

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1625 Clinical Perfusionists
SPONSOR(S): Kottkamp
TIED BILLS: **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	_____	Hamrick	Mitchell
2) Business Regulation Committee	_____	_____	_____
3) Health Care Appropriations Committee	_____	_____	_____
4) Health & Families Council	_____	_____	_____
5) _____	_____	_____	_____

SUMMARY ANALYSIS

HB 1625 establishes the regulation by the Department of Health of clinical perfusionists who operate heart-lung machines used in open heart surgery.

Section 11.62, F.S., the Sunrise Act that establishes criteria for new regulation of professions, states that it is the intent of the Legislature that no profession or occupation be subject to regulation by the state unless the regulation is necessary to protect the public health, safety, or welfare from significant and discernible harm or damage; and no profession or occupation be regulated by the state in a manner that unnecessarily restricts entry into the practice of the profession or occupation. The proponents for regulation of clinical perfusionists provided adequate documentation that the public may be harmed if a clinical perfusionist is not trained appropriately. However, the proponents stated "there is no current primary source data available to correctly document the scope of public harm caused by the incompetent practice of perfusion." According to staff of the Board of Medicine, perfusionists are well-educated, allied health care professionals who assist in over 28,000 open-heart procedures annually and there have been few, if any, reports or concerns with patient safety.

Clinical perfusionists (or "perfusionists") have been recognized as a definable allied health profession by the American Medical Association since 1977. A perfusionist is responsible for the direct control, maintenance, and analysis of a patient's blood pressure, blood flow, temperature, oxygenation/carbon dioxide removal, myocardial preservation, blood and blood product administration, coagulation status, blood chemistries, equipment operation, IV fluid administration, and anesthetic drug administration. Approximately 12 states regulate perfusionists.

HB 1625 creates a regulatory scheme, provides definitions, scope of practice, and continuing education guidelines. 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 bill requires a perfusionist to practice within the framework of a protocol under the supervision of a medical or osteopathic physician. The bill requires licensed perfusionists to maintain medical malpractice insurance or provide proof of financial responsibility.

Fiscal Impact: According to the Department of Health, this profession is projected to be self-sufficient due to the amount of fees a licensed perfusionist will be required to pay. An applicant may be subject to a fee no greater than \$1,500 and a biannual license renewal fee no greater than \$1,500. The Florida Perfusion Society, estimates that there are approximately 225 perfusionist in the state.

The bill takes effect on July 1, 2006.

This document does not reflect the intent or official position of the bill sponsor or House of Representatives.

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DATE: 4/3/2006

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provides limited government-The bill provides for the creation of a regulatory scheme for a new profession.

B. EFFECT OF PROPOSED CHANGES:

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 requires 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.

CURRENT SITUATION

Clinical perfusionists (or “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 a heart-lung machine. To maintain life during open-heart surgery, the patient's heart must be stopped and the patient's blood diverted outside the body, circulated through the heart-lung machine, and returned to the patient. Other procedures that a perfusionist can be involved in are plasmapheresis (a blood purification procedure used to treat several autoimmune diseases), intra-aortic balloon pumping, heart, lung and liver transplants, cardiac catheterization, and chemotherapy treatment.

According to information provided by proponents of the regulation, a perfusionist is responsible for the direct control, maintenance, and analysis of a patient's blood pressure, blood flow, temperature, oxygenation/carbon dioxide removal, myocardial preservation, blood and blood product administration, coagulation status, blood chemistries, equipment operation, IV fluid administration, and anesthetic drug administration. Approximately 12 states regulate perfusionists.¹

Sunrise Act

Section 11.62, F.S., requires the proponents of regulation to submit information, which is structured as a sunrise questionnaire, to document that regulation meets specified criteria.

A sunrise questionnaire was submitted to staff by the proponents of the legislation to assist the Legislature in determining the need for regulation of clinical perfusionists as required by statute. The

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

proponents for the regulation and entity responsible for submitting the sunrise questionnaire is the Florida Perfusion Society (the “proponents” or the “Society”). The Society represents certified clinical perfusionists, clinical perfusionists, and perfusion technologists. Currently, there are 115 active members, 20 associate members, and 2 life members in the Society. The Society estimates that there are approximately 225 perfusionists in the State of Florida.

According to s. 11.62(3), F.S., of the Florida Sunrise Act, the Legislature is required to consider the following factors when determining whether to regulate a profession:

- **The unregulated practice of the profession will substantially harm or endanger the public health, safety, or welfare, and whether the potential for harm is recognizable and not remote.**

The proponents for regulation, provided documentation that in 1989, the number of injuries or deaths from accidents during perfusion was one per 1,000 cases performed.² The Society added that perfusionists rarely publish their failures and the documentation of accidents is difficult to obtain. The proponents argue that if perfusion were not a high-risk procedure, perfusionists would not be rated for malpractice insurance in a liability range equivalent to Emergency Room physicians. The proponents offered that the Wood Insurance Group (largest insurer of perfusionists in the nation), charges premiums of \$5,500-\$6,800 per year. The Society also noted that the heart-lung machine that is used by a perfusionist is classified by the Food and Drug Administration (FDA) as a level V medical device. This is the highest category of consumer risk for medical device products assigned by the FDA. According to the proponents, the consequences of improperly performing any of the many important tasks required of a perfusionist could result in serious patient injury or death.

The proponents for regulation provided adequate documentation that the public may be harmed if a clinical perfusionist is not trained appropriately. However, the proponents did not submit documentation that the unregulated practice of the profession will substantially harm the public. The sunrise questionnaire states “there is no current primary source data available to correctly document the scope of public harm caused by the incompetent practice of perfusion.” The proponents provided documentation from 1989, but nothing more recent.

- **The practice of the profession requires specialized skill or training, and whether that skill or training is readily measurable or quantifiable so that examination or training requirements reasonably assure initial and continuing professional ability.**

The Society provided ample documentation that the practice of clinical perfusion requires specialized skill and training. For a certified clinical perfusionist (CCP) the skill and training is readily measurable or quantifiable. A CCP is required to perform a minimum of 40 clinical activities annually and earn 45 continuing education units (CEUs) every 3 years.

The American Board of Cardiovascular Perfusion is the only certifying body for clinical perfusionists. They administer a two part examination. To be eligible to sit for the examination an applicant must have completed an accredited perfusionist program. There are 21 accredited programs in the US and one located in Florida. According to the provisions in the bill, to be licensed as a clinical perfusionist in Florida the applicant must attend an accredited program.

² Reed, Charles C. and Trudi B. Stafford. 1989. “Cardiopulmonary Bypass.” 2nd edition.

- **The regulation will not unreasonably effect job creation or retention in the state, or place unreasonable restrictions on finding employment by individuals who practice or seek to practice the profession.**

The bill requires individuals who perform clinical perfusion to become licensed. The proponents provide that there are no unregulated occupations that perform all the services of a perfusionist. The licensure fee may not exceed \$1500 biannually.

- **Whether the public is not, or can not, be effectively protected by other means.**

There are currently other mechanisms in place that protect the public. Hospitals are responsible for screening their employees and determining their competence. A clinical perfusionist functions under the supervision of a physician. The majority of perfusionists are employed by hospitals. According to the Society, the Joint Commission (JCAHO) requires employers to annually perform employee competency evaluations. Section 766.110, F.S., provides that 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 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. 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.

- **Whether the overall cost-effectiveness and economic impact of the proposed regulation, including the indirect costs to consumers, is favorable.**

At this time there are no advocacy groups representing Florida consumers on this issue. According to the proponents of the regulation, the impact on consumers will remain the same, but a higher level of patient safety will be achieved. The proponents state that there will be no impact on the cost of services due to licensure since the responsibility for obtaining licensure falls on the practitioner. The licensure fee will cover all costs of regulation.

See the "Fiscal Impact on State Government" for the Department of Health's projections on the fiscal impact.

BACKGROUND

National Organizations that Recognize Clinical Perfusionist

The American Board of Cardiovascular Perfusion (ABCP)

Established in 1975, the ABCP is an independent organization that has no organizational ties or relationships with any other group or entity. The ABCP is the primary certification body that has become the de facto standard in the field and is typically a requirement of most organizations that employ perfusionists. Individuals who become credentialed in perfusion by the ABCP must pass a certification examination to become a Certified Clinical Perfusionist (CCP). It is estimated that at least 70% of the practicing perfusionists are certified. To sit for the CCP certification examination an applicant must be a graduate of an accredited perfusion training program.

The certification examination is composed of two parts. Part I, the Perfusion Basic Science Examination, is a multiple choice examination designed to cover perfusion basic sciences and

cardiopulmonary bypass. Part II, the Clinical Applications in Perfusion Examination, is in a multiple choice format where a series of clinical scenarios are presented and a corresponding series of questions must be answered.

The CCP is conferred for a period of three years, during which time a specified number of approved continuing education credits must be earned in order to be recertified.

The ABCP website specifically states that certification “is not intended to define requirements for employment, to gain special recognition or privileges, to define the scope of extracorporeal circulation, or to state who may not engage in cardiovascular perfusion.” *Further, the certification of a clinical perfusionist does not relieve an employer from determining the professional responsibilities of a cardiovascular perfusionist in his/her specific clinical setting.*³

The American Society of Extracorporeal Technology (AmSECT)

The American Society of Extra-Corporeal Technology was founded in 1964. AmSECT has over 2,000 members nationally and internationally. A member of AmSECT must maintain rigorous continuing education requirements.

Educational Requirements for a Clinical Perfusionist

The current level of training for clinical perfusionists is a Bachelor of Science degree or higher. Currently, there are 21 perfusionist programs in the U.S. accredited by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). 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. In response to the Sunrise questionnaire, the proponents note that new graduates can expect to earn a salary of \$45,000 to \$55,000 annually.

Allied Health Care Professionals Who May Share 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, are respiratory care practitioners and cardiovascular technologists.

According to the proponents for regulation, the practice of perfusion is unique to the equipment they use. For example, a respiratory care practitioner (or respiratory therapist) controls the rate of inhaled air by way of a ventilator. A perfusionist performs the same duty but instead uses an artificial lung.

Respiratory Care Practitioners

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. Respiratory care services include, but not limited to:

- Administration of drugs, in accordance with protocols;
- Maintenance of equipment to assist and support ventilation and respiration; diagnostic 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; and
- Cardiopulmonary resuscitation; insertion and maintenance of artificial airways and intravascular catheters.

³ The American Board of Cardiovascular Perfusion. Introduction. <http://www.abcp.org/introduction.htm> (April 2, 2006).

Cardiovascular Technologists

Cardiovascular technologists, who are not regulated in Florida, assist with cardiac catheterization and cardiac resuscitation. They may also specialize in noninvasive peripheral vascular tests such as limb volume changes, oxygen saturation, cerebral circulation, peripheral circulation, and abdominal circulation. 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.

C. SECTION DIRECTORY:

Section 1. Amends s. 456.048, F.S., to specify the financial responsibility requirements for clinical perfusionists.

Sections 2 and 3. Creates ss. 458.3476 and 459.025, F.S., relating to the practice of allopathic medicine and osteopathic medicine respectively: to provide definitions; require a supervising physician to be qualified in the same field as a clinical perfusionist; provide prescribing duties; require a clinical perfusionist to disclose to a patient that he or she is a clinical perfusionist; authorize clinical perfusionist to perform certain medical tasks and services in a protocol; prohibit the prescription, dispense, order, or compound of certain drugs or medical devices; allow a clinical perfusionist to administer certain drugs, fluids, and blood products under the supervision of a physician; exempt a trainee from the requirements of a clinical perfusionist; provide licensure requirements; authorize the board to impose a penalty, denial or suspension of a licensee; authorize the board to appoint persons to provide advice on the rules for the licensure of clinical perfusionist; require the board to adopt rules; provide that hospitals are not obligated to pay certain costs; and authorize the collection and allocation of fees.

Section 4. Provides that the bill will take effect on July 1, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

According to the Department of Health, the bill provides that the Board of Medicine and Board of Osteopathic Medicine, not the department, will set the fees. Revenue projections by the department assume that the two boards will initially impose the application and renewal fee at \$1,000, with 225 applicants in year 1 and 10 new applicants in year 2. Revenues were computed based on a \$1,000 initial application fee; a \$200 initial licensure fee, and a \$5 unlicensed activity fee. Revenues in year 3 would include the amounts shown in year 2, plus the first biennial renewal estimated at \$235,000 (235 licensees at \$1,000) and unlicensed activity fines estimated at \$1,175. Revenues for year 4 would duplicate the estimated for year 2.

	1st Year	2nd Year (Annualized/ Recurr.)	3 rd Year	4 th Year (Annualized/ Recurr.)
Estimated Revenue				
\$1000 initial application fee	\$225,000	\$10,000	\$10,000	\$10,000
\$200 initial licensure fee	\$45,000	\$2,000	\$2,000	\$2,000
\$5 unlicensed activity fee	\$1,125	\$50	\$1,175	\$50
\$1000 Renewal Fee			\$235,000	
Total Estimated Revenue	\$271,125	\$12,050	\$248,175	\$12,050

2. Expenditures:

According to the Department of Health, three half time positions will be required to implement this bill (a 0.5 position for the Board of Medicine, a 0.5 position for the Board of Osteopathic Medicine and a 0.5 position are required for the Bureau of Management Services).

Estimated Expenditures	1st Year	2nd Year (Annualized/ Recurr.)	3rd Year	4th Year (Annualized/ Recurr.)
Salaries				
.5 FTE, RS II, PG 17, Board of Medicine (BOM).	\$19,275	\$19,275	\$19,275	\$19,275
.5 FTE, RS II, PG 17, Board of Osteopathic Medicine (BOOM)	\$19,275	\$19,275	\$19,275	\$19,275
.5 FTE, RS I, PG 15 (Call Center)	\$13,189	\$17,586	\$17,586	\$17,586
Other Personal Services				
Board Member Compensation	\$4,000	\$4,000	\$4,000	\$4,000
Expense				
Non-recurring for 2 professional staff	\$6,686			
Non-recurring for 1 support staff	\$2,791			
Recurring for 2 professional staff w/no travel	\$12,806	\$12,806	\$12,806	\$12,806
Recurring for 1 support staff	\$5,195	\$5,195	\$5,195	\$5,195
Operating Capital Outlay				
2 professional staff	\$3,800			
1 support staff	\$2,100			
Human Resource Services				
3 FTEs	\$1,179	\$1,179	\$1,179	\$1,179
Allocated Expenses	\$50,000	\$50,000	\$50,000	\$50,000
Total Estimated Expenditures	\$140,296	\$129,316	\$129,316	\$129,316

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Clinical perfusionists in Florida will be subject to an application fee no greater than \$1,500 and a biannual license renewal fee no greater than \$1,500.

D. FISCAL COMMENTS:

According to the Department of Health (DOH), they did not include in the fiscal projection a .25 FTE attorney position and a support staff position. These positions will be needed at the DOH Prosecution

Services Unit. Additional attorney time and support staff time will be required to prosecute all the violations relating to the new regulation for violation by the Clinical Perfusionists including citations for CE violations. The department projects that the allocated expenses could range from \$45,000 to \$55,000 or more annually in addition to the direct expenses shown in this analysis. Allocated expenses were estimated at \$50,000.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The bill provides the Department of Health with adequate rule-making authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The Department of Health has requested that the enactment date be changed to December 1, 2006.

Members of the Board of Medicine and Board of Osteopathic Medicine state that they are not aware of any patient safety issue with perfusionists that would require regulation as a profession under their respective boards.

The Florida Hospital Association (FHA) has stated that historically, the association has opposed additional workforce licensure requirements unless there is a demonstrable need to do so in order to improve patient care. To date, the FHA is unaware of any demonstrated need for the regulation of clinical perfusionists.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES