

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 2444

INTRODUCER: Health Care Committee and Senator Peadar

SUBJECT: Clinical Perfusionists

DATE: April 27, 2006

REVISED: _____

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

I. Summary:

The bill requires the Office of Program Policy Analysis and Government Accountability to study and report on clinical perfusion in Florida, specifies the requirements for the study and report, and requires the Office of Program Policy Analysis and Government Accountability to provide a report to the Legislature by February 1, 2007.

This bill creates an undesignated section of law.

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 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 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

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

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

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.

Sunrise Act

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 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 s. 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 s. 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. Requires the Office of Program Policy Analysis and Government Accountability to study and report upon the practice of clinical perfusion in Florida. The study and report must identify the certifying agencies that provide credentials for persons who provide clinical perfusion; evaluate relevant workforce issues relating to clinical perfusionists, including the number of such perfusionists certified by national certifying agencies who are practicing in Florida and nationally; describe the certification and recertification requirements for clinical perfusionists; and identify the number of clinical perfusionists employed by Florida-licensed

hospitals and other health care facilities that are not certified. Florida-licensed hospitals and health care facilities must provide the Office of Program Policy Analysis and Government Accountability with data regarding the employment of clinical perfusionists, the salaries and costs associated with persons providing clinical perfusion, and other relevant data requested in order for the office to complete the study and report on clinical perfusion. The Office of Program Analysis and Government Accountability must provide the report to the President of the Senate and the Speaker of the House of Representatives by February 1, 2007.

Section 2. Provides an effective date of July 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:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

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

VIII. Summary of Amendments:

None.

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