Florida Senate - 2005

By the Committee on Health Care; and Senator Peaden

587-2359-05

| 1 | A bill to be entitled |
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| 2 | An act relating to clinical perfusionists; |
| 3 | creating ss. 458.3476 and 459.025, F.S.; |
| 4 | providing definitions; requiring a supervising |
| 5 | physician to be qualified in the medical area |
| 6 | in which the clinical perfusionist performs; |
| 7 | prescribing duties of a clinical perfusionist; |
| 8 | requiring a clinical perfusionist to convey |
| 9 | that he or she is a clinical perfusionist to a |
| 10 | patient; authorizing a clinical perfusionist to |
| 11 | perform medical tasks and services within a |
| 12 | certain protocol; prohibiting a clinical |
| 13 | perfusionist from prescribing, ordering, |
| 14 | compounding, or dispensing certain drugs or a |
| 15 | medical device; providing that a clinical |
| 16 | perfusionist may administer certain drugs, |
| 17 | fluids, and blood products under the |
| 18 | supervision of a physician; exempting a trainee |
| 19 | from requirements of a clinical perfusionist; |
| 20 | requiring board approval of training programs |
| 21 | for clinical perfusionists; providing licensure |
| 22 | requirements; providing provisional licensing |
| 23 | requirements; providing for a temporary license |
| 24 | as a clinical perfusionist; authorizing the |
| 25 | Board of Medicine and the Board of Osteopathic |
| 26 | Medicine to impose a penalty against a clinical |
| 27 | perfusionist found guilty of or investigated |
| 28 | for violating ch. 456, ch. 458, or ch. 459, |
| 29 | F.S.; authorizing the chair of each board to |
| 30 | appoint certain persons to advise the board |
| 31 | regarding rules for the licensure of clinical |

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| 1 | perfusionists; providing duties of each board; |
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| 2 | providing a penalty for any person who falsely |
| 3 | holds himself or herself out as a clinical |
| 4 | perfusionist; providing for the denial, |
| 5 | suspension, or revocation of a license; |
| 6 | requiring each board to adopt rules; requiring |
| 7 | the Department of Health to allocate fees |
| 8 | collected to each board; providing exemptions |
| 9 | from clinical perfusionist licensure |
| 10 | requirements; excluding hospitals from payment |
| 11 | of certain costs; amending s. 456.048, F.S.; |
| 12 | specifying financial responsibility |
| 13 | requirements for clinical perfusionists; |
| 14 | providing an effective date. |
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| 16 | Be It Enacted by the Legislature of the State of Florida: |
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| 18 | Section 1. Section 458.3476, Florida Statutes, is |
| 19 | created to read: |
| 20 | 458.3476 Clinical perfusionist |
| 21 | (1) DEFINITIONSAs used in this section, the term: |
| 22 | (a) "Approved program" means a program for the |
| 23 | education and training of clinical perfusion which has been |
| 24 | approved by the boards as provided in subsection (5). |
| 25 | (b) "Boards" means the Board of Medicine and the Board |
| 26 | of Osteopathic Medicine. |
| 27 | <u>(c) "Clinical perfusionist" means a person who has</u> |
| 28 | graduated from an approved program, who is licensed to perform |
| 29 | medical services, and who is prescribed, delegated, or |
| 30 | supervised by a licensed physician. |
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| 1 | (d) "Clinical perfusion" means the functions necessary |
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| 2 | for the support, treatment, measurement, or supplementation of |
| 3 | <u>the cardiovascular, circulatory, or respiratory systems or</u> |
| 4 | other organs, or a combination of those activities, and the |
| 5 | safe management of physiologic functions by monitoring and |
| 6 | analyzing the parameters of the systems under an order and the |
| 7 | supervision of a licensed physician, through extracorporeal |
| 8 | circulation, long-term clinical support techniques, including |
| 9 | extracorporeal carbon-dioxide removal and extracorporeal |
| 10 | membrane oxygenation, and associated therapeutic and |
| 11 | diagnostic technologies, such as counter pulsation, |
| 12 | ventricular assistance, auto transfusion, blood conservation |
| 13 | techniques, myocardial and organ preservation, extracorporeal |
| 14 | life support, isolated limb perfusion, therapeutic aphaeresis, |
| 15 | and platelet rich plasma sequestration. |
| 16 | (e) "Clinical perfusionists' licensing committee" |
| 17 | means the clinical perfusion licensing committee appointed by |
| 18 | the board. |
| 19 | (f) "Continuing medical education" means courses |
| 20 | recognized and approved by the boards, the American Academy of |
| 21 | Physician Assistants, the American Medical Association, the |
| 22 | American Osteopathic Association, the American Board of |
| 23 | Cardiovascular Perfusion, or the Accreditation Council on |
| 24 | Continuing Medical Education. |
| 25 | (q) "Direct supervision" means the on-site, personal |
| 26 | supervision by a licensed clinical perfusionist who is present |
| 27 | when a procedure is being performed and who is in all |
| 28 | instances immediately available to provide assistance and |
| 29 | direction to the clinical perfusionist while clinical |
| 30 | perfusion services are being performed. |
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| 1 | (h) "Extracorporeal circulation" means the diversion |
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| 2 | <u>of a patient's blood through a heart-lung machine or a similar</u> |
| 3 | device that assumes the functions of the patient's heart, |
| 4 | <u>lungs, kidney, liver, or other organs.</u> |
| 5 | (i) "Trainee" means a person who is currently enrolled |
| б | in an approved program. |
| 7 | (j) "Perfusion protocols" means perfusion-related |
| 8 | policies and protocols developed or approved by a licensed |
| 9 | health facility or a physician through collaboration with |
| 10 | administrators, licensed clinical perfusionists, and other |
| 11 | health care professionals. |
| 12 | (k) "Proficiency examination" means an entry-level |
| 13 | examination approved by the boards, including examinations |
| 14 | administered by the American Board of Cardiovascular Perfusion |
| 15 | (ABCP). |
| 16 | (1) "Provisional licensed perfusionist" means a person |
| 17 | provisionally licensed under this section. |
| 18 | (m) "Supervising physician" means an allopathic |
| 19 | physician who holds an active license. |
| 20 | (n) "Temporarily licensed perfusionist" means a person |
| 21 | granted a temporary license under this section. |
| 22 | (2) PERFORMANCE OF A SUPERVISING PHYSICIANA |
| 23 | physician who supervises a clinical perfusionist must be |
| 24 | qualified in the medical areas in which the clinical |
| 25 | perfusionist performs. |
| 26 | (3)(a) PERFORMANCE OF CLINICAL PERFUSIONISTSA |
| 27 | clinical perfusionist may perform duties established by rule |
| 28 | by the board, including the following duties that are included |
| 29 | in the clinical perfusionist's protocol, while prescribed by a |
| 30 | physician or under the supervision of a physician: |
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| 1 | 1. Perform extracorporeal circulation/clinical |
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| 2 | support; |
| 3 | 2. Perform or administer counter pulsation; |
| 4 | 3. Perform circulatory support and ventricular |
| 5 | assistance; |
| 6 | 4. Perform extracorporeal membrane oxygenation (ECMO) |
| 7 | and extracorporeal life support (ECLS); |
| 8 | 5. Perform blood conservation techniques, |
| 9 | autotransfusion, and blood component sequestration; |
| 10 | 6. Perform myocardial preservation; |
| 11 | 7. Perform coagulation and hemotalogic monitoring; |
| 12 | 8. Perform physiological monitoring; |
| 13 | 9. Perform blood gas and blood chemistry monitoring; |
| 14 | 10. Perform induction of hypothermia or hyperthermia |
| 15 | with reversal; |
| 16 | 11. Perform hemodilution; |
| 17 | 12. Perform hemofiltration; |
| 18 | 13. Administer blood, blood products, supportive |
| 19 | fluids, and anesthetic agents via the extracorporeal circuit; |
| 20 | 14. Complete documentation associated with described |
| 21 | <u>duties;</u> |
| 22 | 15. Perform isolated limb and organ perfusion; |
| 23 | 16. Provide surgical assistance; |
| 24 | 17. Perform organ preservation; |
| 25 | 18. Perform dialysis while on clinical bypass; |
| 26 | 19. Perform therapeutic apheresis; |
| 27 | 20. Administer blood, blood products and supportive |
| 28 | fluids via the therapeutic apheresis circuit; and |
| 29 | 21. Perform pacemaker lead and battery analysis. |
| 30 | (b) This section or chapter does not prevent |
| 31 | third-party payors from reimbursing employers of clinical |
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| 1 | perfusionists for covered services rendered by such clinical |
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| 2 | perfusionists. |
| 3 | (c) A clinical perfusionist shall clearly convey to a |
| 4 | patient that he or she is a clinical perfusionist. |
| 5 | (d) A clinical perfusionist may perform medical tasks |
| 6 | and services within the framework of a written practice |
| 7 | protocol developed between the supervising physician and the |
| 8 | <u>clinical perfusionist.</u> |
| 9 | (e) A clinical perfusionist may not prescribe, order, |
| 10 | compound, or dispense any controlled substance, legend drug, |
| 11 | or medical device to any patient. This paragraph does not |
| 12 | prohibit a clinical perfusionist from administering legend |
| 13 | drugs, controlled substances, intravenous drugs, fluids, or |
| 14 | blood products that are ordered by the physician and |
| 15 | administered to a patient while under the orders of such |
| 16 | physician. |
| 17 | (4) PERFORMANCE BY TRAINEES The practice of a |
| 18 | trainee is exempt from the requirements of this chapter while |
| 19 | the trainee is performing assigned tasks as a trainee in |
| 20 | conjunction with an approved program. Before providing |
| 21 | clinical perfusion in conjunction with the requirements of an |
| 22 | approved program, the trainee shall clearly convey to the |
| 23 | patient that he or she is a trainee and is under direct |
| 24 | supervision. |
| 25 | (5) PROGRAM APPROVALThe boards shall approve |
| 26 | programs for the education and training of clinical |
| 27 | perfusionists which meet standards established by board rules. |
| 28 | The boards may recommend only those programs for clinical |
| 29 | perfusionists training which hold full accreditation or |
| 30 | provisional accreditation from the Commission on Accreditation |
| 31 | of Allied Health Education Programs. |
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| 1 | (6) CLINICAL PERFUSIONIST LICENSURE |
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| 2 | (a) Any person seeking to be licensed as a clinical |
| 3 | perfusionist must apply to the department. The department |
| 4 | shall issue a license to any person certified by the board to: |
| 5 | 1. Be at least 18 years of age. |
| 6 | 2. Have satisfactorily passed a proficiency |
| 7 | examination established by the American Board of |
| 8 | Cardiovascular Perfusion (ABCP). The board, on receipt of an |
| 9 | application and application fee, shall waive the examination |
| 10 | requirement for an applicant who at the time of application: |
| 11 | a. Is appropriately licensed or certified by another |
| 12 | state, territory, or possession of the United States if the |
| 13 | requirements of that state, territory, or possession for the |
| 14 | license or certificate are the substantial equivalent of the |
| 15 | requirements of this section determined by the board; or |
| 16 | b. Holds a current certificate as a certified clinical |
| 17 | perfusionist issued by the American Board of Cardiovascular |
| 18 | Perfusion (ABCP), or its successor before July 1, 2005. |
| 19 | 3. Be certified in basic cardiac life support. |
| 20 | 4. Have completed the application form and remitted an |
| 21 | application fee, not to exceed \$1,500, as set by the |
| 22 | department. An application must include: |
| 23 | a. A certificate of completion of an approved program; |
| 24 | b. A sworn statement of any prior felony convictions; |
| 25 | c. A sworn statement of any prior discipline or denial |
| 26 | of licensure or certification in any state; and |
| 27 | d. Two letters of recommendation, one from a physician |
| 28 | and one from a certified or licensed clinical perfusionist. |
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| 30 | Before January 1, 2006, a person is eligible to apply to the |
| 31 | board and receive a license notwithstanding the requirements |
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1 of this subsection if the person was actively engaged in the 2 practice of perfusion consistent with applicable law, and if the person was operating cardiopulmonary bypass systems during 3 4 cardiac surgical cases in a licensed health care facility as the person's primary function and had been operating the 5 6 system for 10 of the 12 years preceding application for 7 licensure. 8 (b) A license must be renewed biennially. Each renewal 9 must include: 10 1. A renewal fee, not to exceed \$1,500, as set by the 11 department; and 12 A sworn statement of no felony convictions in the 2. 13 immediately preceding 2 years. (c) Each licensed clinical perfusionist shall 14 biennially complete continuing medical education as required 15 16 by the board. 17 (d)1. A license as a provisional licensed perfusionist 18 may be issued by the board to a person who has successfully 19 completed an approved perfusion education program and the filing of an application, payment of an application fee, and 20 21 the submission of evidence satisfactory to the board of the 2.2 successful completion of the requisite education requirements. 23 A provisional licensed perfusionist is under the supervision and direction of a licensed perfusionist at all 2.4 25 times during which the provisional licensed perfusionist performs perfusion. Rules adopted by the board governing such 26 27 supervision and direction may not require the immediate 2.8 physical presence of the supervising licensed perfusionist. A provisional license is valid for 2 years from the 29 3. date it is issued and may be extended subject to rule by the 30 board. The application for extension must be signed by a 31

1 supervising licensed perfusionist. Upon notification by the approved testing service, or the board, that any portion of 2 the licensing examination has been failed after the 2-year 3 4 provisional license term, the provisional license must be surrendered to the board. 5 б (e) A license as a temporarily licensed perfusionist 7 may be issued by the department to a person who has 8 successfully completed the perfusion licensure application. 9 (f) The Board of Medicine may impose upon a clinical 10 perfusionist any penalty specified in s. 456.072 or s. 458.331(2) if the clinical perfusionist is found quilty of or 11 12 is investigated for an act that constitutes a violation of 13 this chapter or chapter 456. (7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST 14 TO ADVISE THE BOARD. --15 (a) The chairperson of the board may appoint a 16 17 cardiovascular surgeon and a certified clinical perfusionist 18 to advise the board as to the adoption of rules for the licensure of clinical perfusionists. The board may use a 19 committee structure that is most practicable in order to 2.0 21 receive any recommendations to the board regarding rules and all matters relating to clinical perfusionists, including, but 2.2 23 not limited to, recommendations to improve safety in the clinical practices of licensed clinical perfusionists. 2.4 (b) In addition to its other duties and 25 responsibilities as prescribed by law, the board shall: 26 27 1. Recommend to the department the licensure of 2.8 clinical perfusionists. Develop rules regulating the use of clinical 29 2. perfusionists under this chapter and chapter 459, except for 30 rules relating to the formulary developed under s. 458.347(4). 31

| 1 | The board shall also develop rules to ensure that the |
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| 2 | continuity of supervision is maintained in each practice |
| 3 | setting. The boards shall consider adopting a proposed rule at |
| 4 | the regularly scheduled meeting immediately following the |
| 5 | submission of the proposed rule. A proposed rule may not be |
| б | adopted by either board unless both boards have accepted and |
| 7 | approved the identical language contained in the proposed |
| 8 | rule. The language of all proposed rules must be approved by |
| 9 | both boards pursuant to each respective board's guidelines and |
| 10 | standards regarding the adoption of proposed rules. |
| 11 | 3. Address concerns and problems of clinical |
| 12 | perfusionists to improve safety in the clinical practices of |
| 13 | licensed clinical perfusionists. |
| 14 | (c) When the board finds that an applicant for |
| 15 | licensure has failed to meet, to the board's satisfaction, |
| 16 | each of the requirements for licensure set forth in this |
| 17 | section, the board may enter an order to: |
| 18 | 1. Refuse to certify the applicant for licensure; |
| 19 | 2. Approve the applicant for licensure with |
| 20 | restrictions on the scope of practice or license; or |
| 21 | 3. Approve the applicant for conditional licensure. |
| 22 | Such conditions may include placement of the applicant on |
| 23 | probation for a period of time and subject to such conditions |
| 24 | as the board specifies, including, but not limited to, |
| 25 | requiring the applicant to undergo treatment, to attend |
| 26 | continuing education courses, or to take corrective action. |
| 27 | (8) PENALTYA person who falsely holds himself or |
| 28 | herself out as a clinical perfusionist commits a felony of the |
| 29 | <u>third degree, punishable as provided in s. 775.082, s.</u> |
| 30 | <u>775.083, or s. 775.084.</u> |
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| 1 | (9) DENIAL, SUSPENSION, OR REVOCATION OF |
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| 2 | LICENSUREThe boards may deny, suspend, or revoke the |
| 3 | license of a clinical perfusionist whom the board determines |
| 4 | has violated any provision of this section, chapter, or any |
| 5 | rule adopted pursuant thereto. |
| б | (10) RULESThe boards shall adopt rules to |
| 7 | administer this section. |
| 8 | (11) FEESThe department shall allocate the fees |
| 9 | collected under this section to the boards. |
| 10 | (12) EXEMPTIONS |
| 11 | (a) This section may not be construed to limit the |
| 12 | practice of a physician licensed under this chapter or a |
| 13 | respiratory therapist licensed under chapter 468, so long as |
| 14 | that person does not hold himself or herself out to the public |
| 15 | as possessing a license, provisional license, registration, or |
| 16 | certificate issued under this section or use a professional |
| 17 | title protected by this section. |
| 18 | (b) This section may not be construed to limit the |
| 19 | practice of nursing or to prevent qualified members of other |
| 20 | professions from doing work of a nature consistent with their |
| 21 | training and licensure, so long as those persons do not hold |
| 22 | themselves out to the public as possessing a license, |
| 23 | provisional license, registration, or certificate issued under |
| 24 | this section or use a professional title protected by this |
| 25 | section. |
| 26 | (c) A person need not be licensed under this section |
| 27 | who: |
| 28 | 1. Is licensed in this state under any other law and |
| 29 | is engaging in the profession or occupation for which he or |
| 30 | she is licensed. |
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| 1 | 2. Is a qualified person in this state or another |
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| 2 | state or territory who is employed by the United States |
| 3 | Government or an agency thereof while discharging his or her |
| 4 | official duties. |
| 5 | 3. Is a student providing services regulated under |
| 6 | this chapter who is: |
| 7 | a. Pursuing a course of study that leads to a degree |
| 8 | in a profession regulated by this chapter; |
| 9 | b. Providing services in a training setting, as long |
| 10 | as such services and associated activities constitute part of |
| 11 | a supervised course of study; and |
| 12 | c. Designated by the title "trainee." |
| 13 | 4. Is not a resident of this state but offers services |
| 14 | in this state, provided that: |
| 15 | a. Such services are performed in this state for no |
| 16 | more than 15 days in any calendar year; and |
| 17 | b. Such nonresident is licensed or certified by a |
| 18 | state or territory of the United States or by a foreign |
| 19 | <u>country or province.</u> |
| 20 | (d) Except as stipulated by the board, the exemptions |
| 21 | in this subsection do not apply to any person licensed under |
| 22 | this section whose license has been revoked or suspended by |
| 23 | the board or whose license or certification in another |
| 24 | jurisdiction has been revoked or suspended by the licensing or |
| 25 | certifying authority in that jurisdiction. |
| 26 | (e) This subsection may not be construed to exempt a |
| 27 | person from meeting the minimum standards of performance in |
| 28 | professional activities when measured against generally |
| 29 | prevailing peer performance, including the undertaking of |
| 30 | activities for which the person is not qualified by training |
| 31 | <u>or experience.</u> |

| 1 | (13) PAYMENT OR REIMBURSEMENT BY HOSPITALS OF COSTS OF |
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| 2 | COMPLIANCE WITH PARTA hospital is not required to pay for, |
| 3 | or reimburse any person for, the costs of compliance with any |
| 4 | requirement of this part, including costs of continuing |
| 5 | education. |
| б | Section 2. Section 456.048, Florida Statutes, is |
| 7 | amended to read: |
| 8 | 456.048 Financial responsibility requirements for |
| 9 | certain health care practitioners |
| 10 | (1) As a prerequisite for licensure or license |
| 11 | renewal, the Board of Acupuncture, the Board of Chiropractic |
| 12 | Medicine, the Board of Podiatric Medicine, and the Board of |
| 13 | Dentistry shall, by rule, require that all health care |
| 14 | practitioners licensed under the respective board, and the |
| 15 | Board of Medicine and the Board of Osteopathic Medicine shall, |
| 16 | by rule, require that all anesthesiologist assistants licensed |
| 17 | pursuant to s. 458.3475 or s. 459.023 and clinical |
| 18 | perfusionists licensed pursuant to s. 458.3476 or s. 459.025, |
| 19 | and the Board of Nursing shall, by rule, require that advanced |
| 20 | registered nurse practitioners certified under s. 464.012, and |
| 21 | the department shall, by rule, require that midwives maintain |
| 22 | medical malpractice insurance or provide proof of financial |
| 23 | responsibility in an amount and in a manner determined by the |
| 24 | board or department to be sufficient to cover claims arising |
| 25 | out of the rendering of or failure to render professional care |
| 26 | and services in this state. |
| 27 | (2) The board or department may grant exemptions upon |
| 28 | application by practitioners meeting any of the following |
| 29 | criteria: |
| 30 | (a) Any person licensed under chapter 457, s. |
| 31 | 458.3475, <u>s. 458.3476,</u> s. 459.023, <u>s. 459.025,</u> chapter 460, |
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1 chapter 461, s. 464.012, chapter 466, or chapter 467 who practices exclusively as an officer, employee, or agent of the 2 Federal Government or of the state or its agencies or its 3 subdivisions. For the purposes of this subsection, an agent 4 5 of the state, its agencies, or its subdivisions is a person 6 who is eligible for coverage under any self-insurance or 7 insurance program authorized by the provisions of s. 8 768.28(16) or who is a volunteer under s. 110.501(1). 9 (b) Any person whose license or certification has become inactive under chapter 457, s. 458.3475, <u>s. 458.3476</u>, 10 s. 459.023, <u>s. 459.025</u>, chapter 460, chapter 461, part I of 11 12 chapter 464, chapter 466, or chapter 467 and who is not 13 practicing in this state. Any person applying for reactivation of a license must show either that such licensee 14 maintained tail insurance coverage which provided liability 15 coverage for incidents that occurred on or after October 1, 16 17 1993, or the initial date of licensure in this state, 18 whichever is later, and incidents that occurred before the date on which the license became inactive; or such licensee 19 must submit an affidavit stating that such licensee has no 20 21 unsatisfied medical malpractice judgments or settlements at 22 the time of application for reactivation. 23 (c) Any person holding a limited license pursuant to s. 456.015, and practicing under the scope of such limited 2.4 25 license. (d) Any person licensed or certified under chapter 26 27 457, s. 458.3475, <u>s. 458.3476</u>, s. 459.023, <u>s. 459.025</u> chapter 2.8 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who 29 practices only in conjunction with his or her teaching duties at an accredited school or in its main teaching hospitals. 30 Such person may engage in the practice of medicine to the 31 14

1 extent that such practice is incidental to and a necessary 2 part of duties in connection with the teaching position in the 3 school. 4 (e) Any person holding an active license or 5 certification under chapter 457, s. 458.3475, s. 458.3476, s. б 459.023, <u>s. 459.025</u>, chapter 460, chapter 461, s. 464.012, 7 chapter 466, or chapter 467 who is not practicing in this 8 state. If such person initiates or resumes practice in this 9 state, he or she must notify the department of such activity. (f) Any person who can demonstrate to the board or 10 department that he or she has no malpractice exposure in the 11 12 state. 13 (3) Notwithstanding the provisions of this section, the financial responsibility requirements of ss. 458.320 and 14 459.0085 shall continue to apply to practitioners licensed 15 under those chapters, except for clinical perfusionists 16 17 licensed pursuant to s. 458.3476 or s. 459.025 and 18 anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023 who must meet the requirements of this section. 19 Section 3. Section 459.025, Florida Statutes, is 20 21 created to read: 22 459.025 Clinical perfusionist.--23 (1) DEFINITIONS.--As used in this section, the term: (a) "Approved program" means a program for the 2.4 25 education and training of clinical perfusion which has been approved by the boards as provided in subsection (5). 26 27 (b) "Boards" means the Board of Medicine and the Board 2.8 of Osteopathic Medicine. (c) "Clinical perfusionist" means a person who has 29 30 graduated from an approved program, who is licensed to perform 31

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| 1 | medical services, and who is prescribed, delegated, or |
| 2 | supervised by a licensed physician. |
| 3 | (d) "Clinical perfusion" means the functions necessary |
| 4 | for the support, treatment, measurement, or supplementation of |
| 5 | the cardiovascular, circulatory, or respiratory systems or |
| б | other organs, or a combination of those activities, and the |
| 7 | safe management of physiologic functions by monitoring and |
| 8 | analyzing the parameters of the systems under an order and the |
| 9 | supervision of a licensed osteopathic physician, through |
| 10 | extracorporeal circulation, long-term clinical support |
| 11 | techniques, including extracorporeal carbon-dioxide removal |
| 12 | and extracorporeal membrane oxygenation, and associated |
| 13 | therapeutic and diagnostic technologies, such as counter |
| 14 | pulsation, ventricular assistance, auto transfusion, blood |
| 15 | conservation techniques, myocardial and organ preservation, |
| 16 | extracorporeal life support, isolated limb perfusion, |
| 17 | therapeutic aphaeresis, and platelet rich plasma |
| 18 | sequestration. |
| 19 | (e) "Clinical perfusionists' licensing committee" |
| 20 | means the clinical perfusion licensing committee appointed by |
| 21 | the board. |
| 22 | (f) "Continuing medical education" means courses |
| 23 | recognized and approved by the boards, the American Academy of |
| 24 | Physician Assistants, the American Medical Association, the |
| 25 | American Osteopathic Association, the American Board of |
| 26 | Cardiovascular Perfusion, or the Accreditation Council on |
| 27 | Continuing Medical Education. |
| 28 | (q) "Direct supervision" means the on-site, personal |
| 29 | supervision by a licensed clinical perfusionist who is present |
| 30 | when a procedure is being performed and who is in all |
| 31 | instances immediately available to provide assistance and |
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1 direction to the clinical perfusionist while clinical 2 perfusion services are being performed. (h) "Extracorporeal circulation" means the diversion 3 4 of a patient's blood through a heart-lung machine or a similar 5 device that assumes the functions of the patient's heart, 6 lungs, kidneys, liver, or other organs. 7 (i) "Trainee" means a person who is currently enrolled 8 in an approved program. 9 (j) "Perfusion protocols" means perfusion-related 10 policies and protocols developed or approved by a licensed health facility or a physician through collaboration with 11 12 administrators, licensed clinical perfusionists, and other 13 health care professionals. (k) "Proficiency examination" means an entry-level 14 examination approved by the boards, including examinations 15 administered by the American Board of Cardiovascular Perfusion 16 17 (ABCP). 18 (1) "Provisional licensed perfusionist" means a person provisionally licensed under this section. 19 20 (m) "Supervising physician" means an osteopathic 21 physician who holds an active license. 22 (n) "Temporarily licensed perfusionist" means a person 23 granted a temporary license under this section. (2) PERFORMANCE OF A SUPERVISING PHYSICIAN. -- A 2.4 25 physician who supervises a clinical perfusionist must be qualified in the medical areas in which the clinical 26 27 perfusionist performs. 2.8 (3)(a) PERFORMANCE OF CLINICAL PERFUSIONISTS.--A clinical perfusionist may perform duties established by rule 29 by the board, including the following duties that are included 30 in the clinical perfusionist's protocol, while prescribed by a 31

| 1 | physician or under the supervision of an osteopathic |
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| 2 | physician: |
| 3 | 1. Perform extracorporeal circulation/clinical |
| 4 | support; |
| 5 | 2. Perform or administer counter pulsation; |
| 6 | 3. Perform circulatory support and ventricular |
| 7 | assistance; |
| 8 | 4. Perform extracorporeal membrane oxygenation (ECMO) |
| 9 | and extracorporeal life support (ECLS); |
| 10 | 5. Perform blood conservation techniques, |
| 11 | autotransfusion, and blood component sequestration; |
| 12 | 6. Perform myocardial preservation; |
| 13 | 7. Perform coagulation and hemotalogic monitoring; |
| 14 | 8. Perform physiological monitoring; |
| 15 | 9. Perform blood gas and blood chemistry monitoring; |
| 16 | 10. Perform induction of hypothermia or hyperthermia |
| 17 | with reversal; |
| 18 | 11. Perform hemodilution; |
| 19 | 12. Perform hemofiltration; |
| 20 | 13. Administer blood, blood products, supportive |
| 21 | fluids, and anesthetic agents via the extracorporeal circuit; |
| 22 | 14. Complete documentation associated with described |
| 23 | duties; |
| 24 | 15. Perform isolated limb and organ perfusion; |
| 25 | 16. Provide surgical assistance; |
| 26 | 17. Perform organ preservation; |
| 27 | 18. Perform dialysis while on clinical bypass; |
| 28 | 19. Perform therapeutic apheresis; |
| 29 | 20. Administer blood, blood products and supportive |
| 30 | fluids via the therapeutic apheresis circuit; and |
| 31 | 21. Perform pacemaker lead and battery analysis. |
| | 10 |

| 1 | (b) This section or chapter does not prevent |
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| 2 | third-party payors from reimbursing employers of clinical |
| 3 | perfusionists for covered services rendered by such clinical |
| 4 | perfusionists. |
| 5 | (c) A clinical perfusionist shall clearly convey to a |
| 6 | patient that he or she is a clinical perfusionist. |
| 7 | (d) A clinical perfusionist may perform medical tasks |
| 8 | and services within the framework of a written practice |
| 9 | protocol developed between the supervising physician and the |
| 10 | <u>clinical perfusionist.</u> |
| 11 | (e) A clinical perfusionist may not prescribe, order, |
| 12 | compound, or dispense any controlled substance, legend drug, |
| 13 | or medical device to any patient. This paragraph does not |
| 14 | prohibit a clinical perfusionist from administering legend |
| 15 | drugs, controlled substances, intravenous drugs, fluids, or |
| 16 | blood products that are ordered by the physician and |
| 17 | administered to a patient while under the orders of such |
| 18 | physician. |
| 19 | (4) PERFORMANCE BY TRAINEES The practice of a |
| 20 | trainee is exempt from the requirements of this chapter while |
| 21 | the trainee is performing assigned tasks as a trainee in |
| 22 | conjunction with an approved program. Before providing |
| 23 | clinical perfusion in conjunction with the requirements of an |
| 24 | approved program, the trainee shall clearly convey to the |
| 25 | patient that he or she is a trainee and is under direct |
| 26 | supervision. |
| 27 | (5) PROGRAM APPROVAL The boards shall approve |
| 28 | programs for the education and training of clinical |
| 29 | perfusionists which meet standards established by board rules. |
| 30 | The boards may recommend only those programs for clinical |
| 31 | perfusionists training which hold full accreditation or |
| | 19 |

| 1 | provisional accreditation from the Commission on Accreditation |
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| 2 | of Allied Health Education Programs. |
| 3 | (6) CLINICAL PERFUSIONIST LICENSURE |
| 4 | (a) Any person seeking to be licensed as a clinical |
| 5 | perfusionist must apply to the department. The department |
| б | shall issue a license to any person certified by the board to: |
| 7 | 1. Be at least 18 years of age. |
| 8 | 2. Have satisfactorily passed a proficiency |
| 9 | examination established by the American Board of |
| 10 | Cardiovascular Perfusion (ABCP). The board, on receipt of an |
| 11 | application and application fee, shall waive the examination |
| 12 | requirement for an applicant who at the time of application: |
| 13 | a. Is appropriately licensed or certified by another |
| 14 | state, territory, or possession of the United States if the |
| 15 | requirements of that state, territory, or possession for the |
| 16 | license or certificate are the substantial equivalent of the |
| 17 | requirements of this section determined by the board; or |
| 18 | b. Holds a current certificate as a certified clinical |
| 19 | perfusionist issued by the American Board of Cardiovascular |
| 20 | Perfusion (ABCP), or its successor before July 1, 2005. |
| 21 | 3. Be certified in basic cardiac life support. |
| 22 | 4. Have completed the application form and remitted an |
| 23 | application fee, not to exceed \$1,500, as set by the |
| 24 | department. An application must include: |
| 25 | a. A certificate of completion of an approved program; |
| 26 | b. A sworn statement of any prior felony convictions; |
| 27 | <u>c. A sworn statement of any prior discipline or denial</u> |
| 28 | of licensure or certification in any state; and |
| 29 | d. Two letters of recommendation, one from a physician |
| 30 | and one from a certified or licensed clinical perfusionist. |
| 31 | |

| 1 | Before January 1, 2006, a person is eligible to apply to the |
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| 2 | board and receive a license notwithstanding the requirements |
| 3 | of this subsection if the person was actively engaged in the |
| 4 | practice of perfusion consistent with applicable law, and if |
| 5 | the person was operating cardiopulmonary bypass systems during |
| б | cardiac surgical cases in a licensed health care facility as |
| 7 | the person's primary function and had been operating the |
| 8 | system for 10 of the 12 years preceding application for |
| 9 | licensure. |
| 10 | (b) A license must be renewed biennially. Each renewal |
| 11 | <u>must include:</u> |
| 12 | 1. A renewal fee, not to exceed \$1,500, as set by the |
| 13 | department; and |
| 14 | 2. A sworn statement of no felony convictions in the |
| 15 | immediately preceding 2 years. |
| 16 | (c) Each licensed clinical perfusionist shall |
| 17 | biennially complete continuing medical education as required |
| 18 | by the board. |
| 19 | (d)1. A license as a provisional licensed perfusionist |
| 20 | may be issued by the board to a person who has successfully |
| 21 | completed an approved perfusion education program and the |
| 22 | filing of an application, payment of an application fee, and |
| 23 | the submission of evidence satisfactory to the board of the |
| 24 | successful completion of the requisite education requirements. |
| 25 | 2. A provisional licensed perfusionist is under the |
| 26 | supervision and direction of a licensed perfusionist at all |
| 27 | times during which the provisional licensed perfusionist |
| 28 | performs perfusion. Rules adopted by the board governing such |
| 29 | supervision and direction may not require the immediate |
| 30 | physical presence of the supervising licensed perfusionist. |
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| 1 | 3. A provisional license is valid for 2 years from the |
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| 2 | date it is issued and may be extended subject to rule by the |
| 3 | board. The application for extension must be signed by a |
| 4 | supervising licensed perfusionist. Upon notification by the |
| 5 | approved testing service, or the board, that any portion of |
| 6 | the licensing examination has been failed after the 2-year |
| 7 | provisional license term, the provisional license must be |
| 8 | surrendered to the board. |
| 9 | (e) A license as a temporarily licensed perfusionist |
| 10 | may be issued by the department to a person who has |
| 11 | successfully completed the perfusion licensure application. |
| 12 | (f) The Board of Osteopathic Medicine may impose upon |
| 13 | <u>a clinical perfusionist any penalty specified in s. 456.072 or</u> |
| 14 | <u>s. 458.331(2) if the clinical perfusionist is found quilty of</u> |
| 15 | or is investigated for an act that constitutes a violation of |
| 16 | this chapter or chapter 456. |
| 17 | (7) CARDIOVASCULAR SURGEON AND CLINICAL PERFUSIONIST |
| 18 | TO ADVISE THE BOARD |
| 19 | <u>(a) The chairperson of the board may appoint a</u> |
| 20 | <u>cardiovascular surgeon and a certified clinical perfusionist</u> |
| 21 | to advise the board as to the adoption of rules for the |
| 22 | licensure of clinical perfusionists. The board may use a |
| 23 | committee structure that is most practicable in order to |
| 23 | receive any recommendations to the board regarding rules and |
| 24 25 | all matters relating to clinical perfusionists, including, but |
| 25 26 | not limited to, recommendations to improve safety in the |
| 20 27 | |
| | clinical practices of licensed clinical perfusionists. |
| 28 | (b) In addition to its other duties and |
| 29 20 | responsibilities as prescribed by law, the board shall: |
| 30 | 1. Recommend to the department the licensure of |
| 31 | clinical perfusionists. |

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| 1 | 2. Develop rules regulating the use of clinical |
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| 2 | perfusionists under this chapter and chapter 458, except for |
| 3 | rules relating to the formulary developed under s. 458.347(4). |
| 4 | The board shall also develop rules to ensure that the |
| 5 | continuity of supervision is maintained in each practice |
| б | setting. The boards shall consider adopting a proposed rule at |
| 7 | the regularly scheduled meeting immediately following the |
| 8 | submission of the proposed rule. A proposed rule may not be |
| 9 | adopted by either board unless both boards have accepted and |
| 10 | approved the identical language contained in the proposed |
| 11 | rule. The language of all proposed rules must be approved by |
| 12 | both boards pursuant to each respective board's guidelines and |
| 13 | standards regarding the adoption of proposed rules. |
| 14 | 3. Address concerns and problems of clinical |
| 15 | perfusionists to improve safety in the clinical practices of |
| 16 | licensed clinical perfusionists. |
| 17 | (c) When the board finds that an applicant for |
| 18 | licensure has failed to meet, to the board's satisfaction, |
| 19 | each of the requirements for licensure set forth in this |
| 20 | section, the board may enter an order to: |
| 21 | 1. Refuse to certify the applicant for licensure; |
| 22 | 2. Approve the applicant for licensure with |
| 23 | restrictions on the scope of practice or license; or |
| 24 | 3. Approve the applicant for conditional licensure. |
| 25 | Such conditions may include placement of the applicant on |
| 26 | probation for a period of time and subject to such conditions |
| 27 | as the board specifies, including, but not limited to, |
| 28 | requiring the applicant to undergo treatment, to attend |
| 29 | continuing education courses, or to take corrective action. |
| 30 | (8) PENALTYA person who falsely holds himself or |
| 31 | herself out as a clinical perfusionist commits: |

| 1 | (a) For the first offense, a misdemeanor of the first |
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| 2 | <u>degree, punishable as provided in s. 775.082, s. 775.083, or</u> |
| 3 | <u>s. 775.084.</u> |
| 4 | (b) For the second or subsequent offense, a felony of |
| 5 | the third degree, punishable as provided in s. 775.082, s. |
| 6 | <u>775.083, or s. 775.084.</u> |
| 7 | (9) DENIAL, SUSPENSION, OR REVOCATION OF |
| 8 | LICENSUREThe boards may deny, suspend, or revoke the |
| 9 | license of a clinical perfusionist whom the board determines |
| 10 | has violated any provision of this section, chapter, or any |
| 11 | rule adopted pursuant thereto. |
| 12 | (10) RULESThe boards shall adopt rules to |
| 13 | administer this section. |
| 14 | (11) FEESThe department shall allocate the fees |
| 15 | collected under this section to the boards. |
| 16 | (12) EXEMPTIONS |
| 17 | (a) This section may not be construed to limit the |
| 18 | practice of an osteopathic physician licensed under this |
| 19 | chapter or a respiratory therapist licensed under chapter 468, |
| 20 | so long as that person does not hold himself or herself out to |
| 21 | the public as possessing a license, provisional license, |
| 22 | registration, or certificate issued under this section or use |
| 23 | a professional title protected by this section. |
| 24 | (b) This section may not be construed to limit the |
| 25 | practice of nursing or to prevent qualified members of other |
| 26 | professions from doing work of a nature consistent with their |
| 27 | training and licensure, so long as those persons do not hold |
| 28 | themselves out to the public as possessing a license, |
| 29 | provisional license, registration, or certificate issued under |
| 30 | this section or use a professional title protected by this |
| 31 | section. |
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| 1 | (c) A person need not be licensed under this section |
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| 2 | who: |
| 3 | 1. Is licensed in this state under any other law and |
| 4 | is engaging in the profession or occupation for which he or |
| 5 | she is licensed. |
| 6 | 2. Is a qualified person in this state or another |
| 7 | state or territory who is employed by the United States |
| 8 | Government or an agency thereof while discharging his or her |
| 9 | official duties. |
| 10 | 3. Is a student providing services regulated under |
| 11 | this chapter who is: |
| 12 | a. Pursuing a course of study that leads to a degree |
| 13 | in a profession regulated by this chapter; |
| 14 | b. Providing services in a training setting, as long |
| 15 | as such services and associated activities constitute part of |
| 16 | a supervised course of study; and |
| 17 | c. Designated by the title "trainee." |
| 18 | 4. Is not a resident of this state but offers services |
| 19 | in this state, provided that: |
| 20 | a. Such services are performed in this state for no |
| 21 | more than 15 days in any calendar year; and |
| 22 | b. Such nonresident is licensed or certified by a |
| 23 | state or territory of the United States or by a foreign |
| 24 | country or province. |
| 25 | (d) Except as stipulated by the board, the exemptions |
| 26 | in this subsection do not apply to any person licensed under |
| 27 | this section whose license has been revoked or suspended by |
| 28 | the board or whose license or certification in another |
| 29 | jurisdiction has been revoked or suspended by the licensing or |
| 30 | certifying authority in that jurisdiction. |
| 31 | |
| | |

1 (e) This subsection may not be construed to exempt a 2 person from meeting the minimum standards of performance in professional activities when measured against generally 3 4 prevailing peer performance, including the undertaking of 5 activities for which the person is not qualified by training 6 or experience. 7 (13) PAYMENT OR REIMBURSEMENT BY HOSPITALS OF COSTS OF 8 COMPLIANCE WITH PART. -- A hospital is not required to pay for, or reimburse any person for, the costs of compliance with any 9 10 requirement of this part, including costs of continuing 11 education. 12 Section 4. This act shall take effect January 1, 2006. 13 STATEMENT OF SUBSTANTIAL CHANGES CONTAINED IN 14 COMMITTEE SUBSTITUTE FOR Senate Bill 2372 15 16 17 The Committee Substitute makes the following changes: 18 -- Revises requirements for the licensure of clinical perfusionists; 19 -- Revises the definition of "clinical perfusion," "extracorporeal circulation," and "supervising physician"; 2.0 Increases the application fee for a clinical 21 perfusionist's license from \$1,000 to \$1,500 as set by the 2.2 Department of Health rather than the Board of Medicine and Board of Osteopathic Medicine; 23 Revises requirements for continuing education as a condition of licensure renewal so that 40 hours of continuing 2.4 education are not required to be completed each 2 years; 25 Deletes grounds for which a medical or osteopathic physician may be disciplined for failing to adequately 26 supervise a clinical perfusionist; 27 -- Creates exemptions from the clinical perfusionist 2.8 licensure requirements; 29 Revises the functions that a clinical perfusionist may perform to exclude hemotalogic analysis and blood gas 30 analysis; and -- Requires trainees to be under the direct supervision of a 31 clinical perfusionist to perform assigned tasks. 26