-lung machine during open-heart and other surgeries and fill some other ancillary roles.** Although Perfusionist perform some ancillary roles and tasks (e.g., managing extracorporeal life support in ICUs, organ transport, isolated limb perfusion, autotransfusion, etc.) most of their work revolves around maintaining, setting up and operating the heart-lung machine during surgery, mostly open heart and coronary artery bypass graft (CABG) surgeries, but also organ transplants and other surgeries.
- 2. Perfusion poses an inherent risk of harm to patients.** Proper operation of the heart-lung machine is essential to successful surgery and improper operation may result in permanent injury or death. In addition to operating the heart-lung machine, perfusionists administer blood components, pharmaceuticals and anesthetics, monitor vital signs, assist with autotransfusion, and assist with hypothermic, chemical and physical strategies to protect the heart and/or other organs during surgery.
- 3. Perfusionists work under the supervision of surgeons, anesthesiologists and other licensed medical staff in the surgical suite.** Perfusionists perform virtually all of their work within hospitals. Per CMS Conditions of Participation, perfusionists, including those working as contractors, are credentialed by the hospital and granted privileges by the hospital's medical staff. They are supervised by licensed personnel in the surgical suite.
- 4. Perfusionists are the only professionals who operate the heart-lung machine during surgery.** Despite supervision, surgeons and anesthesiologists rely on perfusionists to operate the heart-lung machine during surgery. No other profession, including advanced practice nurses nor respiratory therapists, perform perfusion.
- 5. Perfusionists are educated at the bachelor, post-graduate certificate or masters degree level.** There are currently 16 perfusionist programs accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). We are unaware of any unaccredited programs.
- 6. Perfusionists may earn the Certified Cardiovascular Perfusionist (CCP) credential from the American Board of Cardiovascular Perfusion (ABCP).** Candidates for certification are graduates of CAAHEP-accredited programs. CCPs must complete continuing education and perform 40 perfusion cases a year. Once certification is obtained, the ABCP does not revoke certification for disciplinary or other reasons. Certification is valid for three years.
- 7. 19 states regulate perfusionists; 31 states and the District of Columbia do not regulate perfusionists.** 17 states license perfusionists, one provides title protection and one requires permits for perfusionists who perform laboratory tests. Of the states that license perfusionists only seven require perfusionists to complete 40 cases annually (i.e., have ABCP or ABCP-equivalent requirements).

8. There are a small number of perfusionists. There are 96 certified perfusionists in Virginia. There are few if any uncertified perfusionists in Virginia. These perfusionists serve 21 open-heart surgery centers in Virginia. The number of perfusionist education programs and graduates has declined by about 50% in the past two decades.

9. The future need of perfusionists is difficult to predict. Technological improvements, pharmaceuticals, prevention and new treatments have reduced the need for open-heart surgery. One study found the number of CABG operations declined by 38% between 2001 and 2008. Despite this, the same study found that the number of centers performing CABG surgeries increased by 12 percent. Additionally, the aging of the baby-boomer generation is expected to push up demand for health services generally.

10. A variety of methods have been used to increase perfusion safety. Researchers cite increased professionalization, written guidelines, technological improvements, quality monitoring, incident registries, automation among other factors that have increased perfusion safety and safety during open heart surgery in general.

RECOMMENDATION

The Regulatory Research Committee reviewed the seven criteria. On properly seconded motion by Ms. Gregory, the Committee recommended that no regulation of Perfusionists was necessary at this time. The vote was not unanimous; Ms. Haynes opposed and Dr. Farquhar abstained. The recommendation was forwarded to the Full Board for review and consideration at its May 14, 2013 meeting. At that meeting, after discussion and several procedural motions, the Board, on properly seconded motion by Dr. Levin, voted to adopt the recommendation of the Regulatory Research Committee. The initial vote was evenly split with six members voting in favor of the Regulatory Research Committees recommendation and six voting to oppose the motion. The tie was broken by the Chair, who voted in favor of adopting the recommendation of the Regulatory Research Committee.

OVERVIEW OF THE PROFESSION

DESCRIPTION OF THE PROFESSION

Perfusionists select and operate the heart-lung machine during surgeries that require cardiopulmonary bypass, effectively functioning as the circulatory and respiratory system of the patient. While the term perfusion refers to the delivery of blood, the practice of perfusion includes monitoring and maintaining circulation, blood volume, oxygen levels, chemical balance, temperature, anti-coagulation and waste removal, as well as blood management. In collaboration with the surgical team, the perfusionist also assists in protecting the heart from damage, including hypothermic, chemical and physical strategies to reduce energy demands on the heart during surgery and to ensure safe reperfusion of the heart. The perfusionist administers blood components, pharmaceuticals and anesthetics through the perfusion equipment. Perfusionists may use their knowledge of cardiopulmonary systems and equipment to support management of pacemakers and other assistive devices. They also may perform point-of-care laboratory tests during surgery.

Perfusionists apply their expertise in extracorporeal life support outside of the cardiac surgery suite. Perfusionists may consult or manage the use of extracorporeal life support (ECLS), including extracorporeal membrane oxygenation (ECMO) and hemodialysis, in intensive care units, during patient transport or in other settings. They assist with organ procurement, transport and preservation. They perform isolated limb or organ perfusion, including the isolated delivery of potentially damaging pharmaceuticals (e.g., chemotherapeutics) through the circulatory system. They may perform extracorporeal cardiopulmonary resuscitation (E-CPR) or manage long-term extracorporeal circulation.

The American Medical Association describes a perfusionist as “a skilled person, qualified by academic and clinical education” (AMA). Students may obtain a baccalaureate degree in perfusion, or a post-graduate certificate or master’s degree. Voluntary certification is available for those who graduate from an accredited program. Perfusionists tend to be either hospital employees or employees of contract groups, however a small number are self-employed or employed directly by physicians (Bui, 2011; Trew, 2011).

EVOLUTION OF THE PROFESSION

After a series of fits and starts, the first successful operation using mechanical cardiopulmonary bypass was performed in 1953 by John H. Gibbon, MD at Jefferson Medical College, Philadelphia, using a machine he developed in collaboration with IBM. It was the only successful mechanical bypass operation of four performed by Gibbon that year. Early heart-lung machines were complex and temperamental, and required up to four technicians to operate. Nevertheless, by the end of the decade three companies were mass-producing heart-lung machines. Over the next few decades, improvements in equipment, technique and preoperative diagnosis increased survival rates each year (Stoney, 2009).

Through the mid-1970s, training of perfusionists was done on the job. Most early perfusionists built on skills from other disciplines, including engineering, surgical technology, nursing, laboratory science and

monitoring technology (AMA). The American Society of Extracorporeal Technology was founded in 1964 and offered its first formal certifications of perfusionists in 1974. Accreditation of educational programs began over the next several years (AmSECT).

During the 1980s, heart-lung machines with bubble oxygenators were replaced by membrane oxygenators (Cecere, 2002). Extracorporeal membrane oxygenators (ECMO) allow for long-term extracorporeal life support (ECLS), expanding the use of heart-lung machines from the surgical suite into the intensive care unit. ECMO machines are also smaller and less complex, allowing for use in trauma rooms, particularly for acute respiratory distress (Conrad). ECLS continues to benefit from technological improvements that improve the safety and expand its use. Recent improvements include continuous inline monitoring, electronic data collection and control, and portable ECMO and circulatory support devices (Conrad; Mueller, 2011; Baker, 2008; Chau & Tak-fu, 2009).

However, the most significant change impacting the profession is the increase in treatment options for persons with heart disease. These include improved prevention & early detection, pharmaceuticals, percutaneous coronary interventions (PCIs) (e.g., balloon angioplasty, stents) and off-pump coronary artery bypass graft (CABG) surgery performed with the heart still beating. One study published in the Journal of the American Medical Association found that the number of CABGs performed declined by 38% between 2001 and 2008 (Epstein, 2011). By 2008, about 20 percent of these CABGs were performed off-pump (Kerendi, 2008).

OVERLAPPING SCOPES OF PRACTICE

The expansion of ECLS into other areas of the hospital has also expanded the numbers and types of practitioners gaining experience operating ECMO and related technologies. In particular, experienced ICU nurses and respiratory therapists are often trained in-house by hospitals to operate and monitor ECLS technology. In some hospitals, particularly hospitals where CABG is performed, perfusionists may manage ECLS use or provide consultation. However, physicians may also fill this role.

These trained practitioners are referred to as ECLS or ECMO Specialists. Advertised positions generally seek an associate or higher-degree registered nurse or respiratory therapist, or a perfusionist, although trained biomedical engineers or other technicians with ICU experience may also become ECLS specialists (ELSO, 2010). A recent announcement from Inova Health System, for instance, sought a registered nurse, respiratory therapist, or certified perfusionist to act “as a key member of the health care team while maintaining the patient on ECLS. Provides expertise in circuit/pump operation, maintenance and troubleshooting”. (Req.#: 10-49756. Accessed on Climber.com, Sept. 27, 2012.).

Some nascent professional development has occurred in this arena. The Extracorporeal Life Support Organization (ELSO) has published guidelines for hospitals with ECMO centers. These guidelines include minimum standards for entry into in-house ECMO specialist training programs, curriculum guidelines and guidelines for continuing education (ELSO 2010). ELSO also has created a Specialist Credentialing committee, although information on its work was not available at the time of this writing. Continued development of an ECMO specialty for registered nurses and respiratory therapists has the potential to create associate and bachelors trained licensed practitioners with formal certification on ECLS equipment.

Perfusionists are often assisted by perfusion assistants. Perfusion assistants support the perfusionists by assisting in setting up and breaking down equipment, transporting and sterilizing equipment, stocking supplies, and disposing of waste. They also provide charting, monitoring and administrative support. During procedures, perfusion assistants may be responsible for technical tasks such as priming circuits, initiating intra-aortic balloon pumping or processing salvaged blood. There are no formal requirements for perfusion assistants; however, they generally have backgrounds in medical assisting, surgical technology, cardiovascular technology, or similar fields.

Cardiology Technologists provide technical support to cardiologists by running tests and monitoring equipment and by assisting during non-invasive and invasive procedures. Cardiology technologists may prepare and monitor patients during open-heart and other cardiac surgeries or assist with inserting catheters and balloon angioplasty. Cardiology Technologists generally complete associate degree programs but some bachelor degree programs are available.

CREDENTIALING

Perfusionists are educated at the bachelor degree level; however, perfusionists may receive bachelor's degrees in other fields before pursuing a post-graduate certificate or master's degree in perfusion. Private, national certification is available from an independent certification board but is not required by all employers. As with all members of the surgical team, perfusionists must be privileged by the medical staff of the responsible hospital to perform perfusion during surgery.

EDUCATION

Perfusion education programs are accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP), a national program-specific accreditation board. CAAHEP is an umbrella organization that accredits programs on the recommendation of individual Committees on Accreditation. Accreditation of perfusion programs is managed by the Accreditation Committee-Perfusion Education (AC-PE). Accreditation includes meeting minimal standards of financial health, facility quality, curriculum and other requirements, confirmed by self-study documentation and periodic site visits. There are currently 16 accredited perfusion programs. None are located in Virginia (CAAHEP website). A preliminary search did not reveal any unaccredited programs.

Accredited programs offer bachelor's degrees (4 programs), post-graduate certificates (5 programs) or master's degrees (7 programs). Students must complete college level coursework in anatomy/pathology, physiology, chemistry, pharmacology, mathematics, and physics separate from the perfusion curriculum (e.g., as a prerequisite or requirement for admission) (CAAHEP, 2005). The perfusion curriculum includes coursework in basic science (including cardiopulmonary anatomy, pathology and surgery, physiology, pharmacology and immunology), cardiopulmonary bypass, mechanical assist, laboratory analysis, biomedical engineering, safety, quality assurance, ethics, history, research methods, business practices and emergency preparedness (AC-PE, 2010). Students must complete at least 75 clinical cases at an AC-PE approved facility, including 10 pediatric cases (CAAHEP Standards).

In 2008, CAAHEP accredited programs graduated 106 students. Five students continued their education, and 98 were employed within one year of graduation. Job placement rates were above 90 percent for all but one year from 2001 to 2008 (AC-PE website).

CERTIFICATION

Certification for perfusionists is administered by the American Board of Cardiovascular Perfusion (ABCP). Candidates are graduates from CAAHEP-accredited perfusion programs, or graduates of programs accredited by the Committee on Accreditation of the Canadian Medical Association, with associated documentation and statements of clinical competency. There is no provision for non-Canadian foreign applicants. The exam consists of two parts. The first part is a basic science exam, consisting of 220 multiple choice questions on perfusion sciences. The second part is a clinical application exam, consisting of 200 to 230 questions related to a series of presented scenarios. The knowledge base for the test has eleven major sections:

1. Anatomy & Physiology
2. Pharmacology
3. Pathology
4. Laboratory Analysis
5. Quality Assurance
6. Devices & Equipment
7. Clinical Management
8. Special Patient Groups
9. Special Procedures/Special Techniques
10. Catastrophic Events & Device Failure
11. Monitoring

Exams are administered by Prometric, Inc, a national testing company. Successful candidates are awarded the Certified Cardiovascular Perfusionist (CCP) credential. CCPs must recertify annually. To recertify, CCPs must complete at least 40 clinical cases annually. Fifteen of these cases may be intraoperative standby or performed as the first assistant to the primary perfusionist. CCPs must also complete at least 45 Continuing Education Units (CEUs) every three years. In addition to other limitations, at least 15 CEUs must be in ABCP accredited activities. ABCP performs random audits on both clinical activity and continuing education reports (ABCP, 2012).

HOSPITAL CREDENTIALING AND MEDICAL STAFF PRIVILEGING

Although perfusionists sometimes engage in medical transport, emergency services or other ancillary services they work within the context of hospitals. The Joint Commission, the main hospital accreditation agency with deeming authority from the Centers for Medicare & Medicaid Services,¹ requires that hospitals verify that

¹ Hospitals accredited by organizations with deeming authority are “deemed” eligible for CMS reimbursement. In addition to the Joint Commission, the Healthcare Facilities Accreditation Program (HFAP) also has deeming authority focused on

employees have the credentials, education, and experience to perform their job responsibilities at time of hire. They also require criminal background checks. Hospitals must also confirm the credentials and qualifications of non-employees brought in by independent practitioners; however, confirmation of credentials “can be accomplished either through the hospital’s regular process or with the licensed independent practitioner who brought in the individual” (The Joint Commission, HR.01.02.05(7) Note: 1). Hospitals must verify required credentials during hiring and when credentials are renewed.

As with all members of the surgical team, the Centers for Medicare & Medicaid Services (CMS) Conditions of Participation (CoPs) require perfusionists to be privileged by the medical staff of the responsible hospital or ambulatory surgical center. Privileging is a separate process from the hiring or selection process. Hiring, for instance, is done by human resource professionals to fill positions based on broad credentials such as education, certification and experience. Medical privileges, by contrast, are granted by medical staff committees (mostly consisting of physicians). Privileges authorize individual practitioners to perform specific procedures or surgical tasks based on the individual training, experience, background and competence of the practitioner with the particular procedure. All persons participating in surgical procedures in a surgical facility, including outpatient surgical centers, must be privileged, regardless of employment status (e.g., consultants, contractors, independent practitioners). Privileges must be reviewed and updated at least every two years (CMS).

CMS CoPs are outlined in the *US Code of Federal Regulations*, and CMS provides State Operations Manuals that provide detailed information for providers and state surveyors. The relevant sections are in CMS State Operations Manual, Appendix A “Hospitals” Section A-0945 (*emphasis added*):

A-0945

(Rev. 37, Issued: 10-17-08; Effective/Implementation Date: 10-17-08)

§482.51(a)(4) - Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.

Interpretive Guidelines §482.51(a)(4)

Surgical privileges should be reviewed and updated at least every 2 years. A current roster listing each practitioner’s specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas/locations.

The hospital must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in

osteopathic facilities. All hospitals in Virginia are accredited by the Joint Commission. Norton Community Hospital is accredited by the Joint Commission and HFAP.

accordance with the competencies of each practitioner. The medical staff appraisal procedures must evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the hospital's QAPI² program, credentialing process, the practitioner's adherence to hospital policies and procedures, and in accordance with scope of practice and other State laws and regulations.

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as MD/DO, dentists, oral surgeons, podiatrists, RN first assistants, nurse practitioners, surgical physician assistants, surgical technicians, etc. When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is physically present in the same OR, in line of sight of the practitioner being supervised) be delineated in that practitioner's surgical privileges and included on the surgical roster.

If the hospital utilizes RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with Federal and State laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO.

When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.

Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and documented privileges.

Despite these process standards, there are no specific requirements for the qualifications of perfusionists in Joint Commission or CMS standards or in statute. Virginia hospitals and their medical staff may set qualifications for perfusionists as they see fit and may change qualifications as they see fit.

² Quality Assessment and Performance Improvement

REGULATION IN OTHER STATES

Currently, 17 states license perfusionists and one provides title protection. Additionally, New York recently required permits for perfusionist performing laboratory tests. While all states require ABCP certification or examinations for initial licensure only five require it for license renewal. Two additional states have largely equivalent case load requirements. In general, states that do not require ABCP certification for renewal set a lower accepted standard for practice than those that do not have licensure at all. In other words, hospitals which previously used ABCP certification as the baseline credential may replace certification with licensure.

State	Year Enacted	Disciplinary Cases, 1999 (or effective date) to 2010	ABCP Certification Required for Application?	ABCP Certification Required for Renewal?	Minimum Cases Required for Renewal (annual).
Licensure					
Arkansas	1999	NA	Yes	No	40
Connecticut	2005	0	Yes	No	-
Georgia	2002	6	Yes	Yes	40
Illinois	2000	4	Yes	No	-
Louisiana	2003	3	Yes	No	-
Maryland	2011	0	Yes	NA*	NA*
Massachusetts	2011	3	Yes	Yes	40**
Missouri	2000	1	Yes	Yes	40
Nebraska	2007	0	Yes	NA*	NA*
Nevada	2009	0	Yes	No	-
New Jersey	1999	3	Yes	No	-
North Carolina	2005	3	Yes	No	-
Oklahoma	1996	4	Yes	Yes	40
Pennsylvania	2008	0	Yes	Yes***	40***
Tennessee	1999	4	Yes	No	-
Texas	1994	5	Yes	No	40
Wisconsin	2002	2	Yes	No	-
Title Protection					
California	1992	-	Yes	Yes	40
Permit to Perform Laboratory Tests					
New York	2012	-	No	No	-
<p>*Regulations not yet developed ** 80 cases for those licensed through grandfather provisions ***The requirement for ABCP certification is part of Pennsylvania's regulation of facilities. It applies to open heart surgery cases only. However, a licensed perfusionist only needs 30 hours of continuing education to renew his license. See <i>Code of Pennsylvania</i> Title 28 §136.14, chapter title "Open Heart Surgical Services".</p>					

THE PERFUSION WORKFORCE

WAGES & SALARIES

Perfusionists belong to an established profession with existing educational norms. Nationally, entry level salaries for perfusionists ranged from \$60,000 - \$75,000, with an average range of \$70,000-\$90,000 in 2006 (AMA). The Virginia Health Careers Registry estimates a salary range of \$50,000-\$90,000 (Bohanon). A salary and benefits survey for perfusionists conducted periodically tends to predict somewhat higher average salaries, however recruitment for these surveys occurs through professional groups and perfusion websites and may not draw a representative sample. Regardless, perfusion salaries are in line with or above median salaries for all workers with bachelor's and master's degrees. In 2011, median salaries for these groups were approximately \$55,000 and \$66,000, respectively (BLS). Additionally, perfusionist salaries are in line with similarly educated health professionals in Virginia (see table). Perfusionists may work irregular hours in a stressful work environment, so higher than average wages are expected.

Profession	Average Annual Wage
Perfusionist	\$70,000-\$90,000
Physician Assistants	\$89,470
Registered Nurses	\$69,110
Occupational Therapists	\$74,970
Physical Therapists	\$79,830
Radiation Therapists	\$79,340
Respiratory Therapists	\$56,260
Speech-Language Pathologists	\$72,000

Source: BLS & AMA. National averages.

WORKFORCE ADEQUACY

Year	Graduates	Number Employed	Continuing Education	Positive Placement rate	Employment rate
2001	121	118	1	98%	98%
2002	117	112	1	97%	97%
2003	117	114	1	98%	98%
2004	112	106	2	96%	96%
2005	135	110	5	93%	85%
2006	113	107	5	99%	99%
2007	111	103	5	97%	97%
2008	106	98	5	99%	97%
Total	932	868	25	96%	96%

Source: AC-PE

As noted in the education section, new graduates are achieving employment placement rates approaching 100 percent in most years, for an average of 96 percent from 2001 to 2008 (See table). These figures, the latest available, indicate that positions are available for new perfusionists even as the number of CABG cases declined by 38 percent (Epstein, 2010). There are several factors that may explain this. The first is that the number of perfusion graduates

has been declining steadily since the early 1990s. Perfusion programs produced 224 new graduates in 1992. Similarly, the number of schools has declined from 35 in 1994 to 17 currently (Shearer, 2010). Perfusionists have also gained employment opportunities as ECLS technology has gained use outside of cardiac surgery. Finally, although the number of CABG procedures has declined, the total number of hospitals providing CABG has increased by 12 percent from 2001 to 2008 (Epstein, 2010). Each of these will likely require some level of perfusionist services even if the volume is low.

DISCUSSION OF ECONOMIC IMPACTS

Although perfusionists do not have long or broad experience with licensure, the highly technical and unique nature of their traditional role has already created barriers to entry similar to licensure. Even without state licensure, perfusionists have largely maintained a lock on operating the heart-lung machine during open-heart surgery.

However, licensure of perfusionists could have a significant effect on labor supply in new and emerging fields that are beginning to adopt ECLS technologies. Currently, ICU nurses and respiratory therapists are incorporating new ECLS skills into their current practice through formalized, on-the-job training. There were 96 perfusionists in Virginia in 2013, and 21 centers providing CABG surgery in Virginia in 2010. There are 107 inpatient hospitals in Virginia. Although ECMO centers are currently only recommended for tertiary-level ICUs, and there are only three in Virginia (ELSO, 2010), any legislation linking use of this technology with the availability of a perfusionist could limit its dispersion, especially if the technology continues to develop. Nevertheless, concerns related to the limited amount of specific training on ECLS received by registered nurses and respiratory therapists, as well as maintaining an adequate case load to develop and maintain expertise, are not unwarranted. ELSO guidelines indicate that ECMO centers in ICUs could serve as few as six patients per year (ELSO, 2010).

According to the American Board of Cardiovascular Perfusion 2013 roster there are 96 certified perfusionists in Virginia, up from 90 in 2012. According to Virginia Health Information, 21 hospitals provided 4,326 CABG surgeries in 2010. Of these hospitals, two were categorized as “Mid-High” volume centers, eight were “Mid-Low” volume centers and eleven were “Low” volume centers, including one hospital that performed one CABG surgery.³ Additionally, Hunter Holmes McGuire VA Medical Center, not included in the VHI roster, provides CABG surgery. Although CABG surgeries make up the bulk of the perfusionist work, they also participate in heart, lung, liver and other transplants, as well as ancillary services.

These small numbers are a concern, decreasing the overall flexibility of the workforce. Over the short-term, limited numbers increase the difficulty of responding to changes in supply of perfusionists or the demand for perfusion services. One unexpected retirement, for instance, decreases the size of the certified perfusion workforce in the state by more than one percent. The impact is magnified at the local level and could result in delays or overworked and fatigued practitioners. Licensure makes it difficult to draw on practitioners from other

³ VHI does not define volume ranges for these classifications. M-d-High volume hospitals reported 494 & 647 CABG, Mid-Low, 184-439 & Low 1-182 (the second lowest was 49).

states or for non-practicing practitioners to return to practice. Even otherwise qualified practitioners must go through the steps of obtaining a license.

Additionally, it may be difficult for the profession to adjust to long-term changes in demand for services. From the early 1990s to the present, the perfusion profession decreased the number of annual graduates from perfusion programs by half and the number of programs from 35 to 17. If demand for perfusion should increase, as the aging of the boomer generation hints it may, that trend may need to be reversed. Closing down and shrinking programs may be an easier task than opening and expanding them, especially from such a small base. In the reverse, the opposite is true. If new treatment modalities continue to edge out CABG surgeries a large pool of highly-trained perfusionists may find themselves without marketable skills. The future of perfusion is a difficult thing for 17 programs to balance.

The most pressing economic challenge for perfusionists is the rather limited specialization—operating the heart-lung machine during select surgeries. Unlike their non-physician counterparts on the surgical team (e.g., anesthesiology assistants, surgical assistants, OR nurses, and surgical technologists) a perfusionist’s skills are not readily transferrable to other types of surgery. This includes other types of cardiac surgery which are often within the purview of more generalist cardiovascular technologists. Perfusionists have managed to expand their role beyond the open heart surgical suite along with the expansion of ECLS technology. However, their limited scope also leads to a more limited role compared to ICU nurses, respiratory therapists or intensivists.

Compared to similar roles the flexibility of the perfusion workforce is limited. The anesthesia role, for instance, may be filled by anesthesiologists, registered nurse anesthetists and unregulated anesthesiologist assistants. Similarly, the first assistant role is filled by physician assistants, registered nurses and unregulated surgical assistants. Perfusion is a unique role that requires specially-trained practitioners. However, the restrictive scope of work combined with the very small number of practitioners limits the flexibility of the perfusionist workforce. Thus, any negative economic effects from licensure may be amplified in the case of perfusionists.

Hospital	Volume Level	Cases
Inova Fairfax Hospital	Mid-High	494
Sentara Norfolk General Hospital	Mid-High	647
Carilion Medical Center	Mid-Low	439
Centra Health	Mid-Low	229
CJW Medical Center	Mid-Low	320
Henrico Doctors' Hospital	Mid-Low	210
Mary Washington Hospital	Mid-Low	197
University of Virginia Medical Center	Mid-Low	279
Winchester Medical Center	Mid-Low	224
VCU Health System	Mid-Low	184
Bon Secours Maryview Medical Center	Low	92
Bon Secours Memorial Regional Medical Center	Low	143
Bon Secours St. Mary's Hospital	Low	162
Children's Hospital of The King's Daughters	Low	1
Danville Regional Medical Center	Low	49
Inova Alexandria Hospital	Low	83
LewisGale Medical Center	Low	182
Riverside Regional Medical Center	Low	141
Rockingham Memorial Hospital	Low	68
Sentara Virginia Beach General Hospital	Low	87
Virginia Hospital Center	Low	97
Total		4328

RISK OF HARM

Most of the potential for harm from the unregulated practice of perfusion stems from practices inherent in the occupation. Perfusionists operate the heart-lung machine during surgery, in effect controlling the circulation, respiratory and other vital systems of the patient. Perfusionists administer anesthesiology and other drugs, engage in myocardial protection, and are instrumental in stopping and reperfusing the heart or other organs. The potential for these practices to cause harm is readily apparent. Another risk comes from the setting and supervisory arrangement of perfusionists. While patients will choose and become familiar with their cardiac surgeon they may not be familiar with their perfusionist. Additionally, they may not have a choice in provider. Rather, they rely on the surgeon and/or the hospital to choose a perfusionist for them and to ensure the perfusionist is qualified and competent. If these processes break down the patient has little or no recourse.

Although perfusionists sometimes work outside of the open heart surgical suite in ancillary roles (e.g., emergency rooms or intensive care units) perfusionists overwhelmingly work in a regulated hospital environment. This fact mitigates much of the risk of the practice of perfusion outside of the framework of professional regulation. Our question is whether adding an additional level of regulation—professional regulation—will decrease the risk of harm.

According to Virginia Health Information, 4,328 CABG surgeries were performed in 21 non-federal hospitals in 2010 (see table, previous page). Sixty-two patients did not survive surgery, a mortality rate of just under 1.5 percent. Of the 21 hospitals, two had high, risk-adjusted mortality rates, statistically differing from other programs at a 95% confidence level.

CABG Surgeries in Virginia, 2010			
Hospital Name	Cases	Mortality	Readmissions
Inova Fairfax Hospital	494	4	31
Sentara Norfolk General Hospital	647	9	71
Carilion Medical Center	439	11*	42
Centra Health	229	7	12
CJW Medical Center	320	4	21
Henrico Doctors' Hospital	210	2	14
Mary Washington Hospital	197	7*	21
University of Virginia Medical Center	279	2	26
Winchester Medical Center	224	4	17
VCU Health System	184	3	26*
Bon Secours Maryview Medical Center	92	0	6
Bon Secours Memorial Regional Medical Center	143	1	13
Bon Secours St. Mary's Hospital	162	1	11
Children's Hospital of The King's Daughters	1	0	0
Danville Regional Medical Center	49	1	3
Inova Alexandria Hospital	83	0	7
Lewis Gale Medical Center	182	2	9
Riverside Regional Medical Center	141	1	6
Rockingham Memorial Hospital	68	1	13*
Sentara Virginia Beach General Hospital	87	1	9
Virginia Hospital Center	97	1	5
Total	4328	62	363
*Worse than expected at a 95% confidence level as reported by Virginia Health Information. Expected rates are risk-adjusted by VHI. See www.vhi.org for more information.			

According to the Virginia Perfusion Society, using information provided by the Virginia Cardiac Surgery Quality Initiative, perfusionists participated in 5,227 surgeries in Virginia, including surgeries other than CABG and those performed in federal hospitals in 2010. Using a rate published in the 1989 text *Cardiopulmonary Bypass* by Reed & Stafford, the Virginia Perfusion Society estimates there were five serious injuries or deaths attributable to perfusionists in 2010, a mortality *or serious injury* rate of 0.096 percent, or just under one percent of one percent.

This figure, however, is based on the 1986 estimate by Reed & Stafford of one perfusionist caused injury or death per 1,000 surgical cases. An updated study performed by Mejak, et al., found perfusionist- or perfusion equipment-caused death or serious injury in 462 of 653,621 cases performed in 797 national hospitals. The 462 serious injuries or death included 147 deaths. All told, Mejak et al., found one serious injury or death per 1,453 cases in 2000 compared to Reed & Stafford's 1 per 1,000 cases in 1989.

Using the Virginia Perfusion Society's method with the updated figures provided by Mejak, et al, we expect there were four (3.7) serious injuries or deaths caused by

perfusionists or perfusion equipment in Virginia in 2010, including one (1.2) death. However, Mejak et al. also provided information on occurrences, finding an incident rate of one per 138 cases. Using the same methodology we expect there were 39 incidents in Virginia, each with the potential to cause serious injury or death.

The expected incident rates for Virginia are speculative and based on data over ten-years old, the most recent data available to Board staff. It is not known whether incident rates are different among perfusionists with

Incident Reported	Cases	Serious Injury	Death	Serious injury or death
Coagulation problem following bypass	857	139	49	188
Arterial dissection (aortic or femoral)	293	56	41	97
Protamine reactionb	871	68	23	91
Clot/thrombus present in circuit during CPB	294	3	12	15
Massive gas embolismc	23	6	6	12
Transfusion reaction from blood product given	109	10	4	14
Line rupture of disconnection	162	3	2	5
Circuit change-out due to gross contamination	29	1	2	3
Incorrect unit of blood given	11	0	2	2
GE via reversed suckers/vent	27	3	2	5
Aortic cannulae dislodgement	161	6	1	7
Electrical/mechanical failure of heart-lung machined	150	0	1	1
GE via cardioplegia	87	3	1	4
Cardioplegia error	79	1	1	2
Heater/cooler failure	371	0	0	0
Air present in bypass circuit	363	2	0	2
Oxygenator failure	273	2	0	2
Mechanical failure of one or more pumps	260	0	0	0
Cases hand cranks were used	200	7	0	7
Power interruption w/no generator backup	163	1	0	1
Medication error (wrong drug, or dosage)	78	3	0	3
Water to blood leak	18	1	0	1
Total	4879	315	147	462
Source: Mejak, et al. 2000. Based on 653,621 surgeries.				

differing qualifications (e.g., board-eligible, certified, lapsed certification) or states with differing regulations, particularly licensure for perfusionists.

When considering perfusion safety, there is a continuing tension between perfusion qualifications and perfusion technology. In his 2005 retrospective study, for instance, Palanzo reported that in one study 21 percent of surgeons surveyed reported that a perfusionist had forgotten to clamp the pump line in at least one of their surgeries, resulting in backflow from the aorta. However, rather than trying to achieve a zero percent error rate for perfusionists, the author of the study recommended the use of flow valves to prevent backflow (pg. 200). However, Palanzo also noted increased professionalism among perfusionists, along with equipment improvements, incident surveys, and improved procedures (e.g., checklists and written protocols) as key factors in improving perfusion safety.

Similarly, Mejak, et al. attribute the decreased injury rate between 1986 & 2000 to improved equipment, including increased use of membrane oxygenators, arterial line filters, centrifugal pumps and to efforts to prevent power outages and mechanical breakdowns. Mejak, et al. noted:

... An interesting point is that protamine reactions were the leading incident seen in the Kurusz study almost 15 years ago. Since the overall incident rate of reported serious injuries or death has decreased, there is reason to believe those incidents, other than protamine reactions and coagulation problems, are being prevented (pp 56, 57).

Mejak, et al. suggested that advancements in biocompatible coatings could prevent protamine reactions and coagulation problems. However, they also noted the high number of deaths caused by arterial dissections and cannulae dislodgements, (combined accounting for 42 of the 147 deaths in the survey) and urged perfusionists to prepare a plan of action for themselves and for the surgical team for when these unpredictable incidents occur.

In the most recent retrospective study known, Kurusz (2011) identifies five periods of increasing perfusion safety (sentence converted to bullet points, emphasis Kurusz’):

- 1970s: Professional credibility recognized with *accreditation* of perfusion educational programs, *certification and recertification* of clinical perfusionists;
- 1980s: Publication of a landmark *FDA-sponsored study* on CPB safety and further problem definition through *survey research*;
- 1990s: Promulgation of national consensus *guidelines*, including *checklists, scopes of practice, clinical recommendations*, and increased use of *written protocols* and *safety devices*;
- 2000s: Adoption of a *systems approach*, use of *Quality Assurance/Quality Improvement* processes, exploration of *analogies* between perfusion and aviation, and a better understanding of *error recognition*;
- 2010 & beyond: Application of *evidence-based practice*, establishment of perfusion *registries*, movement towards *automation*, maturation of *publications*, increased use of perfusion *simulators* and universal embrace of *Internet* resources.

Kurusz notes that combined, these developments have “lowered [cardiopulmonary bypass] complication rates in most instances to negligible levels unheard of a few decades ago” (pg. 11). If Kurusz is correct, we can expect that the incident, injury, and death rates postulated by Reed & Stafford in 1986 and by Mejak et al. in 2000 have diminished even further. Kurusz notes that “the perfusion profession has an admirable track record” in improving safety, pointing out codified education and a robust perfusion literature as keys to disseminating and promoting best practices in the field.

Kurusz’ five periods also point to a series of tools perfusionists, cardiac surgeons, and hospitals can and have leveraged to improve quality and protect patients undergoing perfusion. They may also have a variety of tools unrelated to perfusion at their disposal that may also diminish injury and death in cardiac surgery. The credentialing process associated with professional regulation is only one of these tools. Regulation by the states causes surgeons, hospitals and perfusionist to expend resources on maintenance of certification which may (or may not) be used to otherwise improve safety. Considering the high rate of voluntary certification and the success of other efforts in the absence of licensure, the certification requirements of licensure may have limited impact on incident rates.

Professional regulation may have more of an impact when it comes to disciplining impaired, unethical or incompetent perfusionists, or removing them from practice. Perfusionists released or denied clinical privileges by surgeons, hospitals or perfusionist groups may simply switch employers or locales, or practice as traveling or locum tenens practitioners. Professional regulation provides a method for ensuring these practitioners do not practice in Virginia. The National Practitioner Data Bank (NPDB) collects some information on malpractice claims and discipline of licensed practitioners. The next two tables present data from the NPDB’s public access file on perfusionists. While the malpractice claims mainly deal with errors, the discipline files include criminal conviction (2 cases), substance abuse (2 cases), unprofessional conduct (2 cases) physical impairment or illness (1 case), or incompetence (1 case). Note that not all malpractice claims or adverse license actions related of perfusionists are reported in the NPDB Public Access File.

Malpractice Payments for Perfusionists, National Practitioner Data Bank (Accessed Jan. 25, 2013)					
State of Work	Year of Act	Malpractice Allegation Group	Malpractice Allegation(s)	Severity of Injury	Payment (Perfusionist Portion Only)
Kentucky	1994	IV & Blood Products Related	Improper Technique	Quadriplegic, Brain Damage, Lifelong Care	\$590,001 - \$600,000
Tennessee	2004	Surgery Related	Improper Management; Improper Performance	Death	\$990,001 - \$1,000,000
Arizona	2009	Surgery Related	Improper Performance	Major Permanent Injury	\$2,900,001 - \$3,000,000
Georgia	2011	Surgery Related	Failure to Recognize a Complication	Death	\$390,001 - \$400,000
Georgia	2002	Equipment/Product Related	Equipment Utilization Problem	Death	\$720,001 - \$730,000
Illinois	2005	Surgery Related	Improper Performance	Quadriplegic, Brain Damage, Lifelong Care	\$4,900,001 - \$5,000,000
Missouri	2009	Surgery Related	Administration of Blood or Fluids Problem; Wrong Blood Type	Death	\$140,001 - \$150,000
New York	2005	Monitoring Related	Failure to Report on Patient Condition; Failure to Respond to Patient	Death	\$990,001 - \$1,000,000
Tennessee	2000	Equipment/Product Related	Equipment Malfunction; Equipment Utilization Problem	Unlisted	Unlisted
Texas	2001	Surgery Related	Administration of Blood or Fluids Problem; Improper Technique	Death	\$45,001 - \$50,000

Discipline of Licensed Perfusionists, National Practitioner Database (Accessed Jan. 25, 2013)					
Individual Identifier	Year	State	Basis for Action	Adverse Action	
237045	2003	IL	Criminal Conviction	Probation of License	2 years
251367	2003	OK	Unprofessional Conduct	Probation of License	2 years
253627	2003	TX	Violation of Federal or State Statutes, Regulations or Rules	Reprimand or Censure	Permanent
262698	2004	GA	Other (Not Classified)	Probation of License; Reprimand or Censure; Publicly Available Fine/Money Penalty	5 years
265284	2005	GA	Unprofessional Conduct	Reprimand or Censure; Publicly Available Fine/Money Penalty	Indefinite
267256	2004	MI	Violation of federal or State Statutes, Regulations or Rules	Revocation of License	Indefinite
343697	2007	TX	Unable to Practice Safely: Alcohol or Other Substance Abuse; Unprofessional Conduct	Voluntary Surrender of License	Permanent
350158	2008	MA	Other (Not Classified)	Reprimand or Censure	Permanent
365695	2008	TN	Allowing or Aiding Unlicensed Practice	Reprimand or Censure	Indefinite
390842	2009	NA	Other (Not Classified)	Other Restriction/Limitation of Clinical Privileges	Permanent
390842	2009	NA	Other (Not Classified)	Other Restriction/Limitation of Clinical Privileges	Permanent
391711	2009	TX	Criminal Conviction	Probation of License	2 years
406624	2009	GA	Other (Not Classified)	Reprimand or Censure	Indefinite
406625	2009	GA	Other (Not Classified)	Reprimand or Censure	Indefinite
409507	2012	NC	Unable to Practice Safely: Physical Illness or Impairment	Reprimand or Censure	Indefinite
414098	2010	MT	Unable to Practice Safely: Alcohol or Other Substance Abuse	Probation of License	5 years
414098	2011	MI	Violation of or Failure to Comply w a Licensing Board Order	Voluntary Surrender of License	Indefinite
414098	2011	MT	Basis Code Not Required	Other Licensure Action	Permanent
428886	2010	GA	Allowing or Aiding Unlicensed Practice	Reprimand or Censure; Publicly Available Fine/Money Penalty	Indefinite
494355	2012	OK	Incompetence	Suspension of License	0.16 years
494355	2012	OK	Basis Code Not Required	Probation of License	1 year

SUMMARY OF PUBLIC COMMENT

Public Hearing Held Dec. 23, 2012

Perimeter Center

Henrico County

Written Comment accepted through January 4, 2013

Public Hearing:

Lee Bechtel and Mike Brown, representing the Virginia Perfusion Society, spoke in support of licensure for Perfusionists. In their opening comments, Mr. Brown noted that perfusionists affect surgical outcomes on over 6,500 patients in Virginia annually. He noted that perfusionists perform in complex surgeries, administer anesthetics and other drugs, and the FDA classifies perfusion devices in the highest category for risk of harm. He noted the surgeon's and anesthesiologist's ability to supervise while conducting surgery is limited. He also noted the expanding role of perfusionists in ICU Extracorporeal Life Support and in managing Ventricular Assist Devices.

Following Mr. Brown's opening statement, the committee engaged Mr. Brown and Mr. Bechtel in discussion. The committee sought additional information on the risk of harm posed by perfusion and the ability of licensure to reduce the risk of harm. They discussed the medical staff credentialing process. They discussed the supervision of perfusionists in the surgical suite. They discussed the supply and demand for perfusionists. They discussed the number of certified perfusionists, and the possibility of board-eligible perfusionists practicing.

Susan Ward, representing the Virginia Hospital and Health Care Association, answered questions posed by the committee but did not take a position on regulation of perfusionists at that time. Ms. Ward noted that individual job titles are not mentioned, but that the Joint Commission, CMS and Virginia Statute & Regulations oversee surgical staff and require periodic review of credentials. She also noted that liability concern provide an incentive to maintain staff qualifications.

A transcript of the public hearing is attached by reference.

Written Comment:

The Board received four comments from persons supporting professional regulation of Perfusionists:

Alex Sang Na, M.D. Medical Director, Cardiac Surgery, Mary Washington Hospital

Dr. Na noted that perfusionists perform specialized tasks including administering drugs. He noted cardiac surgeons rely on the independent medical judgment of perfusionists. He noted the need for appropriate training and education, and that the rest of the members of his surgical team are licensed.

R. Edward Houck, Member, Senate of Virginia, 1984-2012

Mr. Houck described the current situation of perfusionists as a public policy double standard. He noted that regulated education and training and the ability to monitor perfusionists will improve the safety of thousands of Virginia's each year. He noted perfusionists perform specialized tasks and administer drugs. He believes perfusionists should be held to the same standards as other vital medical professionals.

Mike Brown, CCP, Virginia Perfusion Society

Mr. Brown provided a statement clarifying that the VPS does not seek to restrict the practice of autotransfusionists, anesthesia techs or ecmo specialists/nurses. Rather, they seek to validate the minimal competency of perfusionists through licensure.

Lee Bechtel, CAE, CL; Virginia Perfusion Society

Mr. Bechtel provided information related to questions and issues raised during the public hearing. He noted a device failure occurs once in every 138 cases and patient deaths can be estimated at six persons per year. He noted that three Virginia perfusionists may not be certified. He noted the failure rate on certification exams is 18 percent and that there is no limit to the number of times a candidate may take the exam. He noted that there have been 38 disciplinary actions taken by 18 states that license perfusionists. He noted that surveys of perfusionists find certification and accreditation to be factors that reduce the risk of accidents. He noted that hospitals may not require certification of perfusionists and that the certification board may not revoke certification for incompetence. He noted that perfusionists are already highly compensated and that licensure would allow perfusionists more freedom to practice in medical teams and remove uncertainty about perfusionists who perform tasks regulated by other licensed professions.

The Board received two comments in opposition to regulation of perfusionists:

James W. Dunn, VP, Advocacy and Community Affairs, Bon Secours Virginia Health System

Mr. Dunn noted that regulation of perfusionists is not required and will not enhance hospital performance. He noted it will increase costs and staff time. He noted that it is not prudent to add additional layers of regulation in an era of health reform.

Susan C. Ward, Vice President and General Counsel, Virginia Hospital & Healthcare Association

Ms. Ward urged the Board to consider regulation in the context of its goals and its affect on the health system. She noted unjustified regulation raises obstacles and reduces workforce flexibility without improving care. She noted that VHHA is not aware of harm supporting regulation of perfusionists. She noted qualifications, training and performance of surgical staff are addressed by the Joint Commission, CMS, and Virginia Hospital regulations. She noted perfusionists practice under the supervision of licensed staff who are legally responsible for perfusionists. She noted hospitals are engaged in patient safety programs and participate in quality measurement and reporting programs. Ms. Ward provided documentation of relevant Joint Commission, CMS and Virginia Hospital standards.

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