

The Florida Senate
BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL: SB 912

INTRODUCER: Senator Peaden

SUBJECT: Clinical Perfusionists

DATE: April 10, 2010

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Harper	Wilson	HR	Pre-meeting
2.	_____	_____	GO	_____
3.	_____	_____	HA	_____
4.	_____	_____	_____	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

I. Summary:

This bill provides for regulation of clinical perfusionists under the jurisdiction of the Board of Medicine and the Board of Osteopathic Medicine. The regulation would allow clinical perfusionists to practice within the framework of a protocol prescribed by or under the supervision of a medical or osteopathic physician.

The bill specifies duties that clinical perfusionists may perform, and specifically prohibits certain medical services. A clinical perfusionist must clearly convey to a patient that he or she is a clinical perfusionist. The bill establishes certification and certification renewal requirements for clinical perfusionists, provisional clinical perfusionists, and temporary clinical perfusionists, and specifies the practice of a perfusionist in training (and provides exemptions from the requirements of this bill for certain health care practitioners). The bill allows certain perfusionists or clinical perfusionists to be grandfathered into the profession if they meet specified requirements. The bill provides the Board of Medicine and the Board of Osteopathic Medicine with the authority to approve programs for the education and training of clinical perfusionists.

The bill requires clinical perfusionists, as a prerequisite for certification or certification renewal, to maintain medical malpractice insurance or provide proof of financial responsibility to cover claims arising out of the rendering of or failing to render professional care and services in Florida (and provides exemptions for certain clinical perfusionists). The bill requires a physician who supervises a clinical perfusionist to be qualified in the medical areas in which the clinical perfusionist performs.

The bill specifies certain duties and responsibilities of the Board of Medicine and the Board of Osteopathic Medicine, and authorizes the boards to establish rules in regard to clinical perfusion.

The bill authorizes the Board of Medicine and the Board of Osteopathic Medicine to deny, suspend, or revoke the certification of a clinical perfusionist for violating provisions of this bill.

The bill establishes fees for initial application for certification as a clinical perfusionist and for certification renewal, and requires the DOH to allocate the fees collected to the Board of Medicine and the Board of Osteopathic Medicine. The bill provides that a hospital is not required to pay for, or reimburse any person for, the costs of compliance with any requirement of this bill.

This bill substantially amends s. 456.048, Florida Statutes.

This bill creates section 468.901 of the Florida Statutes.

II. Present Situation:

Clinical Perfusion

A clinical perfusionist operates the heart-lung machine that diverts a patient's blood and takes over the functions of the patient's heart, lungs, kidneys, liver and other organs as needed during cardiac surgery. A clinical perfusionist operates extracorporeal circulation equipment during any medical procedure where it is necessary to support or replace a patient's cardiopulmonary or circulatory functions. During such a procedure, the clinical perfusionist must manage the patient's physiologic functions by monitoring the patient. A clinical perfusionist is knowledgeable about the equipment used to perform extracorporeal circulation functions and consults with the patient's physician for the appropriate equipment and techniques to be used in the clinical procedure.

The proponent seeking regulation of perfusionists in Florida is the Florida Perfusion Society. In response to a Sunrise questionnaire, the Florida Perfusion Society estimates, based on information provided by the American Board of Cardiovascular Perfusion (ABCP), that there are 225 certified clinical perfusionists and 20 clinical perfusionists in Florida. The Board of Medicine and the Board of Osteopathic Medicine reported that perfusionists are well-educated, allied health care professionals who assist in over 28,000 open-heart procedures annually, with few, if any, reports of patient safety concerns. The Board of Osteopathic Medicine indicates that it is unclear to what extent the regulation of clinical perfusionists would supplant the current quality control systems of hospitals and physicians. Currently, hospitals and surgeons are responsible for providing oversight and setting standards for the performance of perfusionists. The Board of Medicine is neutral on this bill.

Under s. 766.110, F.S., all health care facilities in Florida, including hospitals and ambulatory surgical centers have a duty to assure comprehensive risk management and the competence of their medical staff and personnel through careful selection and review, and are liable for a failure to exercise due care in fulfilling these duties. These duties include among other specified items, a requirement to adopt written procedures for the selection of staff members and a periodic review of the medical care and treatment rendered to patients by each member of the medical staff.

The minimum academic standard for clinical perfusionists is a Bachelor of Science degree. Barry University has the only accredited perfusion program in Florida and graduates about 10 students annually. Perfusion training is also offered in 21 other institutions in the nation. These programs

have been and are accredited by the American Medical Association's (AMA) Committee on Allied Health Education and Accreditation (CAHEA) and its successor accreditation agency, the Commission on Accreditation of Allied Health Education Programs (CAAHEP). The CAAHEP's standards for specific course work, clinical experience, and evaluation techniques were devised and approved jointly by representatives from the ABCP, the AMA, the American Society of Extracorporeal Technology (AmSECT), the American Association for Thoracic Surgery (AATS), the Society of Thoracic Surgeons (STS), the Society of Cardiovascular Anesthesiologists (SCA), and the Perfusion Program Directors' Council.

Currently, certification in clinical perfusion is voluntary and may be attained by satisfactory completion of a course of study approved by the ABCP and subsequent satisfactory performance on a two-part comprehensive ABCP certification examination. There are three national organizations that recognize the perfusion profession: the ABCP, the AmSECT, and the American Academy of Cardiovascular Perfusion (AACP).

Sunrise Act/Questionnaire

The Sunrise Act, codified in s. 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The act requires all legislation proposing regulation of a previously unregulated profession or occupation to be reviewed by the Legislature based on a showing of the following: (1) that substantial risk of harm to the public is a risk of no regulation which is recognizable and not remote; (2) that the skills the profession requires are specialized and readily measurable; (3) that other forms of regulation do not or cannot adequately protect the public; and (4) that the overall cost-effectiveness and economic impact of the proposed regulation is favorable. The act requires proponents of regulation of a previously unregulated profession to provide the agency that is proposed to have jurisdiction over the regulation and the legislative committees of reference information concerning the effect of proposed legislation to initially regulate a previously unregulated profession on the agency's resources to implement and enforce the regulation.

Board of Medicine, Board of Osteopathic Medicine

Chapter 458, F.S., the medical practice act, provides for the regulation of medical physicians by the Board of Medicine within the DOH. Section 458.305, F.S., defines the "practice of medicine" to mean the diagnosis, treatment, operation, or prescription for any human disease, pain, injury, deformity, or other physical or mental condition. Section 458.303, F.S., provides exceptions to the "practice of medicine" for: other duly licensed health care practitioners acting within their scope of practice authorized by statute; licensed out-of-state physicians when meeting in consultation with Florida licensed physicians; medical officers of the United States Armed Forces and of the United States Public Health Service; medical residents; persons furnishing emergency medical assistance; the domestic administration of recognized family remedies; the practice of the religious tenets of any church in Florida; and any person or manufacturer who, without the use of drugs or medicine, mechanically fits or sells lenses, artificial eyes or limbs, or other apparatus or appliances, or is engaged in the mechanical examination of the eyes for the purpose of constructing or adjusting spectacles, eyeglasses, or lenses.

Subsection 458.303(2), F.S., provides that nothing in various enumerated provisions within the medical practice act shall be construed to prohibit any service rendered by a registered nurse or a licensed practical nurse, if such service is rendered under the direct supervision and control of a

licensed medical physician who provides specific direction for any service to be performed and gives final approval to all services performed. Subsection 458.303(2), F.S., also provides that nothing in the medical practice act or any other chapter shall be construed to prohibit any service rendered by a medical assistant in accordance with the provisions of s. 458.3485, F.S. Section 458.3485, F.S., provides that a medical assistant is a professional multi-skilled person dedicated to assisting in all aspects of medical practice under the direct supervision and responsibility of a physician.

Similarly, chapter 459, F.S., provides for regulation of the practice of osteopathic medicine by the Board of Osteopathic Medicine within the DOH. Subsection 459.002(2), F.S., provides that nothing in the osteopathic medical practice act shall be construed to prohibit any service rendered by any person if such service is rendered under the direct supervision and control of a licensed osteopathic physician who must be available when needed, must provide specific directions for any service to be performed, and must give final approval to all services performed.

Allied Health Care Professionals with Similar Scopes of Practice

In addition to perfusionists, other allied health professionals who work in similar occupations and settings may share similar scopes of practice. Cardiovascular technologists are not regulated in Florida and assist with the operation and maintenance of heart-lung machinery for extracorporeal circulation, cardiac catheterization, and cardiac resuscitation. Cardiovascular technologists may receive a bachelor's degree, associate degree, or on-the-job training to perform their work. Cardiovascular technology programs exist at Edison Community College (Ft. Myers), Santa Fe Community College (Gainesville), and Sanford Brown Institute (Tampa). Cardiovascular technologists may receive voluntary certification from the Cardiovascular Credentialing International.

Part V, ch. 468, F.S., governs the regulation of respiratory therapy by the Board of Respiratory Care. Section 468.352, F.S., defines a "respiratory care practitioner" to mean a licensed respiratory care practitioner who is employed to deliver respiratory care services, under direct supervision, pursuant to an order of a Florida-licensed medical physician or osteopathic physician. Under s. 468.352(10), F.S., "respiratory care services" is defined to include: evaluation and disease management; diagnostic and therapeutic use of respiratory equipment, devices, or medical gas; administration of drugs, as duly ordered or prescribed by a Florida-licensed medical or osteopathic physician and in accordance with protocols, policies, and procedures established by a hospital or other health care provider or the Board of Respiratory Care; initiation, management, and maintenance of equipment to assist and support ventilation and respiration; diagnostic procedures, research, and therapeutic treatment and procedures, including measurement of ventilatory volumes, pressures, and flows; specimen collection and analysis of blood for gas transport and acid/base determinations; pulmonary-function testing; and other related physiological monitoring of cardiopulmonary systems; cardiopulmonary rehabilitation; cardiopulmonary resuscitation, advanced cardiac life support, neonatal resuscitation, and pediatric advanced life support, or equivalent functions; insertion and maintenance of artificial airways and intravascular catheters; education of patients, families, the public, or other health care providers, including disease process and management programs and smoking prevention and cessation programs; and initiation and management of hyperbaric oxygen.

III. Effect of Proposed Changes:

Section 1. Amends s. 456.048, F.S., to direct the Board of Medicine and the Board of Osteopathic Medicine to, by rule, require all clinical perfusionists certified pursuant to s. 468.901, F.S., to maintain medical malpractice insurance or provide proof of financial responsibility as a prerequisite for certification or certification renewal. The amount must be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in Florida.

The board or the DOH may grant exemptions to the financial responsibility requirements, upon application, to:

- A certified clinical perfusionist who practices exclusively as an officer, employee, or agent of the Federal Government, the state of Florida, or its agencies, or subdivisions;
- A clinical perfusionist whose certification has become inactive and who is not practicing in Florida;
- A certified clinical perfusionist who practices only in conjunction with his or her teaching duties at an accredited school or in its main teaching hospitals. The certified clinical perfusionist may engage in the practice of medicine to the extent that such practice is incidental to and a necessary part of duties in connection with the teaching position in the school; or
- A clinical perfusionist holding an active certification who is not practicing in Florida. If the clinical perfusionist initiates or resumes practice in this state, he or she must notify the DOH.

A clinical perfusionist who is an agent of the state, its agencies, or its subdivisions is eligible for coverage under any self-insurance or insurance program authorized under s. 768.28(16), F.S., or who is a volunteer under s. 110.501(1), F.S.

A clinical perfusionist applying for reactivation of a certificate must show either that he or she maintained tail insurance coverage which provided liability coverage for incidents that occurred on or after October 1, 1993, or the initial date of licensure in Florida, whichever is later, and incidents that occurred before the date on which the license became inactive. Alternatively, a clinical perfusionist applying for reactivation of a certificate may submit an affidavit stating that he or she has no unsatisfied medical malpractice judgments or settlements at the time of application for reactivation.

Section 2. Creates s. 468.901, F.S., relating to clinical perfusionists. *Subsection (1)* provides the following definitions related to clinical perfusion.

“Approved program” means a program for the education and training of clinical perfusion, which is approved by the boards as, provided in s. 468.901(5), F.S.

“Boards” means the Board of Medicine and the Board of Osteopathic Medicine.

“Clinical perfusionist” means a person who has graduated from an approved program, who is certified pursuant to s. 468.901, F.S., to perform medical services, and who is prescribed, delegated, or supervised by a licensed physician.

“Clinical perfusion” means the functions necessary for the support, treatment, measurement, or supplementation of the cardiovascular, circulatory, or respiratory systems or other organs, or a combination of those activities, and the safe management of physiologic functions by monitoring and analyzing the parameters of the systems, under an order and the supervision of a physician licensed under chapter 458 or chapter 459 of the Florida Statutes, through extracorporeal circulation, long-term clinical support techniques, including extracorporeal carbon-dioxide removal and extracorporeal membrane oxygenation, and associated therapeutic and diagnostic technologies, such as counter pulsation, ventricular assistance, auto transfusion, blood conservation techniques, myocardial and organ preservation, extracorporeal life support, isolated limb perfusion, therapeutic aphaeresis, and platelet rich plasma sequestration.

“Clinical perfusionist’s protocol” means perfusion-related policies and protocols developed or approved by a licensed health facility or a physician through collaboration with administrators, certified clinical perfusionists, and other health care professionals.

“Continuing medical education,” means courses recognized and approved by the boards, the American Academy of Physician Assistants, the American Medical Association, the American Osteopathic Association, the American Board of Cardiovascular Perfusion, or the Accreditation Council on Continuing Medical Education.

“Department” means the Department of Health.

“Direct supervision” means the onsite, personal supervision by a clinical perfusionist who is present when a procedure is being performed and who is in all instances immediately available to provide assistance and direction while clinical perfusion services are being performed.

“Extracorporeal circulation” means the diversion of a patient’s blood through a heart-lung machine or a similar device that assumes the functions of the patient’s heart, lungs, kidney, liver, or other organs.

“Perfusionist in training” means a student enrolled in an approved program who has not yet passed the proficiency examination and works under the direct supervision of a clinical perfusionist.

“Proficiency examination” means an entry-level examination administered by the American Board of Cardiovascular Perfusion.

“Provisional certified clinical perfusionist” means a person provisionally certified under this section.

“Supervising physician,” means a physician licensed under chapter 458 or chapter 459 of the Florida Statutes who holds an active license.

“Temporary clinical perfusionist” means a person granted a temporary certificate under this section.

Subsection (2) requires a physician who supervises a clinical perfusionist to be qualified in the medical areas in which the clinical perfusionist performs.

Subsection (3) specifies duties that clinical perfusionists may perform, as established by rule by the Board of Medicine and the Board of Osteopathic Medicine. The following duties are included in the clinical perfusionist's protocol and may be performed by a clinical perfusionist if prescribed by a physician or under the supervision of a physician. The clinical perfusionist may:

- Perform extracorporeal circulation and its clinical support;
- Perform or administer counter pulsation;
- Perform circulatory support and ventricular assistance;
- Perform extracorporeal membrane oxygenation and extracorporeal life support;
- Perform blood conservation techniques, autotransfusion, and blood component sequestration;
- Perform myocardial preservation;
- Perform coagulation and hematologic monitoring;
- Perform physiological monitoring;
- Perform blood gas and blood chemistry monitoring;
- Perform induction of hypothermia or hyperthermia with reversal;
- Perform hemodilution;
- Perform hemofiltration;
- Administer blood, blood products, supportive fluids, and anesthetic agents via the extracorporeal circuit;
- Perform isolated limb and organ perfusion;
- Provide surgical assistance;
- Perform organ preservation;
- Perform dialysis while on clinical bypass;
- Perform therapeutic apheresis;
- Administer blood, blood products, and supportive fluids via the therapeutic apheresis circuit; and
- Perform pacemaker lead and battery analysis.

A clinical perfusionist must also clearly convey to a patient that he or she is a clinical perfusionist. A clinical perfusionist may perform medical tasks and services within the framework of a written practice protocol developed between the supervising physician and the clinical perfusionist. Clinical perfusionists are prohibited from prescribing, ordering, compounding, or dispensing any controlled substance, legend drug, or medical device to any patient. However, a clinical perfusionist is not prohibited from *administering* legend drugs, controlled substances, intravenous drugs, fluids, or blood products that are ordered by a physician and administered to a patient while under the orders of the physician.

Subsection (4) specifies that the practice of a perfusionist in training is exempt from the requirements of s. 468.901, F.S., while the perfusionist in training is performing assigned tasks in conjunction with an approved program. Before providing clinical perfusion in conjunction with the requirements of an approved program, the perfusionist in training must clearly convey to the patient that he or she is a perfusionist in training and is under direct supervision.

Subsection (5) provides the Board of Medicine and the Board of Osteopathic Medicine authority to approve programs for the education and training of clinical perfusionists, which hold full accreditation or provisional accreditation from the Commission on Accreditation of Allied Health Education Programs or a successor organization, as approved by the boards.

Subsection (6) establishes certification requirements for clinical perfusionists. Any person seeking to be certified as a clinical perfusionist must apply to the DOH. The DOH is authorized to issue a certificate to any person certified by the Board of Medicine and the Board of Osteopathic Medicine who:

- Is at least 21 years of age;
- Has satisfactorily passed a proficiency examination approved by the Board of Medicine and the Board of Osteopathic Medicine;
- Is certified in basic cardiac life support; and
- Has completed the application form and remitted an application fee, not to exceed \$1,000, as set by the DOH.

The Board of Medicine and the Board of Osteopathic Medicine must waive the examination requirement, upon receipt of an application and application fee, for an applicant who at the time of application holds a current certificate issued by a certifying agency approved by the boards,

An application for clinical perfusionist certification must include:

- A certificate of completion of an approved program or its equivalent;
- A sworn statement of any prior discipline or denial of certification or license in any state;
- Two letters of recommendation, one from a physician and one from a certified clinical perfusionist; and
- A set of fingerprints, along with payment in the amount equal to the costs incurred by the DOH for a national criminal history check of the applicant.

Before January 1, 2011, a person is eligible to apply to the Board of Medicine and Board of Osteopathic Medicine and receive certification notwithstanding the requirements of s. 468.901(6), F.S., if the person was actively engaged in the practice of perfusion consistent with applicable law, and if the person was operating cardiopulmonary bypass systems during cardiac surgical cases in a licensed health care facility in Florida as the person's primary function and had been operating the system for at least 9 of the 10 years preceding application for certification.

Between July 1, 2010, and June 30, 2011, an applicant for certification who was not a graduate of an accredited program before 1981, but met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, shall be certified as a perfusionist if the application otherwise complies with s. 468.901, F.S.

A clinical perfusionist certificate must be renewed biennially. Each renewal must include a renewal fee, not to exceed \$1,000, as set by the DOH, and a sworn statement of no felony convictions in the immediately preceding 2 years. Certified clinical perfusionists are required to biennially complete continuing medical education as required by the Board of Medicine and the Board of Osteopathic Medicine.

The Board of Medicine and the Board of Osteopathic Medicine may issue a certificate as a provisional certified clinical perfusionist to a person who has successfully completed an approved perfusion education program, completed an application and remitted an application fee, and submitted evidence satisfactory to the boards of the successful completion of the requisite education requirements. When a provisionally certified clinical perfusionist performs prescribed duties, he or she must be under the supervision and direction of a certified clinical perfusionist at all times.

A provisional certificate is valid for 2 years following the date it is issued and may be extended subject to rule by the Board of Medicine and the Board of Osteopathic Medicine. An application for extension must be signed by a supervising certified clinical perfusionist. Upon notification that any portion of the certifying examination has been failed after the 2-year provisional certificate term, the provisional certificate must be surrendered to the boards.

The DOH may issue a certificate as a temporary clinical perfusionist to a person who has successfully completed the application for perfusion certification and met other requirements as established by the Board of Medicine and the Board of Osteopathic Medicine. The boards shall adopt rules governing supervisory requirements between clinical perfusionists and provisionally certified clinical perfusionists, temporary clinical perfusionists, and clinical perfusionists in training. The Board of Medicine may impose upon a clinical perfusionist any penalty specified in s. 456.072, F.S., or s. 458.331(2), F.S., if the clinical perfusionist is found guilty of or is investigated for an act that constitutes a violation of ch. 456, ch. 457, or ch. 458, F.S.

Subsection (7) authorizes the chairpersons of the Board of Medicine and the Board of Osteopathic Medicine to appoint a cardiovascular surgeon and a certified clinical perfusionist to advise the boards as to the adoption of rules for the certification of clinical perfusionists. The boards may use a committee structure that is most practicable in order to receive any recommendations regarding rules and all matters relating to clinical perfusionists.

The bill specifies certain duties and responsibilities of the Board of Medicine and the Board of Osteopathic Medicine, including:

- Recommending to the DOH the certification of clinical perfusionists;
- Developing rules regulating the use of clinical perfusionists, except for rules relating to the formulary developed under s. 458.347(4), F.S., which only applies to physician assistants;
- Developing rules to ensure that the continuity of supervision is maintained in each practice setting; and
- Addressing concerns and problems of clinical perfusionists to improve safety in the clinical practices of certified clinical perfusionists.

The bill directs the Board of Medicine and the Board of Osteopathic Medicine to consider adopting a proposed rule at the regularly scheduled meeting immediately following the submission of the proposed rule. A proposed rule may not be adopted by either board unless both boards have accepted and approved the identical language contained in the proposed rule. The provisions of all the proposed rules must be approved by both boards pursuant to each respective board's guidelines and standards regarding the adoption of proposed rules.

When the Board of Medicine and the Board of Osteopathic Medicine find that an applicant for certification has failed to meet any of the requirements for certification, the boards may enter an order to:

- Refuse to certify the applicant;
- Approve the applicant for certification with restrictions on the scope of practice; or
- Approve the applicant for provisional or temporary certification.

Subsection (8) provides that the Board of Medicine and the Board of Osteopathic Medicine may deny, suspend, or revoke certification for a clinical perfusionist who has violated any provision of s. 468.901, F.S., or ch. 456, ch. 458, or ch. 459 of the Florida Statutes.

Subsection (9) authorizes the Board of Medicine and the Board of Osteopathic Medicine to adopt rules to administer s. 468.901, F.S.

Subsection (10) requires the DOH to allocate fees collected under s. 468.901, F.S., to the Board of Medicine and the Board of Osteopathic Medicine.

Subsection (11) provides exemptions to the requirements of s. 468.901, F.S. The section does not limit the practice of a physician or respiratory therapist licensed in Florida, so long as that person does not hold himself or herself out to the public as possessing a certificate or provisional certificate issued under s. 468.901, F.S., or use a professional title protected by s. 468.901, F.S. The section also does not limit the practice of nursing or prevent qualified members of other regulated health professions from doing work of a nature consistent with the state laws and rules that govern their respective health professions.

A person does not need be certified under s. 468.901, F.S., if he or she:

- Is a qualified person in Florida or another state or territory who is employed by the U.S. Government or an agency thereof while discharging his or her official duties; or
- Is a student providing services regulated chapter 468, F.S., who meets specified conditions, including being designated by the title “perfusionist in training.”

The bill instructs the Board of Medicine and the Board of Osteopathic Medicine to establish by rule the qualifications necessary for a clinical perfusionist who is not a resident of Florida and is licensed or certified by any other state or territory of the United States. The bill prohibits a clinical perfusionist who is not a resident of Florida, but licensed or certified in another U.S. state or territory, from offering his or her services in Florida for more than 30 days in any calendar year.

Except as stipulated by the Board of Medicine and the Board of Osteopathic Medicine, the exemptions in s. 468.901(11), F.S., do not apply to any person certified under s. 468.901, F.S., whose certificate has been revoked or suspended by either of the boards or whose license or certification in another jurisdiction has been revoked or suspended by the licensing or certifying authority in that jurisdiction.

Section 468.901(11), F.S., does not exempt a person from meeting the minimum standards of performance in professional activities when measured against generally prevailing peer

performance, including the undertaking of activities for which the person is not qualified by training or experience.

Subsection (12) provides that a hospital is not required to pay for, or reimburse any person for, the costs of compliance with any requirement of s. 468.901, F.S., including costs of continuing education. The bill does not prevent third-party payors from reimbursing employers of clinical perfusionists for covered services rendered by clinical perfusionists.

Section 3. Provides an effective date of July 1, 2010.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

The bill requires the DOH to allocate fees collected under s. 468.901, F.S., to the Board of Medicine and the Board of Osteopathic Medicine.

Fees for clinical perfusionists include: an application fee for applicants to be certified as a clinical perfusionist, as set by the DOH, not to exceed \$1,000; payment, by the applicant for certification as a clinical perfusionist, in the amount equal to the costs incurred by the DOH for a national criminal history check of the applicant; and, a biennial renewal fee, not to exceed \$1,000, as set by the DOH.

B. Private Sector Impact:

Persons who apply for and become certified as clinical perfusionists will incur costs.

C. Government Sector Impact:

The bill will create additional costs for the DOH to regulate clinical perfusionists. The DOH estimated these costs would be offset by significant revenues from applications and renewals. However, the revenue generated will be dependent upon the fees charged and is

indeterminate as provided by the language in the bill. Fees for the initial application and for renewal are set by the DOH, and are not to exceed \$1,000.

The bill requires an applicant for certification as a clinical perfusionist to submit a set of fingerprints on a form and under procedures specified by the DOH, along with payment in the amount equal to the costs incurred by the DOH for a national criminal history check of the applicant. The bill does not specifically require a state criminal history check; however, it is likely that the Florida Department of Law Enforcement (FDLE) would be in charge of conducting a state criminal history check and may incur costs to do so.

VI. Technical Deficiencies:

Provisions in section 1 of the bill use the term “practitioner.” The definition of “health care practitioner” under s. 456.001(4), F.S., does not make reference to s. 468.901, F.S., and therefore does not include clinical perfusionists.

Line 153 of the bill makes reference to the Accreditation Council on Continuing Medical Education; however, the correct name is Accreditation Council *for* Continuing Medical Education.

Subsection (3), paragraph (b) requires a clinical perfusionist to clearly convey to a patient that he or she is a clinical perfusionist. It is unclear when a clinical perfusionist is to convey this information. Subsection (4), regarding perfusionists in training, is more specific, using the phrase, “Before providing clinical perfusion ...”

Subsection (6), paragraph (b) provides that, between July 1, 2010, and June 30, 2011, an applicant for certification who was not a graduate of an accredited program before 1981 but met the then-current eligibility requirements for certification as a certified clinical perfusionist and subsequently was certified, shall be certified as a *perfusionist*. This may need to be changed to *clinical perfusionist*.

Subsection (6), paragraph (h) provides that the Board of Medicine may impose a penalty if a clinical perfusionist is found guilty of or is investigated for an act that constitutes a violation of chapter 456, chapter 457, or chapter 458 of the Florida Statutes. Chapter 457 pertains to Acupuncture. Chapter 459, which is not included, pertains to Osteopathic Medicine. Chapter 459 may be more relevant to the profession of clinical perfusion, and may need to replace, or be listed in addition to, chapter 457 in s. 468.901(6)(h), F.S.

Lines 359-364 establish conditions that may be placed on a provisional or temporary certification. These conditions are more appropriate for a conditional certificate. See s. 458.347(9)(d)3., F.S., related to conditional licenses for physician assistants.

On line 367, the term “have” should be replaced with “has.”

VII. Related Issues:

The bill creates s. 468.901, F.S., under chapter 468, F.S., Miscellaneous Professions and Occupations, however a new Part is not created for this section. The placement of the section in the chapter is confusing and may appear to fall under Part XVI, ch. 468, F.S., Mold-Related Services. The new provisions for clinical perfusionists could be created as a new Part XVII. Alternatively, identical provisions could be created in ch. 458 and ch. 459, F.S., for clinical perfusionists as is done for physician assistants and anesthesiologist assistants.

The DOH expressed concern over the use of the term “boards” throughout section 2 of the bill. Currently “boards” is defined as the Board of Medicine *and* the Board of Osteopathic Medicine. The DOH proposes clarifying that the term, as used in the bill, is applicable to *either* board, and not always two separate entities.

Subsection (6), paragraph (e) creates a certificate as a provisional certified clinical perfusionist, and paragraph (f) creates a certificate as a temporary clinical perfusionist. It is not made specifically clear what the difference is between “provisional” and “temporary”, or why a certificate as a temporary clinical perfusionist is necessary.

Subsection (11) provides that s. 468.901, F.S., does not limit the practice of physicians, respiratory therapists, nursing, or other regulated health professions, so long as those persons do not hold themselves out to the public as possessing a certificate or provisional certificate issued under s. 468.901, F.S., or use a professional title protected by s. 468.901, F.S. However, s. 468.901, F.S., does not provide title protection, except as implied in this subsection.

The FDLE indicated that the bill does not meet the Federal Bureau of Investigation’s (FBI) criminal history record check requirements.

The DOH indicated that the proposed effective date does not provide adequate time for both the Board of Medicine and the Board of Osteopathic Medicine to meet the provisions of the bill.

VIII. Additional Information:

A. **Committee Substitute – Statement of Substantial Changes:**
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. **Amendments:**

None.