

# 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.)

BILL: CS/SB 1950

SPONSOR: Health, Aging and Long-Term Care Committee and Senator Sullivan

SUBJECT: Health Regulation

DATE: February 27, 2002      REVISED: \_\_\_\_\_

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HC	Favorable/CS
2.	_____	_____	GO	_____
3.	_____	_____	AHS	_____
4.	_____	_____	AP	_____
5.	_____	_____	_____	_____
6.	_____	_____	_____	_____

## I. Summary:

The Committee Substitute for Senate Bill 1950 does the following:

- transfers consumer complaint services, investigations, and prosecutorial services from the Agency for Health Care Administration (AHCA) to the Department of Health (DOH);
- requires the Office of Program Policy Analysis and Government Accountability (OPPAGA) to conduct a joint audit of all hearings and billings conducted by DOAH for all agencies;
- repeals provisions establishing the health care practitioner credentialing program implemented by DOH;
- provides for the accreditation of physician offices performing specified surgical procedures in lieu of inspection by DOH;
- provides DOH additional powers and duties to implement regulation of health care professions;
- revises allopathic and osteopathic physician licensure requirements relating to credentials verification;
- increases the threshold amount for malpractice judgments or settlements for purposes of disciplining a physician for gross or repeated malpractice;
- revises requirements for the reporting of closed claims by liability insurers;
- requires OPPAGA to review the investigative field office structure and organization of AHCA;
- revises the regulation of radiologic technology and respiratory care;
- transfers statutory provisions relating to the regulation of cadaveric organ and tissue procurement from ch. 381, F.S., relating to DOH, to ch. 765, F.S.;

- defines “medically unnecessary procedure” for purposes of regulation of hospitals, ambulatory surgical centers, and mobile surgical facilities and revises requirements on internal risk management programs in such facilities;
- revises exemptions to registration requirements for certain clinics;
- revises grounds for which a health care practitioner may be disciplined for performing health care services on the wrong patient and establishes an exception to discipline for leaving a foreign body in a patient;
- revises the definition of class II pharmacies for dispensing to hospice patients;
- exempts medical malpractice insurance premiums from an assessment from the Florida Insurance Guaranty Association, Inc.;
- redefines “medical review committee” to add a committee established by a university board of trustees, and a committee comprised of faculty, residents, students and administrators of an accredited college of medicine, nursing, or other health care discipline; and
- requires the Office of Legislative Services to develop a business plan for the outsourcing of regulatory functions of the Board of Dentistry and appropriates funds to do so.

This bill creates 5 undesignated sections of law and sections 458.3093, 459.0053, and, 456.0165, Florida Statutes.

This bill amends ss. 20.43, 456.039, 456.0391, 456.072, 456.077, 458.309, 459.005, 456.004, 456.009, 456.011, 456.026, 458.331, 459.015, 627.912, 456.025, 468.302, 468.352, 468.355, 468.368, 395.2050, 409.815, 765.5216, 765.522, 395.002, 395.0161, 395.0197, 456.0375, 456.072, 465.019, 631.57, and 766.101, F.S.

This bill renumbers ss. 381.0602 (765.53), 381.6021 (765.541), 381.6022 (765.542), 381.6023 (765.544), 381.6024 (765.545), and 381.6026 (765.547), F.S.

This bill renumbers and amends ss. 381.60225 (765.543), and 381.6025 (765.546), F.S.

This bill repeals ss. 456.047, 468.356, and 468.357, F.S.

## **II. Present Situation:**

### **General Regulatory Provisions**

Chapter 456, F.S., provides the general regulatory provisions for health care professions within the Division of Medical Quality Assurance in the Department of Health. Section 456.001, F.S., defines “health care practitioner” to mean any person licensed under ch. 457, F.S., (acupuncture); ch. 458, F.S., (medicine); ch. 459, F.S., (osteopathic medicine); ch. 460, F.S., (chiropractic medicine); ch. 461, F.S., (podiatric medicine); ch. 462, F.S., (naturopathic medicine); ch. 463, F.S., (optometry); ch. 464, F.S., (nursing); ch. 465, F.S., (pharmacy); ch. 466, F.S., (dentistry and dental hygiene); ch. 467, F.S., (midwifery); part I, II, III, IV, V, X, XIII, or XIV of ch. 468, F.S., (speech-language pathology, nursing home administration, occupational therapy, respiratory therapy, dietetics and nutrition practice, athletic trainers, and orthotics, prosthetics, and pedorthics); ch. 478, F.S., (electrology or electrolysis); ch. 480, F.S., (massage therapy); part III or IV of ch. 483, F.S., (clinical laboratory personnel or medical physics); ch. 484, F.S.,

(opticianry and hearing aid specialists); ch. 486, F.S., (physical therapy); ch. 490, F.S., (psychology); and ch. 491, F.S., (psychotherapy).

### **Medical Quality Assurance Trust Fund**

Section 20.435(1)(d), F.S., establishes the Medical Quality Assurance Trust Fund to be credited with revenue related to the licensing of health care practitioners. Section 456.025(5), F.S., requires that all licensure fees, fines, or costs awarded to the agency by a court be paid into the trust fund. Section 456.065(3), F.S., requires that the trust fund also be credited with revenues received from the department's unlicensed activity efforts. Funds in the trust fund are to be used for the purpose of providing administrative support for the regulation of health care practitioners and for such other purposes as may be appropriate in accordance with legislative appropriation. Any balance in the trust fund at the end of any fiscal year remains in the trust fund and is available for carrying out the purposes of the trust fund.

### **Licensure Fees, Receipts and Dispositions**

Section 456.025(1), F.S., requires DOH or each board to set, by rule, licensure renewal fees which are based on specified criteria, including requirements that such fees may not be more than 10 percent greater than the fee imposed for the previous biennium and may not be more than 10 percent greater than the actual cost to regulate that profession for the previous biennium. Section 456.025(3), F.S., requires each board or DOH if there is no board, to determine by rule, the amount of license fees for the profession it regulates, based upon long-range estimates of revenue from DOH. Each board is responsible for ensuring that the licensure fees set out are adequate to cover all anticipated costs in order to maintain a reasonable cash balance. If a board does not take sufficient action within one year after notification from DOH that license fees are projected to be inadequate, the department must set licensure fees within the caps on behalf of the board in order to cover anticipated costs and to maintain required cash balances. The department must include recommended fee cap increases in its annual report to the Legislature.

Section 456.025, F.S., specifies legislative intent that no regulated profession operate with a negative cash balance. The department is authorized to advance funds to a profession with a negative cash balance for a period not to exceed two consecutive years, however, the profession must pay interest. Section 456.025(5), F.S., provides that each board, or the department if there is no board, may collect a one-time fee from each active and voluntary inactive licensee in an amount necessary to eliminate a cash deficit, or if there is not a cash deficit, in an amount sufficient to maintain the financial integrity of the professions; however, no more than one assessment may be made in any four-year period without specific legislative authorization.

Section 456.025(8), F.S., requires DOH to maintain separate accounts in the trust fund for each profession and to charge direct expenses as well as proportionately allocate indirect expenses to each profession. Documentation to support allocated expenses must be maintained and DOH must provide this information to the boards upon request. The department must provide each board with an annual report of revenue and direct and allocated expenses related to the operation of that profession. Boards are required to use these reports and the long-range plan to determine the amount of licensure fees. A condensed management report of this information, with recommendations from the department, is to be included in the annual report submitted to the

Legislature. Additionally condensed quarterly management reports are to be provided to each board.

### **Auditor General Report No. 02-130**

The January 2002 Auditor General Operational Audit noted that the Department of Health took actions to implement recommendations of a previous report, but noted other areas should be addressed:

- License renewal fees are not sufficient to generate revenue to cover the cost of regulating most health care professions.
- The boards had not taken all actions available to eliminate or reduce deficit cash balances.
- Although the Division of Medical Quality Assurance (DMQA) significantly improved the timely distribution of financial reports, improvements are needed in report content and training of users of the reports.
- The Department of Health took actions to analyze its methodology for allocating costs to the Medical Quality Assurance Trust Fund (MQATF), but implementation of changes is ongoing.
- The Agency for Health Care Administration's allocation of administrative costs resulted in under allocating costs to the functions of the DMQA function.
- The annual operating costs of the Department of Health's credentialing program contribute to the decline of the MQATF without providing intended benefits.
- The Division had not taken actions to implement a continuing education tracking system.
- The Department of Health's costs related to administrative hearings have increased significantly.

### **Legal and Investigative Services; Annual Report**

Section 456.009, F.S., requires DOH to provide counsel for boards within the department by contracting with the Department of Legal Affairs, by retaining private counsel pursuant to s. 287.059, F.S., or by providing department staff counsel. DOH must prepare an annual report with statistics and relevant information, profession by profession, pursuant to s. 456.026, F.S.

### **Disciplinary Procedures**

Section 456.073, F.S., sets forth procedures DOH must follow in order to conduct disciplinary proceedings against practitioners under its jurisdiction. The department, for the boards under its jurisdiction, must investigate all written complaints filed with it that are legally sufficient. Complaints are legally sufficient if they contain facts, which, if true, show that a licensee has

violated any applicable regulations governing the licensee's profession or occupation. Even if the original complainant withdraws or otherwise indicates a desire that the complaint not be investigated or prosecuted to its completion, the department at its discretion may continue its investigation of the complaint. The department may investigate anonymous, written complaints or complaints filed by confidential informants if the complaints are legally sufficient and the department has reason to believe after a preliminary inquiry that the alleged violations are true. If the department has reasonable cause to believe that a licensee has violated any applicable regulations governing the licensee's profession, it may initiate an investigation on its own.

When investigations of licensees within the department's jurisdiction are determined to be complete and legally sufficient, the department is required to prepare, and submit to a probable cause panel of the appropriate board, if there is a board, an investigative report along with a recommendation of the department regarding the existence of probable cause. A board has discretion over whether to delegate the responsibility of determining probable cause to the department or to retain the responsibility to do so by appointing a probable cause panel for the board. The determination as to whether probable cause exists must be made by majority vote of a probable cause panel of the appropriate board, or by the department if there is no board or if the board has delegated the probable cause determination to the department.

The subject of the complaint must be notified regarding the department's investigation of alleged violations that may subject the licensee to disciplinary action. When the department investigates a complaint, it must provide the subject of the complaint or her or his attorney a copy of the complaint or document that resulted in the initiation of the investigation. Within 20 days after the service of the complaint, the subject of the complaint may submit a written response to the information contained in the complaint. The department may conduct an investigation without notification to the subject if the act under investigation is a criminal offense. If the department's secretary or her or his designee and the chair of its probable cause panel agree, in writing, that notification to the subject of the investigation would be detrimental to the investigation, then the department may withhold notification of the subject.

If the subject of the complaint makes a written request and agrees to maintain the confidentiality of the information, the subject may review the department's complete investigative file. The licensee may respond within 20 days of the licensee's review of the investigative file to information in the file before it is considered by the probable cause panel. Complaints and information obtained by the department during its investigations are exempt from the public records law until 10 days after probable cause has been found to exist by the probable cause panel or the department, or until the subject of the investigation waives confidentiality. If no probable cause is found to exist, the complaints and information remain confidential in perpetuity.

When the department presents its recommendations regarding the existence of probable cause to the probable cause panel of the appropriate board, the panel may find that probable cause exists or does not exist, or it may find that additional investigative information is necessary in order to make its findings regarding probable cause. Probable cause proceedings are exempt from the noticing requirements of ch. 120, F.S. After the panel convenes and receives the department's final investigative report, the panel may make additional requests for investigative information. Section 456.073(4), F.S., specifies time limits within which the probable cause panel may

request additional investigative information from the department and within which the probable cause panel must make a determination regarding the existence of probable cause. Within 30 days of receiving the final investigative report, the department or the appropriate probable cause panel must make a determination regarding the existence of probable cause. The secretary of the department may grant an extension of the 15-day and 30-day time limits outlined in s. 456.073(4), F.S. If the panel does not issue a letter of guidance or find probable cause within the 30-day time limit as extended, the department must make a determination regarding the existence of probable cause within 10 days after the time limit has elapsed.

Instead of making a finding of probable cause, the probable cause panel may issue a letter of guidance to the subject of a disciplinary complaint. Letters of guidance do not constitute discipline. If the panel finds that probable cause exists, it must direct the department to file a formal administrative complaint against the licensee under the provisions of ch. 120, F.S. The department has the option of not prosecuting the complaint if it finds that probable cause has been improvidently found by the probable cause panel. In the event the department does not prosecute the complaint on the grounds that probable cause was improvidently found, it must refer the complaint back to the board that then may independently prosecute the complaint. The department must report to the appropriate board any investigation or disciplinary proceeding not before the Division of Administrative Hearings under ch. 120, F.S., or otherwise not completed within 1 year of the filing of the complaint. The appropriate probable cause panel then has the option to retain independent legal counsel, employ investigators, and continue the investigation, as it deems necessary.

When an administrative complaint is filed against a subject based on an alleged disciplinary violation, the subject of the complaint is informed of her or his right to request an informal hearing if there are no disputed issues of material fact, or a formal hearing if there are disputed issues of material fact or the subject disputes the allegations of the complaint. The subject may waive her or his rights to object to the allegations of the complaint, which allows the department to proceed with the prosecution of the case without the licensee's involvement. Once the administrative complaint has been filed, the licensee has 21 days to respond to the department. If the subject of the complaint and the department do not agree in writing that there are no disputed issues of material fact, s. 456.073(5), F.S., requires a formal hearing before a hearing officer of the Division of Administrative Hearings under ch. 120, F.S. The hearing provides a forum for the licensee to dispute the allegations of the administrative complaint. At any point before an administrative hearing is held, the licensee and the department may reach a settlement. The settlement is prepared by the prosecuting attorney and sent to the appropriate board. The board may accept, reject, or modify the settlement offer. If accepted, the board may issue a final order to dispose of the complaint. If rejected or modified by the board, the licensee and department may renegotiate a settlement or the licensee may request a formal hearing. If a hearing is held, the hearing officer makes findings of fact and conclusions of law that are placed in a recommended order. The licensee and the department's prosecuting attorney may file exceptions to the hearing officer's findings of facts. The boards resolve the exceptions to the hearing officer's findings of facts when they issue a final order for the disciplinary action.

The boards within DOH have the status of an agency for certain administrative actions, including licensee discipline. A board may issue an order imposing discipline on any licensee under its jurisdiction as authorized by the profession's practice act and the provisions of ch. 456, F.S.

Typically, boards are authorized to impose the following disciplinary penalties against licensees: refusal to certify, or to certify with restrictions, an application for a license; suspension or permanent revocation of a license; restriction of practice or license; imposition of an administrative fine for each count or separate offense; issuance of a reprimand or letter of concern; placement of the licensee on probation for a specified period of time and subject to specified conditions; or corrective action. The department contracts with AHCA to investigate and prosecute disciplinary complaints.

### **Physician Office Surgery and Adverse Incident Reporting**

Licensed medical physicians may perform surgery in their medical offices, ambulatory surgical centers, or hospitals. Sections 458.309 and 459.005, F.S., provide that all allopathic or osteopathic physicians who perform level 2 procedures lasting more than 5 minutes and all level 3 surgical procedures in an office setting must register the office with DOH unless that office is licensed as a facility under ch. 395, F.S.<sup>1</sup> DOH must inspect the physician's office unless the office is accredited by a nationally recognized accrediting agency or an accrediting organization subsequently approved by the Board of Medicine or Board of Osteopathic Medicine. The actual costs for registration and inspection must be paid by the person seeking to register and operate the office setting in which office surgery is performed.

Sections 458.351 and 459.026, F.S., require any medical physician, osteopathic physician, or physician assistant to notify DOH of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under ch. 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. The sections require any medical physician, osteopathic physician, or physician assistant to notify the department in writing and by certified mail of the adverse incident within 15 days after the adverse incident occurred. The notice must be postmarked within 15 days after the adverse incident occurred.

“Adverse incident” is defined under ss. 458.351 and 459.026, F.S., to mean an event over which the physician or physician assistant could exercise control and which is associated in whole or in part with a medical intervention, rather than the condition for which such intervention occurred, and which results in the following patient injuries:

- Death of a patient;
- Brain or spinal damage to a patient;
- Performance of a surgical procedure on the wrong patient;
- Any condition that required the transfer of a patient to a hospital licensed under ch. 395, F.S., from an ambulatory surgical center licensed under ch. 395, F.S., or from any facility or any office maintained by a physician for the practice of medicine which is not licensed under ch. 395; or

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<sup>1</sup> Section 458.309(1), F.S., provides that the Board of Medicine has authority to adopt rules pursuant to ss. 120.536(1) and 120.54, F.S., to implement the provisions of this chapter (the medical practice act) conferring duties upon it. Section 459.005(1), F.S., provides that the Board of Osteopathic Medicine has authority to adopt rules pursuant to ss. 120.536(1) and 120.54, F.S., to implement the provisions of this chapter (the osteopathic practice act) conferring duties upon it.

- Performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure.

Under the definition of adverse incident, a medical physician, osteopathic physician, or physician assistant must provide notice of patient injuries only if they result in death, brain or spinal damage, permanent disfigurement, fracture or dislocation of bones or joints, a limitation of neurological, physical or sensory function, or any condition that required the transfer of the patient. DOH must review each adverse incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action, and provides that the procedures for handling disciplinary complaints under s. 456.073, F.S., apply.

### **Medical Malpractice**

Sections 458.331(1)(t) and 459.015(1)(k), F.S., provide grounds for which an allopathic physician or osteopathic physician may be subject to discipline for gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. "Repeated malpractice" includes three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$25,000 each to the claimant in a judgment or settlement and which involve incidents of negligent conduct by a physician. Section 627.912, F.S., requires self-insurers and insurers or joint underwriting associations providing professional liability insurance to practitioner of medicine, osteopathic medicine, podiatric medicine, or dentistry, or a hospital, health maintenance organization, ambulatory surgical center, or a member of the Florida Bar to report in duplicate to the Department of Insurance any claim or action for damages for personal injuries claimed to be caused by error, omission, or negligence that resulted in a final judgment or settlement. Such reports must be filed with the Department of Insurance and if the insured party is a licensed health care practitioner, with DOH no later than 30 days from the date of the final judgment or settlement.

Chapter 766, F.S., deals with medical malpractice and related matters. Section 766.101, F.S., provides for medical review committees to engage in quality assurance activities and the investigations, proceedings and records of a committee are not subject to discovery or introduction into evidence in any civil or administrative action against a health care provider whose services are the subject of the committee's review.

### **Florida Insurance Guaranty Association, Inc.**

Part II, ch. 631, is the Florida Insurance Guaranty Association Act. The Association pays claims for insolvent property and casualty insurance companies. Section 631.57, F.S., specifies the powers and duties of the Florida Insurance Guaranty Association, Inc., which include assessments on certain insurance entities. Section 631.54, F.S., defines "net direct written premiums" as direct gross premiums written in this state on insurance policies to which this part applies, less return premiums thereon and dividends paid or credited to policyholders on such direct business.



### **Standardized Credentialing for Certain Health Care Practitioners**

Section 456.047, F.S., provides requirements for a standardized credentialing program for certain health care practitioners regulated by DOH. The program provides a mechanism for standardized credentialing of medical physicians, osteopathic physicians, chiropractic physicians, podiatric physicians, and advanced registered nurse practitioners. The section provides legislative intent that a credentials collection program be established to provide that, once a health care practitioner's core credentials data are collected, they need not be collected again, except for corrections, updates, and modifications thereto. The section provides definitions for "core credentials data" as data that is primary source verified and includes professional education, professional training, licensure, current Drug Enforcement Administration certification, and specialty board certification. Under the standardized credentials verification program, DOH must maintain a complete, current file of core credentials data on each health care practitioner, which shall include all updates provided in accordance with the practitioner profiling requirements.

### **Radiation Therapy**

Part IV, ch. 468, F.S., specifies requirements for the regulation of radiation therapy. Under s. 468.302, F.S., a person who is trained and skilled in cardiopulmonary technology and who provides cardiopulmonary technology services at the direction, and under the direct supervision of a licensed practitioner, is exempt from the certification requirements. "Licensed practitioner" is defined to mean a licensed physician or person otherwise authorized by law to practice medicine, chiropody, osteopathic medicine, naturopathy, or chiropractic medicine in Florida.

Section 458.303(2), F.S., provides that nothing in s. 458.331, F.S., relating to grounds for disciplinary action against a medical physician, shall be construed to prohibit services rendered by an unlicensed medical assistant when done under the direct supervision and control of the physician and services rendered by registered nurses or licensed practical nurses when performed under the direct supervision and final approval of the medical physician. Similarly, s. 459.002, F.S., provides that nothing in chapter 459, F.S., shall be construed to prohibit services rendered by *any person* when performed under the direct supervision and control of a licensed osteopathic physician who must be available when needed, provide specific direction and give final approval to all services performed.

### **Respiratory Therapy**

Part V, ch. 468, F.S., governs the practice of respiratory therapy. The part provides definitions and licensure requirements for respiratory care practitioners. Section 468.355, F.S., specifies licensure requirements for a person to become a certified respiratory therapist. To do so, a person must be at least 18 years old and possess a high school diploma or a graduate equivalency diploma. In addition, the applicant must meet at least one of the following criteria: (1) successful completion of a training program for respiratory therapy technicians or respiratory therapists approved by the Commission on Accreditation of Allied Health Education Programs, or the equivalent, as accepted by the Florida Board of Respiratory Care (board); (2) the applicant is currently a "Certified Respiratory Therapist" certified by the National Board for Respiratory Care, or its equivalent, as accepted by the board; (3) the applicant is currently a "Registered

Respiratory Therapist” registered by the National Board for Respiratory Care, or its equivalent, as accepted by the board.

To become licensed as a registered respiratory therapist, an applicant must be at least 18 years old and possess a high school diploma or a graduate equivalency diploma. In addition, the applicant must meet at least one of the following criteria: (1) successful completion of a training program for registered respiratory therapists approved by the Commission on Accreditation of Allied Health Education Programs, or the equivalent, as accepted by the Florida Board of Respiratory Care; or (2) the applicant is currently a “Registered Respiratory Therapist” registered by the National Board for Respiratory Care, or its equivalent, as accepted by the board.

A Florida-licensed respiratory therapist may voluntarily be certified as a Certified Respiratory Therapist or registered as a Registered Respiratory Therapist pursuant to the requirements of the National Board for Respiratory Care. The National Board for Respiratory Care is a national organization recognized by the Council that provides voluntary certification for respiratory care practitioners, which is recognized under Florida licensure laws. The National Board for Respiratory Care currently offers five credentialing programs. These examinations include the: certification examination for entry level respiratory therapists for the designation of (CRT); and the registry examination for advanced respiratory therapy practitioners (RRT).

A Florida-licensed respiratory therapist delivers respiratory care services under the order of a Florida-licensed allopathic or osteopathic physician, and in accordance with protocols established by a hospital, other health care provider, or the Board of Respiratory Care, and who functions in situations of unsupervised patient contact requiring individual judgment. A licensed respiratory care practitioner is employed to deliver respiratory care services under a Florida licensed allopathic or osteopathic physician, and in accordance with protocols established by a hospital, other health care provider, or the Florida Board of Respiratory Care. Under s. 468.355, F.S., the Florida Board of Respiratory Care must establish procedures for temporary licensure of eligible individuals entering Florida and temporary licensure of those persons who have graduated from a program approved by the Florida Board of Respiratory Care. The duration of such temporary licensure may not exceed 1 year.

Respiratory care education programs are accredited through the Committee on Accreditation for Respiratory Care (CoARC), previously the Joint Review Committee for Respiratory Therapy Education (JRCRTE). The Committee on Accreditation for Respiratory Care is responsible for assuring that respiratory therapy education programs comply with the standards adopted by the Commission on Accreditation of Allied Health Education Programs (CAAHEP). Its representatives visit respiratory therapy programs to evaluate applications for accreditation and perform periodic reviews.

The Committee on Accreditation for Respiratory Care has established new education standards that require all accredited education programs to award a minimum of an associate degree to all students who enroll beginning January 1, 2002. Persons seeking to qualify for the National Board for Respiratory Care’s certification examination for the designation Certified Respiratory Therapist who enroll on or after January 1, 2002, must graduate from an entry or advanced level respiratory care program with a minimum of an associate degree. Any National Board for Respiratory Care certification applicants who have started or graduated from any respiratory care

educational program or entered the credentialing system before January 1, 2002, will have until December 31, 2005, to complete the requirements for credentialing without having an associate degree.

Section 468.356, F.S., provides that the approval of educational programs must be in accordance with the Joint Review Committee for Respiratory Therapy Education through the Commission on Accreditation of Allied Health Education Programs, or other accrediting agency recognized by the United States Department of Education. The Board of Respiratory Care may require additional documentation of an intent to achieve full accreditation from any educational program that has not yet received full American Medical Association approval. The board may grant temporary approval for graduates of any program that has not yet achieved full accreditation so that such graduates may sit for the licensure examination.

Section 468.357, F.S., specifies procedures for licensure by examination of persons wishing to practice as certified respiratory therapists. To sit for the examination, the applicant must: complete the required forms and pay the required licensure fee set by the Florida Board of Respiratory Care; submit required documentation; and remit an examination fee set by the examination provider. Examinations for licensure of certified respiratory therapists administered by DOH must be conducted no less than two times a year in a geographical location or method deemed advantageous to the majority of applicants. The licensure examination for certified respiratory therapists must be the same as that given by the National Board for Respiratory Care for entry-level certification of respiratory therapists. DOH must issue a license to any applicant who successfully completes the examination who otherwise qualifies for licensure as a certified respiratory therapist.

The Florida Board of Respiratory Care must prescribe by rule continuing education requirements for respiratory care practitioners and respiratory therapists to meet as a condition for their biennial license renewal. The board must approve continuing education courses and providers of continuing education.

Section 468.368, F.S., specifies exemptions to respiratory care licensure requirements for certain persons including: medical personnel who have been formally trained in modalities used for the delivery of respiratory care services and who are duly licensed or have credentials pertaining to their respective professions; cardiopulmonary testing by individuals who have credentials by the National Board for Respiratory Care as Certified Pulmonary Function Technologists, or individuals who are employed by health care facilities and who are eligible and have applied for that credential; students enrolled in the educational program of any health care profession; gratuitous care of an ill person by a friend or family member who does not hold himself or herself out as a respiratory care practitioner or respiratory therapist; an individual providing respiratory care in an emergency who does not hold himself or herself out as a respiratory care practitioner or respiratory therapist; a person employed in the office of, and who is working under the direct supervision and control of a Florida-licensed allopathic or osteopathic physician; a student who has demonstrated enrollment in the clinical portion of an approved respiratory care educational program to the board and who is employed by a health care facility and who is delivering limited respiratory care support services under the supervision of a licensed respiratory care practitioner or a respiratory care therapist; a graduate of an approved respiratory care educational program who has applied to the board for temporary licensure under s. 468.355,

F.S.; a person involved in the delivery, assembly, setup, testing, and demonstration of oxygen, aerosol, and intermittent positive pressure breathing equipment for use in the home upon order of a Florida-licensed allopathic or osteopathic physician; and a surrogate family member who delivers incidental respiratory care of sick or disabled noninstitutionalized persons as long as such person does not hold himself or herself out as a respiratory care practitioner or respiratory therapist.

Section 468.366, F.S., provides criminal offenses under part V, ch. 468, F.S. (the respiratory care practice act). It is a violation of law for any person, including any firm, association, or corporation: to deliver respiratory care services, as defined by part V, ch. 468, F.S., or by rule of the board, unless such person is duly licensed to do so under the part or unless such person is exempted under s. 468.368, F.S.; and to knowingly employ unlicensed persons in the delivery of respiratory care services, unless exempted by part V, ch. 468, F.S. Such violations constitute a third degree felony punishable by imprisonment up to 5 years and imposition of a fine up to \$5,000.

### **Organ and Tissue Donation**

Section 381.0602, F.S., provides for the membership and responsibilities of the Organ Transplant Advisory Council within AHCA. Section 381.6021, F.S., requires AHCA to establish a program for the certification of organizations, agencies, or other entities engaged in the procurement of organs, tissues, and eyes for transplantation. An organization, agency, or other entity may not engage in the practice of organ procurement in Florida without being designated as an organ procurement organization by the secretary of the United States Department of Health and Human Services and being certified by AHCA. Applicants for certification must have the managing employee or similarly titled individual responsible for the daily operation or financial operation of the organization, agency, or entity undergo a criminal background check.

### **Internal Risk Management**

Chapter 395, F.S., governs the licensure of hospitals, ambulatory surgical centers, and mobile surgical facilities. As a licensure requirement, each facility must, at a minimum, under s. 395.0197, F.S., establish an internal risk management program. Such a program is considered to be part of what is known as the quality assurance process that hospitals, ambulatory surgical centers, and mobile surgical facilities use in their daily operations to ensure that adverse incidents, service-related accidents, and patient dissatisfaction are conscientiously examined on a continuous basis. An internal risk management program must provide for: 1) the investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents causing injury to patients; 2) the development of appropriate measures to minimize the risk of injuries and adverse incidents to patients; 3) the analysis of patient grievances that relate to patient care and the quality of medical services; and 4) the development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed facility to report adverse incidents.

The responsibility for the internal risk management program is with the governing board. The board is required to hire a licensed risk manager to implement and oversee the program. Risk managers are exempted from liability and legal action for activities they undertake in

implementing an internal risk management program that is in conformity with law so long as they are not intentionally fraudulent in their conduct.

Each hospital, ambulatory surgical center, and mobile surgical facility must report within 15 working days certain specified adverse or untoward incidents that occur in the facility or that arise from health care prior to admission to the facility. These reports are not available to the public, except that a health care professional against whom probable cause of violation of the law has been established, upon written request, may obtain the records on which the determination of probable cause was made.

### **Pharmacy**

Chapter 465, F.S., provides for the regulation of pharmacy. The chapter provides definitions. Section 465.019, F.S., defines “class I pharmacies” as those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that licensed nursing homes may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a class I pharmacy. “Class II pharmacies” are defined under s. 465.019, F.S., as those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution.

### **III. Effect of Proposed Changes:**

**Section 1.** Provides that all powers, duties, functions, records, personnel, property, and unexpended balances or appropriations, allocations, and other funds of the Agency for Health Care Administration (AHCA) which relate to consumer complaint services, investigations, and prosecutorial services currently provided by AHCA under a contract with DOH are transferred to DOH by a type two transfer as defined in s. 20.06(2), F.S. The transfer of funds must include all advance payments made from the Medical Quality Assurance Trust Fund to AHCA.

Two hundred fifty-nine full-time equivalent positions are eliminated from AHCA’s authorized positions and are transferred to DOH. Any position transferred to DOH which remains unfilled 90 days after the transfer must be eliminated. All records, personnel, and funds of the consumer complaint and investigative services units and of the health care practitioner prosecutorial unit of AHCA are transferred and assigned to the Division of Medical Quality Assurance of the Department of Health.

DOH is deemed the successor in interest of all legal proceedings and contracts currently involving AHCA related to health care practitioner regulation. The interagency agreement between DOH and AHCA terminates on June 30, 2002.

**Section 2.** Amends s. 20.43, F.S., relating to the Department of Health, to provide for the Board of Respiratory Care, as created under part V, ch. 468, F.S., and to eliminate an authorization for DOH to contract with AHCA to provide consumer complaint, investigative, and prosecutorial services required by the Division of Medical Quality Assurance, councils, or boards, as appropriate.

**Section 3.** Requires the Office of Program Policy Analysis and Government Accountability and the Auditor General to conduct a joint audit of all hearings and billings conducted by the Division of Administrative Hearings for all state agencies and nonstate agencies. The findings and recommendations regarding the manner in which the Division of Administrative Hearings charges for its services must be presented in a report to the President of the Senate and the Speaker of the House of Representatives on or before January 1, 2003. The report must recommend alternative billing formulas.

**Section 4.** Repeals s. 456.047, F.S., relating to standardized credentialing for certain health care practitioners.

**Section 5.** Provides that all revenues associated with the health care practitioner credentialing system, and collected by DOH on or before July 1, 2002, must remain in the Medical Quality Assurance Trust Fund, and no refunds shall be given.

**Section 6.** Amends s. 456.039, F.S., relating to specified information required for designated health professionals upon initial licensure or licensure renewal, to delete references to the health care practitioner credentialing system.

**Section 7.** Amends s. 456.0391, F.S., relating to specified information required for advanced registered nurse practitioners upon initial certification or certification renewal, to delete references to the health care practitioner credentialing system.

**Section 8.** Amends s. 456.072, F.S., relating to grounds for which a practitioner may be disciplined for failing to comply with requirements for profiling and credentialing, to delete references to the health care practitioner credentialing system.

**Section 9.** Amends s. 456.077, F.S., relating to the Department of Health's authority to issue citations for specified disciplinary violations to health care practitioners, to delete references to the health care practitioner credentialing system.

**Section 10.** Amends s. 458.309, F.S., relating to the Board of Medicine's authority to adopt rules, to require physician offices in which specified surgeries are performed and that are subject to registration to be accredited by a nationally recognized accrediting agency or an accrediting organization that is approved by the Board of Medicine by rule. The requirement for DOH to annually inspect physicians' offices in which specified surgeries are performed and that are not accredited is deleted. Each office that is registered but not accredited by a Board of Medicine approved agency or organization must achieve full and unconditional accreditation no later than July 1, 2003, and must maintain unconditional accreditation as long as specified surgeries are performed. Accreditation reports must be submitted to DOH. The Board of Medicine may adopt rules to implement these provisions regarding physician offices in which specified surgeries are performed.

**Section 11.** Amends s. 459.005, F.S., relating to the Board of Osteopathic Medicine's authority to adopt rules, to require physician offices in which specified surgeries are performed and that are subject to registration to be accredited by a nationally recognized accrediting agency or an accrediting organization that is approved by the Board of Medicine or the Board of Osteopathic

Medicine by rule. The requirement for DOH to annually inspect physicians' offices in which specified surgeries are performed and that are not accredited is deleted. Each office that is registered but not accredited must achieve full and unconditional accreditation no later than July 1, 2003, and must maintain unconditional accreditation as long as specified surgeries are performed. Accreditation reports must be submitted to DOH. The Board of Osteopathic Medicine may adopt rules to implement these provisions regarding physician offices in which specified surgeries are performed.

**Section 12.** Amends s. 456.004, F.S., relating to the powers and duties of the Department of Health over the regulation of health care professions, to: require objective performance measures for all bureaus, units, boards, contracted entities, and board executive directors which reflect the expected quality and quantity of services; and consider all board requests to use private vendors for particular regulatory functions. When considering a board request, DOH must conduct an analysis to determine if the function could be appropriately and successfully performed by a private entity at a lower cost or with improved efficiency. If after reviewing the department's analysis the board desires to contract with a vendor for a particular regulatory function and the board has a positive cash balance, the department must enter into a contract for the service. The contract must include objective performance measures that reflect the expected quality and quantity of the service and must include a provision that terminates the contract if the service falls below expected levels. A "regulatory function" is defined to include licensure, licensure renewal, examination, complaint analysis, investigation, or prosecution.

**Section 13.** Amends s. 456.009, F.S., relating to legal and investigative services for health professional boards within DOH, to require the department to annually review all legal and investigative services to determine if such services are meeting the performance measures specified in law and in the contract. All contracts for legal and investigative services must include objective performance measures that reflect the expected quality and quantity of the contracted services.

**Section 14.** Amends s. 456.011, F.S., relating to board organization, meetings, compensation and travel expenses, to require meetings of board committees, including probable cause panels, to be conducted electronically unless held concurrently with, or on the day immediately before or after, a regularly scheduled in-person board meeting. If a particular committee meeting is expected to last more than 5 hours and cannot be held before or after the in-person board meeting, the chair of the committee may ask the director of the Division of Medical Quality Assurance to hold an in-person committee meeting in Tallahassee.

**Section 15.** Amends s. 456.026, F.S., regarding the annual report by DOH for health professions, to include statistics and relevant information on the performance measures for all bureaus, units, boards, and contracted entities to reflect the expected quality and quantity of services, and a description of any effort to improve the performance of such services.

**Section 16.** Creates s. 458.3093, F.S., to require all applicants for initial medical physician licensure to submit their credentials to the Federation of State Medical Boards. Effective January 1, 2003, the Florida Board of Medicine and DOH may only consider applications for initial physician licensure which have been verified by the Federation of State Medical Boards

Credentials Verification Service or an equivalent program approved by the Florida Board of Medicine.

**Section 17.** Creates s. 459.0053, F.S., to require all applicants for initial osteopathic physician licensure to submit their credentials to the Federation of State Medical Boards. Effective January 1, 2003, the Florida Board of Osteopathic Medicine and DOH may only consider applications for initial osteopathic physician licensure which have been verified by the Federation of State Medical Boards Credentials Verification Service or an equivalent program approved by the Florida Board of Osteopathic Medicine.

**Section 18.** Amends s. 458.331, F.S., relating to grounds for which a medical physician or physician assistant may be subject to discipline, to revise the definition of “repeated malpractice,” for purposes of a violation of gross or repeated malpractice, to mean three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$50,000, rather than \$25,000, for a physician’s negligent conduct. For reports that have been reported under s. 456.049, F.S., by the physician or reported by an insurer under s. 627.912, F.S., the requirement for the Department of Health to investigate such reports of medical liability actions is limited to those in which a physician has had three or more claims in a 5-year period with payments in excess of \$50,000 rather than \$25,000, for physician negligence.

**Section 19.** Amends s. 459.015, F.S., relating to grounds for which an osteopathic physician or physician assistant may be subject to discipline, to revise the definition of “repeated malpractice,” for purposes of a violation of gross or repeated malpractice, to mean three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$50,000, rather than \$25,000, for a physician’s negligent conduct. For reports that have been reported under s. 456.049, F.S., by the physician or reported by an insurer under s. 627.912, F.S., the requirement for the Department of Health to investigate such reports of medical liability actions is limited to those in which a physician has had three or more claims in a 5-year period with payments in excess of \$50,000 rather than \$25,000, for physician negligence.

**Section 20.** Amends s. 627.912, F.S., relating to closed liability claims paid for specified professional negligence, to limit the filing of closed claim reports involving Florida-licensed medical physicians, osteopathic physicians, or podiatric physicians, to those claims in which the final judgment or settlement was in an amount of more than \$50,000. The filing of closed claim reports involving dentists or dental hygienist is limited to those claims in which the final judgment or settlement was in an amount of more than \$25,000.

**Section 21.** Requires the Office of Program Policy Analysis and Governmental Accountability to review the investigative field office structure and organization of AHCA to determine the feasibility of eliminating all or some field offices, the feasibility of combining field offices, and the feasibility of requiring field inspectors and investigators to telecommute from home in lieu of paying for office space. The review must include all agency programs that have field offices including health practitioner regulation, even if health practitioner regulation is transferred to DOH. The review must be completed and a report issued to the Legislature no later than January 1, 2003.



**Section 22.** Amends s. 456.025, F.S., relating to fees, to eliminate the limitations on the authority of DOH or boards to set licensure renewal fees that restricted licensure renewal fees to: no more than 10 percent greater than the fee imposed for the previous biennium and no more than 10 percent greater than the actual cost to regulate that profession for the previous biennium.

**Section 23.** Creates s. 456.0165, F.S., to provide that a college, university or vocational school in Florida may serve as the host school for a health care practitioner licensure examination. The college, university, or vocational school may not charge DOH for rent, space, reusable equipment, utilities, or janitorial services. A college or vocational school may charge DOH only the actual cost of nonreusable supplies provided by the school at the request of the department.

**Section 24.** Amends s. 468.302, F.S., relating to certification requirements for radiologic technology, to modify an existing exemption from the certification requirements so that a person who is trained and skilled in invasive cardiovascular technology, including the radiological technology duties associated with these procedures, rather than cardiopulmonary technology, and who provides invasive cardiovascular, rather than cardiopulmonary, technology services at the direction, and under the direct supervision, of a licensed allopathic or osteopathic physician need not be certified. Such persons must successfully complete a didactic and clinical training program in specified areas before performing radiologic technology duties. The areas include: principles of x-ray production and equipment operation; biological effects of radiation; radiation exposure and monitoring; radiation safety and protection; evaluation of radiographic equipment and accessories; radiographic exposure and technique factors; film processing; image quality assurance; patient positioning; administration and complications of contrast media; and specific fluoroscopic and digital x-ray imaging procedures related to invasive cardiovascular technology.

**Section 25.** Substantially rewords s. 468.352, F.S., relating to definitions for the regulation of respiratory care, to revise the definition of the various terms. “Critical care” is redefined to mean care given to a patient in any setting involving a life-threatening emergency. “Direct supervision” is redefined to mean supervision under the direction of a licensed, registered, or certified respiratory therapist who is physically on the premises and readily available, as defined by the board. The definition in current law for “noncritical care” is eliminated. The term, “physician supervision” (currently defined as “direct supervision”) is defined to mean supervision and control by a licensed allopathic or osteopathic physician who assumes legal liability for the services rendered by the personnel employed in his or her office.

“Certified respiratory therapist” is redefined to mean any person licensed under part V, ch. 468, F.S., who is certified by the National Board for Respiratory Care or its successor, who is employed to deliver respiratory care services, under the order of a Florida-licensed allopathic or osteopathic physician in accordance with protocols established by a hospital or other health care provider or the Board of Respiratory Care, and who functions in situations of unsupervised patient contact requiring individual judgment. “Registered respiratory therapist” is redefined to mean any person licensed under this part who is registered by the National Board for Respiratory Care or its successor, and who is employed to deliver respiratory care services under the order of a Florida-licensed allopathic or osteopathic physician in accordance with protocols established by a hospital or other health care provider or the Board of Respiratory Care, and who functions in situations of unsupervised patient contact requiring individual judgment.

The “practice of respiratory care” or “respiratory therapy” is defined to mean the allied health specialty associated with the cardiopulmonary system that is practiced under the orders of a Florida-licensed allopathic 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. “Respiratory care practitioner” is defined to mean any person licensed under part V, ch. 468, F.S., to deliver respiratory care services under direct supervision and pursuant to an order of a Florida-licensed allopathic or osteopathic physician.

The definition of “respiratory care services” is revised 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 allopathic 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; 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; performing sleep-disorder studies; education; and the initiation and management of hyperbaric oxygen.

**Section 26.** Substantially rewords s. 468.355, F.S., relating to eligibility for respiratory care licensure and temporary licensure, to revise licensure requirements for respiratory therapists. To be eligible for licensure as a respiratory therapist an applicant must be certified as a “Certified Respiratory Therapist” or registered as a “Registered Respiratory Therapist” by the National Board for Respiratory Care, or its successor.

**Section 27.** Substantially rewords s. 468.368, F.S., relating to exemptions to respiratory care regulation for certain persons, to substantially revise the exemptions. Under the revised exemptions to respiratory care regulation, the regulation may not be construed to prevent or restrict the practice, service, or activities of: any person licensed in Florida by any other law from engaging in the profession or occupation for which he or she is licensed; any legally qualified person in Florida or another state or territory who is employed by the United States government while such person is discharging his or her official duties; a friend or family member who is providing respiratory care services to an ill person and who does not represent himself or herself to be a respiratory care practitioner or respiratory therapist; an individual providing respiratory care services in an emergency who does not represent himself or herself as a respiratory care practitioner or respiratory therapist; any individual employed to deliver, assemble, setup, or test equipment for use in a home, upon the order of a Florida-licensed allopathic or osteopathic physician; any individual credentialed by the Board of Registered Polysomnographic Technologists, as a registered polysomnographic technologist, who is involved in the diagnosis and evaluation of treatment for sleep disorders; any individual certified or registered as a pulmonary function technologist who is credentialed by the National Board for Respiratory Care from performing cardiopulmonary diagnostic studies; any student who is enrolled in an accredited respiratory care program approved by the Florida Board of Respiratory Care, while performing respiratory care as an integral part of a required course; the delivery of incidental respiratory care to noninstitutionalized persons by surrogate family members who do not represent themselves as registered or certified respiratory care therapists; and any individual

credentialed in hyperbaric medicine by the Underseas Hyperbaric Society, or its equivalent as determined by the Florida Board of Respiratory Care, while performing related duties.

**Section 28.** Repeals s. 468.356, F.S., which provides requirements for the approval of respiratory care therapy educational programs, and repeals s. 468.357, F.S., which specifies procedures for the licensure by examination of persons wishing to practice as certified respiratory therapists.

**Section 29.** Renumbers ss. 381.0602 (765.53), 381.6021 (765.541), 381.6022 (765.542), 381.6023 (765.544), 381.6024 (765.545), and 381.6026 (765.547), F.S., respectively providing for the regulation of organizations engaged in the practice of cadaveric organ and tissue procurement.

**Section 30.** Amends and renumbers s. 381.60225, F.S., relating to background screening of specified individuals responsible for the financial operation of organizations engaged in the practice of cadaveric organ and tissue procurement, as s. 765.543, F.S., to change a statutory cross-reference to conform to changes in the bill renumbering the statutory provisions relating to the practice of cadaveric organ and tissue procurement from ch. 381, F.S., to ch. 765, F.S.

**Section 31.** Amends s. 381.6025, F.S., relating to physician supervision of cadaveric organ and tissue procurement coordinators, and renumbers as s. 765.546, F.S., to change a statutory cross-reference to conform to changes in the bill renumbering the statutory provisions relating to the practice of cadaveric organ and tissue procurement from ch. 381, F.S., to ch. 765, F.S.

**Section 32.** Amends s. 395.2050, F.S., relating to routine inquiry for organ and tissue donation, to change statutory cross-references to conform to changes in the bill renumbering the statutory provisions relating to the practice of cadaveric organ and tissue procurement from ch. 381, F.S., to ch. 765, F.S.

**Section 33.** Amends s. 409.815, F.S., relating to health benefits coverage under the Kidcare program, to change a statutory cross-reference to conform to changes in the bill renumbering the statutory provisions relating to the practice of cadaveric organ and tissue procurement from ch. 381, F.S., to ch. 765, F.S.

**Section 34.** Amends s. 765.5216, F.S., relating to organ and tissue donor education panel, change a statutory cross-reference to conform to changes in the bill renumbering the statutory provisions relating to the practice of cadaveric organ and tissue procurement from ch. 381, F.S., to ch. 765, F.S.

**Section 35.** Amends s. 765.522, F.S., relating to immunity for specified actions by entities involved with organ and tissue procurement, to change a statutory cross-reference to conform to changes in the bill renumbering the statutory provisions relating to the practice of cadaveric organ and tissue procurement from ch. 381, F.S., to ch. 765, F.S.

**Section 36.** Amends s. 395.002, F.S., relating to licensed hospitals and ambulatory surgical centers, to provide a definition for “medically unnecessary procedure” to mean a surgical or other invasive procedure that no reasonable physician, in light of the patient’s history and

available diagnostic information, would deem to be indicated in order to treat, cure, or palliate the patient's condition or disease.

**Section 37.** Amends s. 395.0161, F.S., relating to licensure inspections by AHCA, to require AHCA to adopt rules governing the conduct of inspections or investigations that it initiates in response to adverse incident reports and other reports filed pursuant to s. 395.0197, F.S., complaints alleging violations of state or federal emergency access laws, and complaints made by the public alleging violations of law by licensed hospitals and ambulatory surgical centers or personnel. Such rules must set forth procedures to be used in the investigations or inspections to protect the due process rights of licensed facilities and personnel and to minimize disruption of facility operations and the cost to facilities resulting from those investigations.

**Section 38.** Amends s. 395.0197, F.S., relating to internal risk management, to eliminate the limitation that a risk manager may not be made responsible for more than four internal risk management programs in separate licensed hospitals or ambulatory surgical centers, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals. The access that AHCA has to records in all licensed facilities to complete its duties to review risk management reports and other reports filed as part of risk management, is limited, to rules adopted governing the conduct of inspections or investigations. AHCA's authority to conduct inspections necessary to determine whether a risk management program for a licensed facility meets the requirements of law, is limited, to an employee of AHCA who is licensed as a health care risk manager. Any determination must be based on the care, skill, and judgment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar licensed risk managers.

**Section 39.** Amends s. 456.0375, F.S., relating to the registration of certain clinics, to revise the definition of "clinic" to clarify that an exemption applicable to nonprofit entities also applies to community college and university clinics. An exemption for clinics wholly owned by a licensed health care practitioners if one of the owners who is a licensed health care practitioner is supervising the services performed and is legally responsible for the entity's compliance with federal and state laws, is revised to clarify that no health care provider may supervise the delivery of health care services beyond the scope of the practitioner's license. A health care practitioner who owns a clinic which is exempt is not prohibited from providing administrative or managerial supervision for personnel purposes.

**Section 40.** Amends s. 456.072, F.S., relating to grounds for which a licensed health care practitioner may be subject to discipline, to limit a ground under which a licensed health care practitioner is liable for performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition to actually performing the prohibited act rather than attempting to perform it. An exception to the prohibition on leaving a foreign body in a patient is established if the foreign body is medically indicated and documented in the patient record. For purposes of the prohibition, it is legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the patient unless medically indicated and documented in the patient record.

**Section 41** Amends s. 465.019, F.S., relating to institutional pharmacies, to revise the definition of “class II institutional pharmacies” to allow the pharmacy to provide dispensing and consulting services on the premises to patients receiving care in a hospice located on the premises of that pharmacy’s institution.

**Section 42.** Amends s. 631.57, F.S., relating to powers and duties of the Florida Insurance Guaranty Association, Inc., notwithstanding any law, to provide that the net direct premiums of medical malpractice insurance are not subject to assessment under s. 631.57, F.S., to cover claims and administrative costs for (property insurance) the type of insurance defined in s. 624.604, F.S.

**Section 43.** Amends s. 766.101, F.S., relating to medical review committees, to revise the definition of “medical review committee” or “committee,” to add a committee established by a university board of trustees, and a committee comprised of faculty, residents, students, and administrators of an accredited college of medicine, nursing, or other health care discipline.

**Section 44.** Requires the Office of Legislative Services to develop a business plan with accompanying revenue and cost analysis, for the Board of Dentistry with regard to outsourcing of administrative, investigative, legal, and prosecutorial functions and other tasks and services that are necessary to carry out the regulatory responsibilities of the board; employing its own executive director and other staff; and obtaining authority over collections and expenditures of funds paid by dentists and dental hygienists into the Medical Quality Assurance Trust Fund (MQATF). The sum of \$50,000 is appropriated to the Office of Legislative Services from the Board of Dentistry account within the MQATF for the purpose of developing the plan. The completed business plan must be submitted to the Governor and Legislature by January 1, 2003.

**Section 45.** Provides an effective date of July 1, 2002, except as otherwise provided in the bill.

#### **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 Art. VII, s. 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 Art. I, s. 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 Art. III, s. 19(f) of the Florida Constitution.

**V. Economic Impact and Fiscal Note:****A. Tax/Fee Issues:**

None.

**B. Private Sector Impact:**

Persons who are already licensed in another state or eligible graduates of respiratory care programs will no longer be able to obtain temporary licenses to practice in Florida. To practice respiratory care in Florida, such persons will incur costs to meet the requirements for Florida licensure as a respiratory therapist.

**C. Government Sector Impact:**

The proposed fiscal year 2002-2003 budget in the Senate currently provides for 20 positions to be cut from the Agency for Health Care Administration from a base of 279 positions leaving a remainder of 259 positions and \$16,241,094 to be transferred to the Department of Health representing legal, investigative, and consumer services.

The Department of Health estimates that it may have a total cost savings of \$8,217,603 in FY 2002-2003 and \$5,179,869 in FY 2003-2004, which are related to the transfer of consumer complaint, investigation, and prosecution functions from AHCA, repeal of credentialing, and the out-sourcing the verification of medical and osteopathic physician licensure verification. The Department of Health assumes that information technology resources transferred from AHCA will be sufficient to cover both transition and on-going operations.

The Department of Health will incur minimal costs to revise existing administrative rules for the Board of Respiratory Care.

The bill appropriates \$50,000 from the MQATF within DOH to the Office of Legislative Services for costs associated with the development of a business plan for the Board of Dentistry to outsource specified regulatory functions.

**VI. Technical Deficiencies:**

None.

**VII. Related Issues:**

Section 5 of the bill provides that no refunds shall be given to persons who paid for services from the credentialing program that is set for repeal in the bill. Current law requires certain entities to only collect information through the credentialing program with specified exceptions.

**VIII. Amendments:**

None.

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

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