

SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

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

Prepared By: Health Care Committee

BILL: CS/SB 2372

SPONSOR: Health Care Committee and Senator Peaden

SUBJECT: Clinical Perfusionists

DATE: April 28, 2005

REVISED: _____

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	Fav/CS
2.			CJ	
3.			HA	
4.				
5.				
6.				

I. Summary:

The bill provides for the licensure of clinical perfusionists under the regulatory jurisdiction of the Board of Medicine or the Board of Osteopathic Medicine and for joint rulemaking by these boards for aspects of the practice of this profession. The regulation would allow a clinical perfusionist to practice within the framework of a protocol under the supervision of a medical or osteopathic physician. The bill provides definitions and standards of practice and performance for clinical perfusionists. The Board of Medicine and the Board of Osteopathic Medicine are given rulemaking authority to implement the provisions of the bill regulating clinical perfusionists.

The bill specifies requirements for education and training of clinical perfusionists and other licensure requirements, including the expanded duties of the Board of Medicine and the Board of Osteopathic Medicine over this profession. The bill creates a criminal offense for any person who falsely holds himself or herself out as a clinical perfusionist. The bill requires the Board of Medicine and the Board of Osteopathic Medicine, by rule, to require all clinical perfusionists licensed under section 458.3476 or section 459.025, F.S., to maintain medical malpractice insurance or provide proof of financial responsibility.

This bill amends sections 456.048, Florida Statutes.

This bill creates sections 458.3476 and 459.025, Florida Statutes.

II. Present Situation:

Clinical Perfusion

A clinical perfusionist operates the heart-lung machines that divert a patient's blood and take 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 with 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.

In response to a Sunrise questionnaire, the Florida Perfusion Society estimates that there are approximately 232 perfusionists practicing in Florida. The Board of Medicine staff reports 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. Hospitals and surgeons are responsible for providing oversight and setting standards for the performance of perfusionists. The Department of Health indicates that it is unclear to what extent the regulation of clinical perfusionist would supplant the current quality control system of hospitals and physicians.

Under section 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 current level of training for clinical perfusionists is either a Bachelor of Science degree or higher. In response to the Sunrise questionnaire, proponents note that new graduates can expect to earn a salary of \$45,000 to \$55,000 annually. Barry University has the only accredited perfusion program in Florida and graduates about 10 students annually. As part of the clinical perfusion program at Barry University, in addition to coursework, students must perform a minimum of 75 satisfactory adult clinical bypass procedures and perform or observe a minimum of 10 pediatric clinical bypass procedures; and satisfactorily complete a final written and clinical simulation examination. Voluntary certification in Clinical Perfusion may be attained from the American Board of Cardiovascular Perfusion (ABCP). The ABCP certification requirements for clinical perfusion include successful completion of a two-part comprehensive certification examination. Approximately 12 states regulate perfusionists.¹

¹ Arkansas, California, Georgia, Illinois, Louisiana, Massachusetts, Missouri, New Jersey, Oklahoma, Tennessee, Texas, and Wisconsin.

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, chapter 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 section 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; initiation and management of hyperbaric oxygen.

Sunrise Act

The Sunrise Act, codified in section 11.62, F.S., requires the Legislature to consider specific factors in determining whether to regulate a new profession or occupation. The act requires that all legislation proposing regulation of a previously unregulated profession or occupation 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.

Proponents of the regulation of perfusionists did not provide any documentation of the nature and extent of harm to the public caused by the unregulated practice of clinical perfusion. Proponents assert that there is no primary source of data available to correctly document the scope of harm caused by the incompetent practice of perfusion. In response to a Sunrise questionnaire, the proponents of the proposed regulation indicated that the proposed regulation would have “no impact” on the practice of unregulated practitioners in the same or similar occupational groups, because “[i]n Florida, clinical perfusionists are the only health care profession currently unregulated in the state which performs perfusion through an extracorporeal circuit.” The proponents note that there are only two situations where an extracorporeal circuit, which is a specialized type of equipment, used for extracorporeal membrane oxygenation, extracorporeal carbon dioxide, counter pulsation, and extracorporeal life support is used. It is used with heart-lung bypass during open-heart surgery, which is exclusively provided by trained clinical perfusionists according to the proponents and in the neonate in which it is used by a clinical perfusionist, registered nurse with specialized training, or respiratory therapist. However, some groups which are unlicensed in Florida and who work with other licensed health care practitioners in providing care to patients with cardiovascular conditions may perform similar functions, such as cardiovascular technologists. Representatives for the Florida Society of Perfusion assert that the definition of “respiratory care services” under section 468.352(10), F.S., prohibits clinical perfusionists from practicing with respiratory care licensure or an exemption from such licensure requirements.

Practice of Medicine and Osteopathic Medicine

Chapter 458, F.S., the medical practice act, provides for the regulation of medical physicians by the Board of Medicine within the Department of Health. 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 section 458.3485, F.S. Section 458.3485, F.S., provides that a medical assistant is a professional multiskilled 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 the practice of osteopathic medicine.

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.

III. Effect of Proposed Changes:

Section 1. Creates section 458.3476, F.S., to provide for the regulation of clinical perfusionists by the Board of Medicine and for joint rulemaking by the Board of Medicine and the Board of Osteopathic Medicine for aspects of the practice of this profession.

Subsection (1) provides definitions. The term “clinical perfusionist” is defined to mean a person who has graduated from an approved program, who is licensed to perform medical services, and who is prescribed, delegated, or supervised by a licensed physician.

“Clinical perfusion” is defined to mean 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 licensed physician. The term includes the use of extracorporeal circulation and long-term clinical support techniques, including extracorporeal carbon-dioxide removal and extracorporeal membrane oxygenation, and associated therapeutic and diagnostic technologies.

“Boards” is defined to mean the Board of Medicine and the Board of Osteopathic Medicine. Definitions are also provided for the terms “approved program” and “continuing medical education.” “Direct supervision” is defined to mean the on-site, personal supervision by a licensed clinical perfusionist who is present when a procedure is being performed and who is in all instances immediately available to provide assistance and direction to the clinical perfusionist while clinical perfusion services are being performed.

“Extracorporeal circulation” is defined to mean 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. “Perfusion protocols” is defined to mean perfusion-related policies and protocols developed or approved by a licensed health facility or a physician through collaboration with administrators, licensed clinical perfusionists and other health care professionals.

“Proficiency examination” is defined to mean an entry-level examination approved by the boards, including the examination administered by the American Board of Cardiovascular Perfusion. “Trainee” means a person who is currently enrolled in an approved program.

“Provisional licensed perfusionist” is defined to mean a person provisionally licensed under this

section. “Temporarily licensed perfusionist” is defined to mean a person granted a temporary license 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 may be included in the clinical perfusionist’s protocol while such practitioner is under the supervision of a physician. The bill provides that nothing in the regulatory provisions for clinical perfusionists or the medical practice act prevent third-party payers from reimbursing employers of clinical perfusionists for covered services rendered by such clinical perfusionists. A clinical perfusionist must clearly convey to the 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. Clinical perfusionists are prohibited from prescribing, ordering, compounding or dispensing any controlled substance, legend drug, or medical device to any patient. This section does not prohibit a clinical perfusionist from administering legend drugs, controlled substances, intravenous drugs, fluids, or blood products that are ordered by the physician and administered to a patient while under the orders of such physician.

Subsection (4) specifies that the practice of clinical perfusion trainees is exempt from the requirements of the medical practice act while the trainee is performing assigned tasks as a trainee in conjunction with an approved program. Before providing clinical perfusion, in conjunction with the requirements of an approved program, the trainee must clearly convey to the patient that he or she is a trainee and is under direct supervision.

Subsection (5) gives the Board of Medicine and the Board of Osteopathic Medicine authority to approve education and training programs for clinical perfusionists. The boards must approve programs, which meet standards established by rules of the boards. The boards may only recommend those clinical perfusionists-training programs that hold full or provisional accreditation from the Commission on Accreditation of Allied Health Education Programs.

Subsection (6) establishes licensure requirements for clinical perfusionists. Any person who desires to be licensed must be certified by the Board of Medicine to: be at least 18 years old; have satisfactorily passed a proficiency examination established by the American Board of Cardiovascular Perfusion; be certified in basic cardiac life support; and complete an application form and remit an application fee no greater than \$1,500 established by rule of the boards.

Items that the applicants must submit are specified, including a certificate of completion of approved training; a sworn statement of any felony convictions; prior licensure discipline or denials in any state; and two letters of recommendation, one from a physician and one from a certified or licensed clinical perfusionist. Biennial licensure renewal requirements are specified, which include a renewal fee of no greater than \$1,500 as set by the boards; a sworn statement of no felony convictions in the immediately preceding two years; and completion of continuing medical education as required by the board.

The Board of Medicine may waive the examination requirement for an applicant who:

- Is appropriately licensed or certified by another state, territory, or possession of the United States if the requirements of that license are the substantial equivalent of the requirements of this section as determined by the Board of Medicine; or
- Holds a current certificate as a certified clinical perfusionist issued by the American Board of Cardiovascular Perfusion, or its successor before July 1, 2005.

Before January 1, 2006, a person is eligible to apply for a clinical perfusionist license and receive a license 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 as the person's primary function and had been operating the system for 10 of the 12 years preceding application for licensure.

Requirements for the issuance of a 2-year provisional license are specified for a person who has successfully completed an approved perfusion education program, filed an application and fee, and submitted evidence satisfactory to the Board of Medicine showing successful completion of the perfusionist education requirements for licensure. When a provisionally licensed perfusionist performs perfusion, he or she must be under the supervision and direction of a licensed perfusionist. The Board of Medicine may not adopt rules governing such supervision and direction that require the immediate physical presence of the supervising licensed perfusionist. The Board of Medicine may extend by rule the provisional license beyond two years. Any application for an extension of the provisional license must be signed by the supervising licensed perfusionist. Upon notification that any portion of the licensing examination has been failed after the 2-year provisional license term, the provisional license must be surrendered to the Board of Medicine.

A temporary license to practice perfusion may be issued to an applicant who has successfully completed the perfusion license application.

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. 458, F.S., or ch. 456, F.S.

Subsection (7) authorizes the chairman of the Board of Medicine to appoint a cardiovascular surgeon and a clinical perfusionist to advise the board regarding the adoption of rules for the licensure of clinical perfusionists. The Board of Medicine may use a committee structure that is most practicable in order to receive any recommendations to the board regarding rules and all matters relating to clinical perfusionists. The Board of Medicine's duties over the regulation of clinical perfusionists are specified. The Board of Medicine must: recommend to Department of Health the licensure of clinical perfusionists; develop all rules regarding the use of clinical perfusionists, except for rules relating to the formulary developed under section 458.347(4), F.S., which only applies to physician assistants; develop rules to ensure that the continuity of supervision of a perfusionist is maintained in each practice setting; and address concerns and problems of clinical perfusionists to improve safety in the clinical practices of licensed clinical perfusionists.

The boards must consider 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. Requirements for the Board of Medicine to enter an order regarding a license application are specified. The Board of Medicine may refuse to certify an applicant for licensure; approve the applicant for licensure with restrictions on the scope of practice or license; or approve the applicant for conditional licensure.

Subsection (8) provides that a person who falsely holds himself or herself out as a clinical perfusionist commits a felony of the third degree.

Subsection (9) provides that the boards may impose discipline on a clinical perfusionist for violation of applicable grounds for discipline in this section or chapter 458, F.S.

Subsection (10) provides that the boards may adopt rules to administer this section.

Subsection (11) requires the Department of Health to allocate the fees collected from the clinical perfusionists to the boards.

Subsection (12) provides exemptions to the requirements of the section for: the practice of medical physicians or a respiratory therapists if that person does not hold himself or herself out to the public as possessing a license, provisional license, registration, or certificate issued under this section; the practice of nursing or prevent qualified members of other professions from doing work of a nature consistent with their training and licensure, if the person does not hold himself or herself out to the public as possessing a license, provisional license, registration, or certificate issued under this section or use a professional title protected by this section. A person need not be licensed under this section who:

- Is licensed in Florida under any other law and is engaging in the profession or occupation for which he or she is licensed;
- Is a qualified person in Florida or another state or territory who is employed by the U.S. Government while discharging his or her official duties;
- Is student providing services regulated under the medical practice act who meets specified conditions; and
- Is not a Florida resident but offers services in Florida if such services are performed in Florida for no more than 15 days in any calendar year, and the nonresident person is licensed or certified by a state or territory of the United States or by a foreign country or province.

Except as stipulated by the Board of Medicine, the exemptions in subsection (12) do not apply to any person licensed under this section whose license has been revoked or suspended by the Board of Medicine or whose license or certification in another jurisdiction has been revoked or suspended by the licensing or certifying authority in that jurisdiction.

Subsection (12) 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 (13) provides that a hospital is not required to pay for, or reimburse any person for, or reimburse any person for, the costs of compliance with any requirement of this part, including costs of continuing education.

Section 2. Amends section 456.048, F.S., to require the Board of Medicine and the Board of Osteopathic Medicine (boards), by rule, to require all clinical perfusionists licensed under section 458.3476, F.S., or section 459.025, F.S., to maintain medical malpractice insurance or provide proof of financial responsibility in an amount and in a manner determined by the boards to be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in Florida. The section is also amended to include clinical perfusionists in existing exemptions to the financial responsibility requirements.

Section 3. Creates s. 459.025, F.S., to provide for the regulation of clinical perfusionists by the Board of Osteopathic Medicine and for joint rulemaking by the Board of Medicine and the Board of Osteopathic Medicine for aspects of the practice of this profession. These provisions are the same as those in section 1 of the bill.

Section 4. Provides an effective date of January 1, 2006.

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. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The bill subjects clinical perfusionist licensure applicants to an application fee no greater than \$1,500 as set by the Board of Medicine and the Board of Osteopathic Medicine and license renewal applicants will be subject to a fee no greater than \$1,500 as set by the boards. Provisional licensure or temporary licensure applicants are not responsible for any fees for their application.

B. Private Sector Impact:

Employers or persons who pay for the services of clinical perfusionists may incur the additional costs associated with licensure of such practitioners.

C. Government Sector Impact:

The Department of Health will incur costs to regulate clinical perfusionists. The department estimates that it will spend \$65,269 in fiscal year 2005-06 and \$55,209 in fiscal year 2006-07. This expenditure will be offset by revenues of \$383,625 in fiscal year 2005-06 and \$17,050 in fiscal year 2006-07. The department assumes 225 applicants in 2005-06 and 10 applicants in 2006-07. The computation is based on a \$1,500 initial application fee, a \$200 initial licensure fee, and a \$5 unlicensed activity fee.

With an initial application fee set at the statutory fee cap of \$1,500, the department indicates that based on the number of estimated licensees, this profession is expected to operate with a surplus cash balance. The cash balance, according to the department, is subject to being adjusted with the allocated expenses that are not part of the estimated expenditures; the allocated expenses may range between \$45,000 to \$55,000.

VI. Technical Deficiencies:

On page 13, line 2 and line 4, and on page 26, line 8 and line 10, the reference to “part” should refer to “section.”

VII. Related Issues:

On page 9, lines 6-8, and on page 22, lines 9-11, a license as a temporarily licensed perfusionist may be issued an applicant who has successfully completed the perfusion application. It is unclear why and under what circumstance the temporary license should be issued. The bill does not provide any additional requirements for such license or specify the duration of the license pending a license application denial or provide any limitations on practice of the temporarily licensed perfusionist.

On page 10, lines 27-30, the bill creates a criminal offense punishable as a third-degree felony for any person who falsely holds himself or herself out as a clinical perfusionist. On page 23, line 30 through page 24, line 6, the bill creates a criminal offense for any person who falsely holds himself or herself out as a clinical perfusionist which is punishable as a first degree misdemeanor for the first offense and punishable as a third-degree felony for a second or subsequent offense. The provisions for holding oneself as a clinical perfusionist should be uniform in the practice acts for medical physicians and osteopathic physicians.

VIII. Summary of Amendments:

None.

This Senate staff analysis does not reflect the intent or official position of the bill's sponsor or the Florida Senate.
