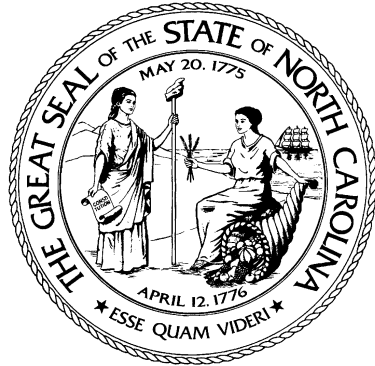


LEGISLATIVE COMMITTEE ON NEW LICENSING BOARDS

Assessment Report
For
PERFUSIONISTS

House Bill 903
Senate Bill 1059



LEGISLATIVE COMMITTEE ON NEW LICENSING BOARDS

April 27, 2005

The Legislative Committee on New Licensing Boards is pleased to release this assessment report on the certification of perfusionists. This report constitutes both the preliminary and final assessment report.

Representative Drew Saunders

**LEGISLATIVE COMMITTEE ON NEW LICENSING BOARDS
(2005-2006)**

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PREFACE

The Legislative Committee on New Licensing Boards is a 9-member joint committee of the House and Senate created and governed by statute (Article 18A of Chapter 120 of the General Statutes). The primary purpose of the Committee is to evaluate the need for a new licensing board or the proposed licensing of previously unregulated practitioners by an existing board. The Committee has been in existence since 1985.

The Committee solicits written and oral testimony on each licensing proposal in carrying out its duty to determine whether the proposal meets the following criteria:

- 1) Whether the unregulated practice of the profession can substantially endanger the public health, safety, or welfare, and whether the potential for such harm is recognizable and not remote or dependent upon tenuous argument.
- 2) Whether the profession possesses qualities that distinguish it from ordinary labor.
- 3) Whether practice of the profession requires specialized skill or training.
- 4) Whether a substantial majority of the public has the knowledge or experience to evaluate the practitioner's competence.
- 5) Whether the public can effectively be protected by other means.
- 6) Whether licensure would have a substantial adverse economic impact upon consumers of the practitioner's good or services.

The Committee issues an assessment report on its findings and recommendations. The recommendation in the report is not binding on other committees considering the proposal.

HOUSE BILL 903 and SENATE BILL 1059

PERFUSIONISTS LICENSURE

BACKGROUND¹

Current Standards.

Perfusionists have been recognized as a definable allied health profession by the American Medical Association since 1977. Working under the direct supervision of a surgeon, perfusionists are the only non-licensed health care professionals who routinely administer drugs and blood products to patients. A perfusionist is the person responsible for the selection, set-up, and operation of the heart-lung machine. To maintain life during open-heart surgery, the patient's heart must be stopped and the patient's blood is diverted outside the body, circulated through the heart-lung machine, and returned to the patient.

Certification by the American Board of Cardiovascular Profusion (ABCP) is currently the accepted state and national standard for perfusionists.² Perfusion has evolved professionally to a point where regulation is the next step in order to protect the patient from unqualified practitioners and to recognize the profession's higher standards and skills and the role they play in the complex technology of critical medicine. Toward that end, the perfusionists of North Carolina³ offer the proposed legislation enacting the Perfusionist Licensure Act.⁴

CERTIFICATION REQUIREMENTS

Who Must Be Certified.

On or after July 1, 2006, no person shall practice or offer to practice perfusion as defined in this Article, use the title 'licensed perfusionist', 'certified clinical perfusionist', or 'provisional licensed perfusionist', use the letters 'LP', 'CCP', or 'PLP', or otherwise indicate or imply that the person is a licensed perfusionist, clinical certified perfusionist, or a provisionally licensed profusionist unless that person is currently licensed or certified as provided in this Article.

Exemptions from Certification.

Persons who are not required to be certified include:

¹ **Source:** *Response to Questionnaire for the Legislative Committee for New Licensing Boards.* A copy of the questionnaire is attached to this report.

² To be certified by the ABCP, a person must be a graduate of a post-secondary perfusion education program, accredited by the AMA's Committee on Allied Health Education Accreditation, and successfully complete both the Perfusion Basic Science Examination and the clinical Applications in Perfusion Examination. To maintain certification, a perfusionist must complete 45 CEU credit hours of continuing education every three years and perform a minimum of 40 cardiac perfusions a year.

³ There are approximately 90 perfusionists practicing in North Carolina.

⁴ 11 states license perfusionists: Arkansas, Texas, Tennessee, Oklahoma, New Jersey, Missouri, Massachusetts, Illinois, Wisconsin, Louisiana, and Georgia.

- 1) Any person registered, certified, credentialed, or licensed to engage in another profession or occupation or any person working the supervision of a person registered, certified, credentialed, or licensed to engage in another profession or occupation in this State if the person is performing work incidental to the practice of that profession or occupation and the person does not represent himself or herself as a licensed perfusionist or a provisionally licensed perfusionist.
- 2) A student enrolled in an accredited perfusion education program if perfusion services performed by the student are an integral part of the student's course of study and are performed under the direct supervision of a licensed perfusionist.
- 3) A perfusionist employed by the United States government when performing duties associated with that employment.
- 4) A person performing autotransfusion or blood conservation techniques under the direct supervision of a licensed physician.

Initial Certification Requirements.

General Requirements: All applicants for certification must meet the following conditions:

- 1) Be at least 18 years old.
- 2) Complete an application on a form provided by the Committee.
- 3) Successfully complete a perfusion education program approved by the Committee.
- 4) Pay the required fee under G.S. 90-689
- 5) Be certified as a certified clinical perfusionist. An applicant shall be certified as a certified clinical perfusionist if the applicant submits proof satisfactory to the Committee that the applicant has been certified as a certified clinical perfusionist by the American Board of Cardiovascular Perfusion or its successor organization and pays the required fee under G.S. 90-689.

The proposed legislation provides that the Committee must issue a license to a person who meets the following requirements:

- 1) Has practiced perfusion in a licensed health care facility in the five years immediately preceding application for licensure or within five of the last eight years preceding application for licensure.
- 2) Applies for and obtains a license from the Committee within 90 days after the Committee begins issuing licenses.

Reciprocity: The Committee may grant, upon application and payment of proper fees, a license to a person who has been licensed to practice perfusion in another state or territory of the United States whose standards of competency are substantially equivalent to those provided in this Article or holds a current certificate as a certified clinical perfusionist issued by the American Board of Cardiovascular Perfusion or its successor organization.

Provisional license: The Committee may grant a provisional license for a period not exceeding 12 months to any applicant who has successfully completed an approved perfusion education program and pays the required fee under G.S. 90-689. A provisional license shall allow the individual to practice perfusion under the supervision and direction of a licensed perfusionist and in accordance with rules adopted pursuant to this Article. A license is provisional and stating the terms and conditions of its use by the licensee and shall state the date the license was granted and the date it expires. Provisional licenses shall be renewed in accordance with the provisions of G.S. 90-690.

Certification Renewal Requirements.

Renewal of licenses: All licenses to practice perfusion shall expire two years after the date they were issued. The Committee shall send a notice of expiration to each licensee at his or her last known address at least 30 days prior to the expiration of his or her license. All applications for renewal of unexpired licenses shall be filed with the Committee and accompanied by proof satisfactory to the Committee that the applicant has completed the continuing education requirements established by the Committee and the renewal fee as required by G.S. 90-689.

An application for renewal of a license that has been expired for less than three years shall be accompanied by proof satisfactory to the Committee that the applicant has satisfied the continuing education requirements established by the Committee and the renewal and late fees required by G.S. 90-689. A license that has been expired for more than three years shall not be renewed, but the applicant may apply for a new license by complying with the current requirements for licensure under this Article.

Fees. Fees are set by the Board and cannot exceed the following amounts:

Purpose of Fee	Fee Amount
Initial application	\$25.00
Issuance of license	\$350.00
Biennial renewal of license	\$350.00
Late renewal of license	\$100.00
Provisional license	Cost
Copies of rules	\$25.00

Disciplinary Actions. The Committee may deny, refuse to renew, suspend, or revoke an application or license or order probation or issue a reprimand if the applicant or licensee:

- 1) Gives false information or withholds material information from the Committee in procuring or attempting to procure a license.
- 2) Gives false information or withholds material information from the Committee during the course of an investigation conducted by the Committee.

- 3) Has been convicted of or pled guilty or no contest to a crime that indicates the person is unfit or incompetent to practice perfusion as defined in this Article or that indicates the person has deceived, defrauded, or endangered the public.
- 4) Has a habitual substance abuse or mental impairment that interferes with his or her ability to provide appropriate care as established by this Article or rules adopted by the Committee.
- 5) Has demonstrated gross negligence, incompetency, or misconduct in the practice of perfusion as defined in this Article.
- 6) Has had an application for licensure or a license to practice perfusion in another jurisdiction denied, suspended, or revoked for reasons that would be grounds for similar action in this State.
- 7) Has willfully violated any provision of this Article or rules adopted by the Committee.

CIVIL PENALTIES; DISCIPLINARY COSTS

Authority to Assess Civil Penalties: The Committee may assess a civil penalty not in excess of one thousand dollars (\$1,000) for the violation of any section of this Article or the violation of any rules adopted by the Committee. The clear proceeds of any civil penalty assessed under this section shall be remitted to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2.

Consideration Factors: Before imposing and assessing a civil penalty, the Committee shall consider the following factors:

- 1) The nature, gravity, and persistence of the particular violation.
- 2) The appropriateness of the imposition of a civil penalty when considered alone or in combination with other punishment.
- 3) Whether the violation was willful and malicious.
- 4) Any other factors that would tend to mitigate or aggravate the violations found to exist.

Schedule of Civil Penalties: The Committee shall establish a schedule of civil penalties for violations of this Article and rules adopted by the Committee.

Costs: The Committee may assess the costs of disciplinary actions against a person found to be in violation of this Article or rules adopted by the Committee.

GOVERNING BOARD

North Carolina Perfusion Advisory Committee. The Board shall consist of six members who shall serve staggered terms. The initial Committee members shall be selected on or before October 1, 2005 as follows:

- 1) The North Carolina Medical Board shall appoint three licensed perfusionists, two of whom shall serve a term of three years and one of whom shall serve a term of two years.
- 2) The North Carolina Medical Board shall appoint one physician who is licensed under Article 1 of Chapter 90 of the General Statutes and is a cardiothoracic surgeon or a cardiovascular anesthesiologist, who shall serve a term of two years.
- 3) The North Carolina Hospital Association shall appoint one hospital administrator, who shall serve a term of one year.
- 4) The Governor shall appoint one public member, who shall serve a term of one year.

Powers of the Committee. The Committee shall have the power and duty to:

- 1) Administer this Article.
- 2) Issue interpretations of this Article.
- 3) Adopt, amend, or repeal rules as may be necessary to carry out the provisions of this Article.
- 4) Employ and fix the compensation of personnel that the Committee determines is necessary to carry into effect the provisions of this Article and incur expenses necessary to effectuate this Article.
- 5) Determine the qualifications and fitness of applicants for licensure, provisional licensure, licensure renewal, and reciprocal licensure.
- 6) Issue, renew, deny, suspend, or revoke licenses, order probation, issue reprimands, and carry out any other disciplinary actions authorized by this Article.
- 7) Set fees for licensure, provisional licensure, reciprocal licensure, licensure renewal, and other services deemed necessary to carry out the purposes of this Article.
- 8) Establish continuing education requirements for licensees.
- 9) Establish a code of ethics for licenses.
- 10) Maintain a current list of all persons who have been licensed under this Article.
- 11) Conduct investigations for the purpose of determining whether violations of this Article or grounds for disciplining licensees exists.
- 12) Maintain a record of all proceedings and make available to all licensees and other concerned parties an annual report of all Committee action.
- 13) Adopt a seal containing the name of the Committee for use on all official documents and reports issued by the Committee.

FINDINGS AND RECOMMENDATIONS

Findings. The Legislative Committee on New Licensing Boards finds that the sponsors have met the six criteria by which the Committee judges licensure proposals. Specifically, the Committee finds that:

- (1) The unregulated practice of perfusion can substantially harm or endanger the public health, safety, or welfare since perfusionists operate mechanical support devices, such as the heart-lung machine, intra-aortic balloon pump, and the extra-corporeal membrane oxygenator.
- (2) The profession possesses qualities that distinguish it from ordinary labor since perfusionists must know basic anatomy, physiology, pharmacology, and pathology as well as undergo both didactic and practical training in the use of extra-corporeal circulation.
- (3) The practice of the perfusion requires specialized skill or training.
- (4) A substantial majority of the public does not have the knowledge or experience to evaluate the competence of a perfusionist.
- (5) The public cannot be effectively protected by other means.
- (6) Licensure would not have a substantial adverse economic impact upon consumers of the perfusionist's services.

Recommendation. The Legislative Committee on New Licensing Boards recommends the licensing of perfusionists. This assessment report constitutes both the preliminary and final assessment report for the licensure of perfusionists. The report is based on the proposed licensing of perfusionists as set out in House Bill 903 and Senate Bill 1059, the response to the Committee's questionnaire (Attachment), and testimony before the Committee on April 25, 2005.

ATTACHMENT

Response to Questionnaire for the Legislative Committee on New Licensing Boards

QUESTIONS FOR THE
LEGISLATIVE COMMITTEE ON
NEW LICENSING BOARDS

1. In what ways has the marketplace failed to regulate adequately the profession or occupation?

The practice of perfusion is defined as those functions necessary for the support, treatment, measurement, or supplementation of the cardiopulmonary and circulatory system of the patient. A perfusionist is a skilled person, qualified by academic and clinical education that operates extracorporeal circulation equipment during any medical situation where it is necessary to support or replace the patient's cardiopulmonary/circulatory function and ensures the proper management of physiologic functions by monitoring the necessary variables. These duties, upon prescription by a physician and in accordance with hospital policy, include but are not limited to the safe performance and/or management of:

Extracorporeal circulation/cardiopulmonary support, counter pulsation, circulatory support/ventricular assistance, extracorporeal membrane oxygenation (ECMO), blood conservation techniques/auto transfusion, myocardial preservation, anticoagulation and hematological monitoring/analysis, physiological monitoring/analysis, blood gas and blood chemistry monitoring/analysis, induction of hypothermia/hyperthermia with reversal, hemodilution, hemofiltration, administration of medications, blood components and anesthetic agents via the extracorporeal circuit and documentation extracorporeal circuit and documentation.

The improper management of perfusion devices and techniques, or unavoidable accidents in the hands of skilled perfusionists often results in death or severe impairment to the patient. Replacing a patient's blood flow, pulmonary function or blood volume requires the ability to respond instantaneously to changes in patient status or device function. The skilled perfusionist draws upon experience, scientific principles and training to

rapidly assess clinical situations, effect smooth and safe resolution of problems and manage problems and manage routine cases. Marketplace factors which might limit a practitioner's employment or service contract would only become effective after the clinician had been involved in several perfusion accidents, with the resulting dire patient consequences. The death or harm to numerous patients is clearly too high a price for the health care consumer to pay, when qualifications and suitability can be regulated and assured ahead of time.

Perfusion is a low profile entity. Most cardiac patients are unaware of the existence or importance of this member of the open heart team, and a poor patient outcome due to a "pump accident" is more likely to reflect on the surgeon than the perfusionist—thus the marketplace control may be misplaced in limiting the surgeon's referrals rather than weeding out the incompetent technologist. While the affected surgeon will likely exert a control on the perfusionist's future employment at that hospital, dependence on such a system of control is unfair to the surgeon, unsafe for the public and damaging to the profession. There is no disciplinary action in place to keep an incompetent perfusionist from just moving to another hospital down the street. Clearly, the public safety and welfare is better served by preventative measures than retroactive punishment, when the risk to the patient is so high.

Currently, no regulations exist to guarantee the employer or perfusionists or the surgeon that an individual representing himself as a perfusionist is qualified. Waiting for the marketplace to sense a pattern of clinical failures which might affect physicians' referral patterns is a roundabout and unacceptable means of regulation. Although there are anecdotal reports of patient hazard resulting from care by unqualified perfusionists, the private nature of the physician-patient contract and resulting litigation make documentation impossible to obtain.

2. Have there been any complaints about the unregulated profession or occupation?

Please give specific examples including (unless confidentiality must be maintained) complainants' names and addresses.

It has been noted that possibly one patient per thousand cases performed result in injury or death associated with the heart lung machine. Based on the above, if there were 13,000 to 17,000 procedures performed by perfusionists each year in North Carolina this would equate to 13 - 17 injuries or deaths per year. Cardiac surgery itself carries a 3% mortality (death) rate both state wide and nationally. Taking the average number of procedures that are done in our state (15,000 times a mortality rate of 3%), gives you approximately 450 deaths in North Carolina per year. Risk management reviews most of these incidents internally. This information is very seldom if ever shared with any outside sources. In the extremely complex nature of cardiac surgery it is often not one single catastrophic event that causes the injury or death. Most of the time, an undesirable outcome is due to many smaller things that fail or go unnoticed during the procedure or the overall health of the patient. The incidents involving perfusionist are remarkably low and difficult to track. This however does not remove the responsibility or liability of that health care professional. A greater effort and responsibility falls to us as professionals to have a mechanism in place to prevent those who are incapable from jeopardizing the health, safety and welfare of North Carolinians. Licensure will assure the people of North Carolina that the quality of education and clinical practice of perfusion will remain at the forefront and prevent those few unqualified professionals from continuing to practice in our state.

3. In what ways has the public health, safety or welfare sustained harm or is in imminent danger of harm because of the lack of state regulation? Please give specific examples.

Perfusion is a demanding profession, requiring a unique combination of highly specialized medical and mechanical training. The proposed regulation will serve to protect the consumer public from untrained and unqualified practitioners performing critical medical procedures and/or operating in a capacity beyond their expertise. Does this go beyond freedom from Harm? Yes. The cardiac team functions like a machine in requiring all of its members to utilize their expertise unison. This maximizes the outcome of the procedure and shortens the patient's length of stay in the hospital, reducing medical care costs. Currently all cardiac

team members are regulated except the perfusionists. Essentially the person who can do the most harm to the patient goes un-regulated.

Patients (and their families) about to undergo open-heart surgery, coronary angioplasty, coronary stenting or any of a variety of general surgeries require and deserve protection. These patients do not question the expertise of members of the surgical team, assuming that all are suitably qualified to perform their respective jobs. There is not any consumer group that would not benefit from this regulation and it would be capricious to suggest that there is a part of the public population that would be less affected. Anyone who is about to undergo surgery should have the guarantee of the best quality care. If this regulation is enacted all consumers will enjoy equal benefit knowing that members of the surgical team are qualified.

4. Is there potential for substantial harm or danger by the profession or occupation to the public health, safety or welfare? How can this potential harm or danger be recognized?

Charles C. Reed and Trudi B. Stafford, 1989 have reported it in the second edition of Cardiopulmonary Bypass, that “the number of injuries or deaths from accidents during perfusion was one per 1000 cases performed”. One of the most catastrophic accidents is arterial air embolism. This can result from inattention by the perfusionist to the level of the blood in the reservoir in the heart lung machine. Loss of blood flow to the heart lung machine can result in emptying of this reservoir and pumping massive amounts of air into the patient. This scenario can occur in less than 15 seconds. Massive amounts of air into the brain can result in a persistent vegetative state or death to the patient. There are also a variety of other perfusion related causes of air embolism.

Perfusionists are required to add various drugs, IV fluids and blood products during the course of cardiopulmonary bypass. Errors in drug doses, wrong drugs, incompatible blood products, inappropriate

speed of administration can result in a variety of physical effects, including extremely low or high blood pressure, fibrillation of the heart, or depression of the heart muscle function. Errors in IV fluids can generally be tolerated by an adult patient, but can be lethal to an infant on cardiopulmonary bypass. The possible effects of adding the wrong solution could include the swelling of cells and tissues of the body, aberrations in electrolyte levels, or inappropriate increase of the serum glucose level.

The physical, social, intellectual, financial, or other consequences to the consumer of services resulting from incompetent practitioner practice include the deleterious effects of blood administration to patients. The possibilities of infecting a patient with AIDS or hepatitis virus have been well documented as two of the more serious hazards. The perfusionist is frequently involved in the decision to transfuse blood to a patient on cardiopulmonary bypass. The decision is always with the approval of a physician. The perfusionist does have the responsibility of making sure that the blood has been typed and crossed matched to the patient prior to administration through the extracorporeal circuit. There have been mistakes in the administration of incompatible blood types, which can cause many catastrophic outcomes for the patient including but not limited to renal failure, embolic episodes and death.

The perfusionist is responsible for controlling the cooling or warming of the patient's blood and therefore, the patient's body. This accomplished by using a device called a heater cooler unit and a heat exchanger. The perfusionist controls and monitors the temperature of the water bath in the heater cooler unit. This water is circulated to the heat exchanger, which is a series of metal tubes that allows the water to circulate on one side while the patient's blood circulates on the other side. If the temperature gradient between the water and blood becomes too great, while attempting to warm the patient, air bubbles may begin to appear in the patient's blood, leading to possible organ damage from air

embolism. Another dire consequence can occur if there is a leak in the metal tubing of the heat exchanger which would result in water to blood leak. The patient's red blood cells would be irreversibly damaged from this event. It is the perfusionist's responsibility to check the integrity of the heat exchanger prior to patient use.

The perfusionist is responsible for utilizing sterile technique while assembling and priming the extracorporeal circuit. Breaks in sterile technique are frequently known only to the offending practitioner. It is imperative that this person has the integrity to correct the situation, even if it means dismantling the heart lung circuitry and starting again.

Clearly, the physical impairment resulting from these untoward events can leave a patient and his family with major impact on their financial standing, as well as attendant social and emotional factors. The most common long-standing effect of a perfusion accident is neurological damage, which permanently alters the patient's intellectual function, often removing him from his work force or society at large. This type of patient also represents a greatly increased financial burden on society, both in terms of post-operative care, and long-term rehabilitation. Frequently, death is the outcome of such an accident, with all the devastating effects on the survivors.

The legal remedies available to redress consumer injury and abuse are the same as those available surrounding any malpractice incident, i.e. the use of litigation through the judicial system or arbitration.

Administrative remedies that may impact perfusion services but are not routinely available to consumer utilization exist within the hospital. These include but may not be limited to: the use of "Incident Reports", an internal reporting of unusual occurrences or behaviors that are reviewed by clinical and risk managers; the utilization of hospital staff committees such as the Ethics Committee, Allied Health Professionals Committee and Cardiac or Cardiology Subsections that review client care patterns, which fall outside the expected norm.

The current available remedies are generally sufficient to address consumer injury. However, they are not sufficient to limit or prevent consumer injury or abuse. The same criticisms that are offered about the existing malpractice litigation system should be considered. Litigation does little to prevent injury to the client and seldom provides a restoration of health or lifestyle to levels existent prior to the injury.

5. Has this potential harm or danger to the public been recognized by other states or the federal government through the licensing or certification process? *Please list the other states and any applicable federal law (including citations).*

Perfusionists have been recognized as a definable allied health profession by the AMA since 1977. As a young and rapidly growing specialty, practitioners have been active for the past several years constructing and consolidating the agencies and organizations necessary for a medical profession: educational organizations, scientific journals, accreditation board, and voluntary certification board. Perfusion has now evolved as a profession to a point where governmental regulation is the next step both to protect the patient from the high liability of unqualified practitioners, and to recognize the unique and high level of medical judgment and skill and its important role in critical medicine. New Jersey's State Medical Practice Act has regulations citing the number of perfusionists who must be present during cardiopulmonary bypass and their requirement for certification or qualification. Currently, Arkansas, Texas, Tennessee, Oklahoma, New Jersey, Missouri, Massachusetts, Illinois, Wisconsin, Louisiana and Georgia have passed mandatory licensing for their perfusionists. California has passed mandatory titling for their perfusionists. Several states such as Pennsylvania, New York, Kansas and Connecticut are in the process of licensure.

6. What will be the economic advantage of licensing to the public?

- a. *Increased quality of care; decrease length of stay in the hospital.*
- b. *Decrease in contained health care costs.*
- c. *Decreased out of pocket expenses for the patient.*
- d. *Decrease in private insurance, Medicare and Medicaid payments.*
- e. *Back to work sooner avoiding excessive loss of income.*

7. What will be the economic disadvantage of licensing to the public?

There will be no economic disadvantage of licensing to the public since all expenses will be paid for by practitioners license fees.

- a. *Cost of program administration, including may be compared to the costs associated with an existing state board which fall to the practitioner and not passed on to the public. Since we will be under the North Carolina Medical Board costs will be less and paid for with licensing fees.*
- b. *There will be no costs of developing and/or administering examinations to the public or government since we will be using the existing ABCP which is paid for by the practitioner.*
- c. *Costs associated with enforcement programs will utilize the court system and therefore no associated program costs.*

8. What will be the economic advantage of licensing to the practitioners?

- a. *There is no economic advantage of licensing to the practitioner. Licensing will not create an avenue for higher salaries in North Carolina and has not shown to be the case in the 12 states that have mandatory licensing for perfusionists. These states include Texas, Missouri, Oklahoma, Arkansas, Illinois, Tennessee, New Jersey, Massachusetts, Georgia, Wisconsin, California and Louisiana.*
- b. *Future changes in tort reform may serve as an economic advantage to the practitioner by providing capitation of monetary awards which may result in a decrease of malpractice insurance premiums (perfusionist pay approximately \$6000.00 per year and are considered Class V care givers. E.g. emergency room physicians).*

c. *In at least one state (Va.), un-licensed health care providers are not covered under the capitation of 1.5 million dollars per occurrence law. This means that for a non-licensed perfusionist there is no protection from exorbitant malpractice awards.*

9. What will be the economic disadvantage of licensing to the practitioners?

The will be the costs associated with the licensure process and the fees associated with license application.

- a. *Cost of program administration, including may be compared to the costs associated with an existing state board which fall to the practitioner and not passed on to the public. Since we will be under the North Carolina Medical Board costs will be less and paid for with licensing fees.*
- b. *There will be no costs of developing and/or administering examinations to the public or government since we will be using the existing ABCP which is paid for by the practitioner.*

10. Please give other potential benefits to the public of licensing that outweigh the potential harmful effects of licensure such as a decrease in the availability of practitioners and higher costs to the public.

There is evidence of “net” benefit when the following possible effects of regulation are considered:

- A. *Restriction of opportunity to practice: Perfusion is a complex technology, which should be restricted to those who have demonstrated training and competence through a formal examination process. The proposed legislation will ensure that all practitioners have met the educational and experiential prerequisites set forth by the regulating board before being allowed to practice in this state. Since 50 % (another 25 % are eligible) of the perfusion community nationwide and 88-90 % in the state meet the proposed entry*

requirements, this regulation will not be unduly restrictive. The net benefit will be a higher standardization of patient care.

- B. Restricted supply of practitioners: The perfusion schools nationwide have kept up with demand for qualified personnel and this regulation will in no way affect the supply of practitioners.*
- C. Increased costs of service to consumer: The cost to the consumer should not increase, since the responsibility for obtaining a license that of the practitioner, and all costs of the regulation should be covered by the licensing fees.*
- D. Increased governmental intervention in the market place: The need for public safety in critical care medicine outweighs the burden of governmental intervention. Additionally, the proposed legislation is written with the intent to screen qualifications not to control or restrict the application of the medical services and providers. The net benefit will be a higher standardization of patient care.*

11. Please detail the specific specialized skills or training that distinguishes the occupation or profession from ordinary labor.

The perfusion practitioners make judgments of consequence, independently, on a daily basis and continually during the operation of the heart lung machine. They are responsible for the choices of oxygenators (artificial lungs), blood circuitry, degree of hypothermia for specific procedures and often for choices of arterial and venous cannulae; they make decisions during the heart lung machine operation which determine the safety margin provided the patient (such as the operating blood level in the oxygenator to prevent the passage of air emboli to the patient's

arterial system). *Cardiopulmonary Bypass is a dynamic system in which changes occur minute to minute. The perfusionist constantly adjusts and responds to the surgeons' actions or the patient's fluctuations, which can drastically affect the function and safety of the bypass system. Thus perfusionists are required to constantly make judgments of consequence when performing cardiopulmonary bypass for cardiac surgery. Consequences may result from improper conduct of perfusion during operation of the heart-lung machine.*

1. *Post perfusion neurological damage resulting from hypoxia (inadequate oxygen delivery) or emboli leading to stroke, paralysis or impaired mentation.*
2. *Post perfusion pulmonary insufficiency leading to shock-lung, "pump" lung (micro-emboli throughout the lung tissue), or pulmonary edema.*
3. *Renal complications requiring diuretics or dialysis.*
4. *Hepatic congestion or alteration of hepatic function due to hypoxia, emboli or drug reactions.*
5. *Necrosis of cutaneous circulation or tissue due to inadequate control of anticoagulants.*
6. *Destruction of blood components due to improper heart-lung machine operation, fluid additions or drug additions resulting in anemia, bleeding and low blood protein.*
7. *Transmission of transfusion-related diseases such as AIDS or hepatitis.*
8. *Virtually any degree of physiological or neurological damage or impairment to the extent of death.*

Practitioners working as or for independent contractors or surgeon employed constitute 30% of the total perfusion work force in the state. As, such, they may be less directly supervised by the hospital administrative structure at the clinical level. As with their hospital

employed counterparts, they are under the general supervision of the physician-in-charge in all clinical situations. perfusionists working under the auspices of an organization, employer or supervisor still function with a high degree of independence in performing their work. Although the surgeon is supervising the perfusionist and may provide protocols as a guide, the actual decision-making is taking place at the heart lung machine by the perfusionists on a minute-to minute basis. When problems occur, split second analysis and response is required, without time for consultation with the supervising physician. While a nurse anesthetist can call the anesthesiologist and the physician assistant can call their supervising physician if there is a problem, the perfusionist does not enjoy that luxury. The perfusionist is the only one in the room with the knowledge and understanding of the heart lung machine and how to fix it if there is a problem. If the perfusionist is working alone, there may be no one to call if a problem arises and therefore must handle the situation alone. The growth in the complexity of perfusion technology, and the proliferation of device options have recently resulted in the physician finding himself or herself unfamiliar with the intricacies of the machinery utilized during cardiopulmonary bypass.

The types of decisions made by the perfusionists rely upon a firm knowledge of perfusion science, physics and physiology, as well as, protocols derived in consultation with the physician. The data, which comprises perfusion science, is unique and highly technical and does not relate to any other allied health profession. To varying degrees, complications may arise during cardiac surgery, which require the surgeon's complete focus, leaving the perfusionist totally responsible for decisions regarding the conduct of perfusion. It is during these critical times when a perfusionist must perform quickly and independently with a high degree of cognitive medical skill, knowledge and strategy in assisting the surgeon to provide life saving measures of patient care.

The proposed regulatory scheme positively defines a scope of activity, which requires licensing of this occupation. Evidence of this can be found in reviewing the scope of practice section of the proposed legislation and learning that many of the techniques used by perfusionists rely on knowledge of principles which are not taught in the curricula of any other allied health profession. There are subject areas, which are unique to perfusion science and are not similar to curricular items in other allied health professions course work. They include training in: blood propelling devices, hemodilution, myocardial preservation, hypothermia, perfusion circuitry, right and left heart bypass, ventricular assist devices, total artificial heart, pulsatile perfusion techniques, circulatory arrest, perfusion of the pregnant patient, total body washout, hypothermic resuscitation perfusion, isolated limb perfusion. Retrograde coronary perfusion, immuno-hematology, portable cardiopulmonary support, level sensing and coagulation management (for the fully anticoagulated patient). In particular, many techniques in common use require that the patient be subjected to conditions, which are unnatural and aphysiologic, such as intentional severe hemodilution, anticoagulation and hypo or hyperthermia. The dangers inherent in thus altering normal human physiology are significant if the techniques are not properly understood and applied. Only fully trained perfusionists should attempt to utilize these techniques. Their qualifications to perform these tasks are best assured through professional licensing.

A 1995 national survey of perfusion practitioners by AmSECT addresses this question. The survey shows that the primary functions of a perfusionist are cardiopulmonary bypass, myocardial preservation, body fluid management, including the management of drugs, blood components, crystalloid solutions and the control of physiologic blood gases and pressures, anticoagulation and the assembly and operation of cardiac support devices. This national survey tracks closely to the primary functions of a perfusionist in the state.

The job description for perfusion always includes: physiologic monitoring of patient's vital signs (ECG, all physiologic blood pressure and coronary blood flow measurements); interpretation of hemodynamic and physiologic data during CPB in consultation with the surgeon and anesthesiologist; appropriate actions to maintain or improve the best physiologic condition of the patient; and calibration and maintenance of all equipment utilized in association with CPB or related procedures. The perfusionist may also be involved in assisting the design and fabrication of new specialty perfusion circuits, catheters, etc., assisting surgeons in refining new operative procedures in cardiovascular research labs before clinical introduction in the operating room; assisting other medical professionals in developing specialty perfusion projects; acting as a consultant to develop new applications of perfusion technology (such as isolated limb perfusion for treatment of melanoma, controlled cryonics for neurosurgery and hyperthermia for the treatment of AIDS); teaching and providing in-service training for pre-op and post-op cardiac care nurses, physicians in training, and other allied health professionals on the principles of CPB, intra-aortic balloon pumping. Cell salvage, etc., training new perfusionists; compilation of data and preparation of research papers for presentation at local and national medical meetings.

12. What are other qualities of the profession or occupation that distinguishes it from ordinary labor?

The operation of the heart lung machine is exclusively in the domain of the perfusionists, due to its unique nature. Those without perfusion training cannot safely operate cardiac assist devices and extracorporeal temperature regulating devices. As stated above, most of the commonly applied techniques of perfusion require extreme alteration of the patient's normal physiology, and highly specialized education and training are necessary to ensure the safety of these techniques: hyperthermia (as in Isolated Limb Perfusion for melanoma, or for

treatment of AIDS), controlled cryonics (as in some neurosurgery), deep hypothermia for circulatory arrest (as in pediatrics for cardiac malformation and aortic aneurysms in adults), total anticoagulation (used in all cardiac surgeries) and severe hemodilution (used in most cardiac surgeries) all constitute inherent hazards to the patient if improperly applied or inadequately reverse. Although Registered Nurses, Certified Nurse Anesthetists, Physician Assistants and Respiratory Therapists are regulated in the state and have high levels of responsibility similar to those of a perfusionist, none have in their core curricula or knowledge base for examination the principles or techniques needed to master these common perfusion practices.

Perfusionists cannot be legitimately considered as a branch of any currently regulated occupation in the state due to the nature of the scope of practice for this profession. Considering the high level of cognitive medical skill required, the manner in which perfusionists perform patient care, and the utilization of independent medical judgment, individual regulation of this health care specialty is warranted.

13. Will licensing requirements cover all practicing members of the occupation or profession? If any practitioners will be exempt, what is the rationale for this exemption?

Since most of the formalized perfusion training programs only came into being in the late 1970's, along with the establishment of accreditation and certification, many perfusionists are still in practice who were trained "on the job" (OJT) before schools were available. Most of these clinicians were grandfathered in with the first round of the American Board of Cardiovascular Perfusion (ABCP) certification in 1972. Since 1981 OJT's (less than 1% of North Carolina Perfusionists) have not been allowed to take the ABCP exam. The remaining 99% of the current perfusion community was trained in accredited programs,(or

certified under the grandfather clause) with the number rising steadily as the original OJTs reach retirement age and/or leave the profession.

As, proposed, the perfusion licensing legislation extends grandfathering to only those perfusionists who can document that they have been clinically active performing cardiopulmonary bypass (CPB) during cardiac surgery in a licensed health care facility in North Carolina for 5 years immediately preceding application to the Board, or within 5 of the last 8 years preceding application to the Board.

Clinical care would be disrupted and the ability of hospitals to continue to perform cardiac surgery would be severely impaired if these practicing perfusionists were not allowed entry to the regulated group. The number of students graduating from Commission on Accreditation of Allied Health Education Programs (CAAHEP) accredited schools has grown, guaranteeing that there will be adequate numbers of perfusionists who readily meet the proposed entry criteria. In the meantime, the current workforce needs to be included if all patients are to be treated. Once licensed, all practicing perfusionists will be required to engage in continuing education (CE) for purposes of license renewal. Such efforts are now only voluntary, and not undertaken by some of those who fall into the “grandfather” category. The legal requirement for them to stay abreast of changes in the field through CE will elevate the level of knowledge in the perfusion community and improve patient care and safety.

14. What is the approximate number of persons who will be regulated and the number of persons who are likely to utilize the services of the occupation or profession?

There are now 88 practicing unlicensed perfusionists in North Carolina. They are all involved in at least 150 – 200 open heart, cardiovascular or cardiothoracic cases per year on infants, children, adolescents and adults. As well as other specialties within the hospital that may require specific

procedures performed by the perfusionist. That translates to 13,200 – 17,600 people who will utilize the services of a perfusionist. These numbers will most likely increase as the population of North Carolina advances in age.

15. What kind of knowledge or experience does the public need to evaluate the services offered by the practitioner?

Clients have no direct control over their exposure to risks from perfusion other than limiting their exposure to cardiac or cardiovascular procedures. They indirectly can exert control over their exposure to risk through careful selection of hospital and physician services. (Some states offer a consumer guide referred to as the HC4 Data (Health Care Consumer Cost Containment Data) for the consumer to be able to choose the cardiac surgeon and hospital based on published Coronary Artery Bypass Surgery Results). Similarly, clients do not directly locate or select perfusion services. In selecting hospitals or physicians for medical treatment, clients will be accepting the existing services provided to the client's physicians. Perfusion services may be provided through employment by the hospital, employment by the physician or through contract services provided by an independent perfusion service.

Current sources to inform consumers of the inherent risks of perfusion services rely on the informed consent process involved in receiving any cardiac or cardiovascular treatment in the hospital setting. Consumers are reliant on the information received from the physicians and the ensuing discussions regarding the treatment. The Perfusion Practitioner has no control over the information delivered to the client. Seldom is there any differentiation between the general risks of cardiac/cardiovascular surgery and the specific risks to the client from perfusion services. There are no sources available to the consumer separate from information that the consumer's physician may provide about competent or incompetent performance or perfusionists.

Consumers are reliant upon the decisions made by their physicians as to acceptance or rejection of practitioner behaviors.

16. Does the occupational group have an established code of ethics, a voluntary certification program or other measures to ensure a minimum quality of service?

The perfusion profession has in place a Professional Code of Ethics, Codes of Practice enforced by Professional Associations, Dispute-Resolution mechanisms such as mediation or arbitration, Recourse to current applicable law, Regulation of those who employ or supervise practitioners and Other previous measures attempted.

The only mechanism currently in place to protect the cardiac patient from unqualified perfusionists is the Joint Commission on Accredited Health Organization (JCAHO) requirement that hospitals “credential” all health care workers and physicians. Credentialing is done through a random hospital inspection process by the JCAHO. The process often consists of no more than the completion of an application form. The hospital administration is confronted by a profession which comprises very few workers, whose scope of practice is not legally defined. In most cases the administration does not have access to criteria on which to judge performance, education or training. Most often they have to rely on the perfusionists themselves to determine their own criteria for employment, certification and training. Clearly, the range of control, and therefore assurance of public safety is broad. It must be stressed that the certification process for perfusionists is voluntary and that in some hospitals in our state certification may not be required.

A Code of Ethics: Three professional organizations, the American Society of Extra-Corporeal Technology (AmSECT), the American Academy of Cardiovascular Perfusion (AACP) and the certifying agency, the American Board of Cardiovascular Perfusion (ABCP) publish codes of ethics for perfusionists. While these are useful as a construct and

guidepost, membership in any of these groups is voluntary and censure from any of them is very unlikely to affect one's ability to practice. To protect against litigation, the very few instances of action against a perfusionist for unethical conduct by any of these organizations remain closely guarded secrets within the respective ethic committees. This certainly does little harm to the person charged and does not affect a perfusionist's ability to continue to deliver perfusion services.

Codes of Practice enforced by Professional associations: Only recently has AmSECT or the AACP undertaken the task of defining standards of practice. Those which exist cover general topics: the use of perfusion checklists, safe patient management, proper record-keeping and adequate staffing. As in most medical professions, these organizations shy away from specific codes of practice for fear of litigation (i.e. from a practitioner involved in a malpractice suit in which the prosecution cites a violation of the code as evidence of negligence, when that practitioner asserts that the code is incorrect, biased, out-dated, etc.). In any case, these associations have no means of enforcement, since membership is voluntary. Their educational efforts serve to unify community care standards to a degree, but this does nothing to assure the public that the local perfusionist applies the recommended safeguards and techniques.

Dispute-resolution mechanism such as mediation or arbitration: perfusion malpractice results in fatalities or great bodily harm. These cases are dealt with through litigation or settlement with insurance carriers, not through mediation. As discussed earlier, this addresses the injury after the fact, rather than pro-actively attempting to safeguard against it. Perfusion competence is a tangible safety issue, not an area of abstract debate or dispute.

Recourse to current applicable law: There are no laws in the state, which address the issue of perfusionists in any way. The only laws, which in any way affect an unqualified perfusionist, are the tort laws and

malpractice statutes. As stated earlier punishment after the patient has been harmed is less desirable than regulatory attempts to prevent it.

Regulation of those who employ or supervise practitioners: This is currently the most effective control on the quality of care offered by perfusionists. But, as stated above, the hospital administrators who hire or contract perfusionists, and the physicians who supervise them have no access to accepted criteria for judging the adequacy of training, experience, or the need for certification of these professionals, or even the validity of the certification process. Further, very few of the physicians and administrators charged with supervising and evaluating perfusion teams are well versed in this complex high-tech specialty, which renders them incapable of assessing competence. Fair employment laws, and the realization that accidents statistically occur, increase the likelihood that an unqualified practitioner will have to precipitate multiple clinical disasters before he can be legitimately removed from his position. This does not serve the interest of public safety. There is also nothing to stop a perfusionist who has been released from employment due to continual mishaps to go to the hospital down the street and apply for employment. Due to the confidential information surrounding the dismissal of a perfusionist, one employer may not be permitted to divulge pertinent information regarding work performance or professional ethics. The extent of risk incurred in this field is not universally understood.

Other previous measures attempted: There are hospitals in the state, which require ABCP certification or eligibility for acceptance of perfusion applicants. This is voluntary, and therefore not all patients are protected. However, it is important to realize that even a regulation requiring hospitals to employ only certified perfusionists would only be a halfway measure. Currently each hospital decides which patient care areas are assigned to unlicensed medical providers, often using nothing more than precedent as a guide. A well-considered definition of perfusion services is necessary if safety standards are to be firmly established.