

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 for CS/SB 562 and SB 1912

SPONSOR: Committee on Judiciary, Health, Aging, and Long-Term Care and Senator Saunders and Senator Peaden

SUBJECT: Health Care

DATE: April 11, 2003

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|------------------|----------------|-----------|---------------------|
| 1. | <u>Munroe</u> | <u>Wilson</u> | <u>HC</u> | <u>Favorable/CS</u> |
| 2. | <u>Greenbaum</u> | <u>Roberts</u> | <u>JU</u> | <u>Favorable/CS</u> |
| 3. | _____ | _____ | <u>AP</u> | _____ |
| 4. | _____ | _____ | _____ | _____ |
| 5. | _____ | _____ | _____ | _____ |
| 6. | _____ | _____ | _____ | _____ |

I. Summary:

This bill revises regulations regarding healthcare facilities:

- Requires patient safety plans, including appointment of patient safety officers and committees;
- Provides for certification of patient safety programs and for discount on liability insurance for use of same;
- Adds mental and physical abuse of a nurse or other staff member to listing of grounds for discipline at healthcare facility; limits monetary liability of defendant under the relevant section of law to \$250,000;
- Revises internal risk management requirements;
- Requires healthcare facility to provide testing without charge to victim of sexual abuse which occurred at facility;
- Must inform individual of adverse medical incidents that result in harm to the individual; and
- Makes activities done pursuant to peer review panels immune to liability.

This bill revises licensure requirements and regulations regarding healthcare professionals:

- Removes caps on license renewal fees;
- Revises practitioner profile elements and reporting requirements;
- Revises reporting requirements concerning claims against licensee alleging medical malpractice and provides for fines for failure to report; and
- Requires the suspension of the license of a medical or osteopathic physician when settlement amounts have not been paid pursuant to statutory requirements.

This bill revises the following agency duties:

- Revises administrative procedures including the burden of proof in disciplinary cases; assessment of costs associated with a disciplinary action; requiring that the Administrative Law Judge have medical expertise; revising rights of respondent licensee in disciplinary cases; allowing licensure boards to “reassess and resolve conflicting evidence;” and revises the prohibition on Department of Health (DOH) and boards to appoint administrative law judges;
- Requires DOH to provide to the Agency for Health Care Administration (AHCA) copies of complaints alleging negligence against facilities licensed under ch. 395, F.S.;
- Requires AHCA to review copies of complaints alleging negligence against hospitals for noncompliance with licensure requirements and to proceed in disciplinary actions against such hospital for noncompliance;
- Requires AHCA to deliver copies of adverse incident reports to the Florida Center for Excellence in Health Care;
- Requires several reports to be prepared concerning healthcare professionals and claims against those licensees;
- Revises Department of Financial Services closed claim reporting activities;
- Gives DOH additional subpoena power in prosecuting disciplinary cases;
- Requires DOH and healthcare professional boards to adopt rules concerning the reporting of allegation of sexual misconduct;
- Requires DOH and healthcare professional boards to adopt rules governing the prescribing of drugs to patients via the internet;
- Directs DOH to identify the types of standard of care cases that are eligible for mediation; and
- Revises the monetary thresholds for what constitutes for disciplinary purposes gross or repeated malpractice.

This bill creates the following activities:

- Creates the Florida Center for Excellence in Health Care to design improvements in patient safety and health care quality;
- Requires AHCA to conduct or contract for a study to determine feasibility of providing certain information to the public to facilitate health care decisions;
- Authorizes patient safety organizations and secures patient safety data obtained by such organizations from disclosure;
- Mandates a statement to be included in all settlements of medical malpractice claims;
- Requires OPPAGA and Auditor General to conduct study of practitioner disciplinary cases and closed claims; and
- Requires medical, nursing, and allied health programs to include instruction in patient safety.

This CS has a severability provision. This CS has an effective date of upon becoming law unless otherwise provided for in the bill.

This PCS substantially amends the following sections of the Florida Statutes: ss. 120.57 & 120.80; ss. 395.004, .0193, & .0197; ss. 456.025, .026, .039, .041, .042, .049, .051, .057, .063, .072, .073, .077, & .078; ss. 458.320, & .331; ss. 459.0085 & .015; s. 460.413; s. 466.028; s. 627.912; and s. 766.106.

This CS creates the following sections of the Florida Statutes: s. 381.0409; ss. 395.1012, & .1051; s.1004.08; and s. 1005.07. This CS also creates nine undesignated sections of law.

II. Present Situation:

Governor's Select Task Force on Healthcare Professional Liability Insurance

In recognition of the problems with the affordability and availability of medical malpractice insurance, Governor Bush appointed the Governor's Select Task Force on Healthcare Professional Liability Insurance on August 28, 2002, to address the impact of skyrocketing liability insurance premiums on health care in Florida. The Task Force was charged with making recommendations to prevent a future rapid decline in accessibility and affordability of health care in Florida and was further charged to submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by January 31, 2003.

The Task Force had ten meetings at which it received testimony and discussed five major areas: (1) health care quality; (2) physician discipline; (3) the need for tort reform; (4) alternative dispute resolution; and (5) insurance premiums and markets. The final report of the Task Force includes findings and 60 recommendations to address the medical malpractice crisis in Florida. The reports and information received by the Task Force, as well as transcripts of the meetings, were compiled into thirteen volumes that accompany the main report.

The following recommendations relating to health care quality are included in the final report of the Task Force.

Recommendation 1. The Legislature should establish a Patient Safety Authority, or an entity similar in concept, as both a short-term and long-term strategy to improve patient safety. There are two options that should be considered. The first option, which is recommended by the Institute of Medicine (IOM), is to have two systems, one for the mandatory reporting of adverse events and another system for the voluntary reporting of near misses. The second option is similar to the Patient Safety Authority established and existing in Pennsylvania, which analyzes all adverse events and near misses in that state. Experts employed by both systems would analyze data received and make recommendations about how to reduce these adverse events and near misses. Information would not be subject to discovery in lawsuits.

Recommendation 2. The Legislature should timely develop or adopt statewide electronic medical records and protocols for a physician medication ordering system. The system should be developed collaboratively with hospitals, physicians, and other healthcare providers. The physician medication ordering system should be implemented first. The system could be implemented initially with a web-based data exchange platform which establishes interconnectivity among providers. Another possibility is to begin with business functions, which provide an early return on investment, and then include clinical functions.

Recommendation 3. The Legislature should consider creating a statutory public-private non-profit entity that would administer the Patient Safety Authority, statewide electronic medical records, and build an information technology infrastructure to support the delivery of healthcare that would include a statewide physician medication ordering system. Funding could possibly come from a \$1 per year surcharge on all health professional licenses; all hospital, ambulatory care surgery center, nursing home, home health agency, and birth center discharges; and all individuals in managed care plans and insurance plans licensed under chapters 627 and 640, Florida Statutes. Healthcare providers, insurers, businesses, and government would be represented on the governing board of directors. Options for implementation include:

- Affiliating with a university for the analysis of voluntarily reported adverse events and “near misses.”
- Contracting with an Information Technology firm(s) for a statewide physician medication ordering system, web-based platform for health provider interconnectivity, and electronic patient record.
- Developing a business plan and future financing strategy to supplement the \$1 annual surcharge, which will likely be necessary to achieve full implementation.
- Including in the business plan a strategy to begin with computerizing business functions, for providers to quickly achieve cost-savings due to automation efficiencies, and then include clinical functions.

Recommendation 6. The Legislature should require each hospital and ambulatory surgery center to have a patient safety plan, a patient safety committee, and a patient safety officer. Members of the public should have representation on patient safety committees.

Recommendation 7. The Legislature should require healthcare providers to notify patients who experience serious medical injuries to be notified of the injury in person.

Recommendation 8. The Legislature should examine the feasibility of using Medicaid funding to create a pilot project for an electronic medical record and a physician medication ordering system for Medicaid patients.

Recommendation 9. The Legislature should examine the feasibility of developing a process in the Insurance Code for hospitals and other healthcare facilities to receive malpractice insurance discounts if they implement certified patient safety programs.

Recommendation 10. The Legislature should establish a high-technology simulation center for use by all health providers. Florida should encourage use of this center by practitioners in other states to help offset the costs for the center.

Recommendation 11. The Legislature should require all medical schools, nursing schools, and allied health schools to include in their curricula courses on patient safety and patient safety improvement.

Recommendation 12. The Legislature should require the Agency for Health Care Administration (AHCA) to conduct a study to determine if it is feasible to provide

information to the public to help them make better healthcare decisions regarding the choice of a hospital. The information would not be presented in a “report card” format. AHCA should be provided with sufficient resources to conduct the study in cooperation with hospitals, physicians, and other healthcare providers and provide the Governor and Legislature with a report.

Recommendation 13. The Legislature should allow the healthcare provider regulatory boards to appoint administrative law judges with expertise in the profession to hear standard of care cases.

Recommendation 14. The Legislature should statutorily provide that standard of care decisions are, as a matter of law, infused with overriding policy considerations best left to the healthcare provider regulatory boards.

Recommendation 15. The Legislature should authorize the healthcare provider regulatory boards to reassess and resolve conflicting evidence in standard of care cases based on the record in the case.

Recommendation 16. The Legislature should require physician profiles to provide professional qualifications information regarding physicians to consumers.

Recommendation 17. The Legislature should provide for an audit of the Department of Health’s (DOH) disciplinary process and closed claims files.

Recommendation 18. The Florida Legislature should strengthen Florida’s peer review requirements so they can lead to earlier dismissal of meritless claims brought against hospitals by aggrieved physicians and protect physicians and hospitals from costly lawsuits and liability.

Recommendation 19. The Legislature should expand the DOH’s subpoena authority to include the retrieval of patient records when the patient refuses to cooperate, is unavailable, or fails to execute a patient release. Records obtained under these circumstances would be confidential.

Recommendation 20. The Legislature should require that all first offense citations be non-disciplinary and non-reportable to the national data banks.

Recommendation 21. The Legislature should expand the timeframe for forwarding cases to the Division of Administrative Hearings from fifteen days to forty-five days when a demand for a formal hearing, pursuant to section 120.57(1), Florida Statutes, is received.

Recommendation 22. The Legislature should require all healthcare provider regulatory boards to designate those violations that may be handled in a one-time, non-reportable, and confidential mediation proceeding. Appropriate standard of care cases should be included.

Recommendation 23. The Legislature should modify upward the dollar amount threshold for closed claims cases to be reported and investigated by the Department.

Recommendation 24. The Legislature should grant exclusive authority to the healthcare provider regulatory boards to determine the amount of administrative costs to be recovered when final action occurs and a respondent is disciplined.

Recommendation 25. The Legislature should change the burden of proof in disciplinary actions from the “clear and convincing evidence” standard, to the “greater weight of the evidence” standard, which is the same burden of proof for a medical malpractice case.

Recommendation 26. The Legislature should expand the healthcare provider regulatory board’s rulemaking authority in the areas of Internet prescribing and sexual misconduct cases so as to better address critical areas of discipline.

General Regulatory Provisions for Health Care Practitioners

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).

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.

Alternatives to Disciplinary Actions

Notwithstanding s. 456.073, the board or department if there is no board, must adopt rules to permit the issuance of citations. The citation must clearly state that the subject may choose, in lieu of accepting the citation, to follow the standard procedures for a disciplinary action under

s. 456.073, F.S. If the subject does not dispute the matter in the citation within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. The penalty for a citation must be a fine or other conditions as established by rule.

Notwithstanding s. 456.073, F.S., the board or department if there is no board, must adopt rules to designate which violations of the applicable practice act are appropriate for mediation. They may designate as mediation offenses those complaints where harm caused by the licensee is economic in nature or can be remedied by the licensed health care practitioner.

Administrative Law

Except as provided in the specified exceptions in sections 120.80 and 120.81, Florida Statutes, an administrative law judge assigned by the Division of Administrative Hearings must conduct all hearings involving the substantial interests of a party affected by an agency action except for hearings before agency heads or a member thereof.¹ In disciplinary cases involving professionals licensed by the Department of Health, formal hearings may not be conducted by the Secretary of the Department of Health, or a board or member of a board within the Department of Health for matters relating to the regulation of professions.² For disciplinary cases involving licensed health care practitioners under the Division of Medical Quality Assurance within the Department of Health, a formal hearing before an administrative law judge from the Division of Administrative Hearings must be held pursuant to the Administrative Procedure Act (ch. 120, F.S.), if there are any disputed issues of material fact.³ The administrative law judge must issue a recommended order pursuant to ch 120, F.S. If any party raises an issue of disputed fact during an informal hearing, the hearing must be terminated and a formal hearing pursuant to ch. 120, F.S., must be held.

When an administrative complaint is filed against a subject based on an alleged disciplinary violation, the subject of the complaint is informed of his or her 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.⁴ 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.

When an administrative complaint involving a licensed health care practitioner is referred to the Division of Administrative Hearings, the affected party is granted a de novo hearing involving disputed issues of fact to be conducted by an administrative law judge. After hearing the evidence presented in the case, the administrative law judge renders a recommended order that includes findings of fact, conclusions of law, and a recommended penalty or disposition.⁵ The

¹ See s. 120.57(1)(a), F.S.

² See s. 120.80(15), F.S. See also s. 120.80(4)(b), F.S., which contains a similar provision prohibiting the Secretary of the Department of Business and Professional Regulation (DBPR) or any board or member of a board within the department from conducting formal hearings for matters relating to the regulation of professions by DBPR.

³ See s. 456.073(5), F.S.

⁴ See s. 456.073(5), F.S. See also s. 120.60(5), F.S., which provides that in a proceeding, which involves the revocation, suspension, annulment, or withdrawal of any license, the agency must serve an administrative complaint and must provide the licensee an opportunity to request a hearing pursuant to ss. 120.569 and 120.57, F.S.

⁵ See s. 120.57(1)(k), F.S.

board or Department of Health, as appropriate, may adopt the recommended order, or may reject or modify the findings of fact.⁶ Findings of fact in a recommended order may not be rejected or modified unless the agency (board or Department of Health) states with particularity in its final order that the findings were not based upon competent substantial evidence or that the proceedings on which the findings are based did not comply with the essential requirements of law.⁷ The agency is not permitted to weigh the evidence, judge the credibility of the witnesses, or interpret the evidence to fit its ultimate conclusions.⁸ The agency may not rely on its own expertise to reverse the administrative law judge's finding that a particular statute was violated.⁹

One exception under which an agency may reverse an administrative law judge is under the "deference rule." The "deference rule" recognizes that policy considerations left to the discretion of an agency may take precedence over findings of fact by an administrative law judge. The rule provides that matters that are susceptible of ordinary methods of proof, such as determining the credibility of witnesses or the weight to accord evidence, are factual matters to be determined by the hearing officer. On the other hand, matters infused with overriding policy considerations are left to agency discretion.¹⁰

In cases involving issues that are determinable by ordinary methods of proof through the weighing of evidence and the judging of the credibility of witnesses, courts in Florida have held that such functions are "solely the prerogative of the hearing officer as finder of fact."¹¹ "Courts have generally held that the issue of whether an individual violated a statute by breaching the applicable standard of care is a factual issue that is susceptible to ordinary methods of proof and is an issue that is not infused with policy considerations."¹² The Third District Court of Appeal in wrestling with this issue declared that:

[I]t is settled Florida doctrine that the rule which ascribes effect to an agency's determination of ultimate 'facts' on a subject about which it may rightfully claim expert insight, which originated in *McDonald v. Department of Banking and Finance*, 346 So.2d 569, 579 (Fla. 1st DCA 1977), is not applicable to disciplinary proceedings in general, and to ones like this which are based upon an alleged breach of a broad standard of conduct in particular. In such an instance, the issue of whether the licensee's conduct was indeed in violation of a statutory standard is one of fact which not only must be established by

⁶Boards are agencies for purposes of disciplinary action pursuant to s. 120.57, F.S.

⁷ See s. 120.57(1)(l), F.S.

⁸ See *Gross v. Department of Health*, 819 So.2d 997, 1001 (Fla.5th DCA 2002).

⁹ *Id.* at 1001.

¹⁰ See *Baptist Hosp., Inc. v. Department of Health & Rehabilitative Servs.*, 500 So.2d 620, 623 (Fla. 1st DCA 1986) and *McDonald v. Department of Banking & Finance*, 346 So.2d 569 (Fla. 1st DCA 1977).

¹¹ *Id.* at 1003. See also, *B.B. v. Department of Health & Rehabilitative Servs.*, 542 So.2d 1362, 1364 (Fla. 3d DCA 1989) (quoting *Holmes v. Turlington*, 480 So.2d 150, 153 (Fla. 1st DCA 1985).

¹² *Id.* at 1003. The court also noted that whether a doctor deviated from the applicable standard of care is an issue of fact to be determined by the administrative judge. See also *Hoover v. Agency for Health Care Admin.*, 676 So.2d 1380 (Fla. 3d DCA 1996); *Nest v. Department of Prof'l Regulation, Bd. Of Med. Exam 's*, 490 So.2d 987 (Fla. 1st DCA (1986); *Holmes; Johnston v. Department of Prof'l Regulation, Bd. Of Med Exam 'rs*, 456 So.2d 939 (Fla. 1st DCA 1984); *Bush v. Brogan*, 725 So.2d 1237 (Fla. 2d DCA 1999).

‘conventional’ proof, but as to which the prosecuting agency bears a significantly enhanced burden.¹³

The court was concerned that in disciplinary proceedings, the board has the burden of proving the applicable standard of conduct by competent substantial evidence and made a distinction between evidence which substantially supports conventional forms of regulatory action and evidence which is required to support substantially “a retrospective characterization of conduct requiring suspension or revocation of the actor’s license.” The court held that an agency may not rely upon its own expertise to retrospectively reverse a hearing officer’s finding of no violation.¹⁴

A conclusion of law that is based on the application of rules of law is also issued as part of the hearing officer’s order and, up until recent changes in the law, did not come to the agency with a presumption of correctness. The reviewing agency was free to disagree with the hearing officer’s conclusions of law and could substitute its own. In 1999, the Legislature further narrowed an agency’s authority to reject or modify a hearing officer’s recommended conclusions of law by requiring that the agency state with particularity its reason for rejecting or modifying the recommended conclusion of law and by requiring that the agency find that its substituted conclusion of law is as, or more, reasonable than the rejected or modified conclusion.¹⁵ Further the agency in its final order may reject or modify only those conclusions of law over which the agency has substantive jurisdiction.¹⁶

Sexual Misconduct

Pursuant to s. 456.063, F.S., sexual misconduct in the practice of a health care profession means violation of the professional relationship through which the health care practitioner uses such relationship to engage or attempt to engage the patient or client, or an immediate family member, guardian, or representative of the patient or client in, or to induce or attempt to induce such person to engage in, verbal or physical activity outside the scope of the professional practice of such health care profession. Sexual misconduct in the practice of a health care profession is prohibited. A candidate for licensure must be refused the license if the candidate has had any license revoked or surrendered based on a violation of sexual misconduct and that license has not been reinstated; or committed any act in any state, territory or possession of the United States that would constitute sexual misconduct.

Practitioner Profiles

Section 456.039, F.S., requires each licensed physician, osteopathic physician, chiropractic physician, and podiatric physician to submit specified information which, beginning July 1, 1999, has been compiled into practitioner profiles to be made available to the public. The information must include: graduate medical education; hospitals at which the physician has privileges; the address at which the physician will primarily conduct his or her practice; specialty

¹³ *Cohn v. Department of Prof'l Regulation*, 477 So.2d 1039, 1046 (Fla. 3d DCA 1985).

¹⁴ *Id.* at 1047. See also *Heifetz v. Department of Business Regulation*, 475 So.2d 1277 (Fla. 1st DCA 1985); *Purvis v. Professional Regulation*, 461 So.2d 134 (Fla. 1st DCA 1984); *Johnston v. Department of Professional Regulation*, 456 So.2d 939 (Fla. 1st DCA 1984); *Snej v. Department of Professional Regulation*, 454 So.2d 795 (Fla. 3d DCA 1984).

¹⁵ See Section 6, chapter 99-379, Laws of Florida.

¹⁶ *Id.*

certification; year the physician began practice; faculty appointments; a description of any criminal offense committed; a description of any final disciplinary action taken within the most recent 10 years; and professional liability closed claims reported to the Department of Insurance within the most recent 10 years exceeding \$5,000. In addition the physician may submit: professional awards and publications; languages, other than English, used by the physician to communicate with patients; and an indication of whether the physician participates in the Medicaid program. Each person who applies for initial licensure as a medical physician, osteopathic physician, chiropractic physician, or podiatric physician must, at the time of application, and each medical physician, osteopathic physician, chiropractic physician, or podiatric physician must, in conjunction with the renewal of the license, submit the information required for practitioner profiles.

National Center for Patient Safety

One entity in Florida has been designated as a national center for patient safety. A partnership between the University of South Florida Health Sciences Center and the Veteran's Health Administration has resulted in the formal designation of the University of South Florida as the State's only National Center for Patient Safety Research and Evaluation by the Federal Agency for Healthcare Research and Quality, and of the partnership as a National Patient Safety Center of Inquiry by the Veteran's Administration.

Adverse Incident Reporting

Ambulatory surgical centers and hospitals must be licensed under chapter 395, F.S. Chapter 395, F.S., imposes requirements on ambulatory surgical centers and hospitals that include inspection and accreditation, and reporting of adverse incidents that result in serious patient injury. Ambulatory surgical centers and hospitals, under s. 395.0197(8), F.S., must report the following incidents within 15 calendar days after they occur to AHCA: death of a patient; brain or spinal damage to a patient; performance of a surgical procedure on the wrong patient; performance of a wrong-site surgical procedure; performance of a wrong surgical procedure; performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition; surgical repair of damage resulting to the patient from a planned surgical procedure where damage is not a recognized specific risk, as disclosed to the patient and documented through the informed consent process; or performance of procedures to remove unplanned foreign objects remaining in a patient following surgery.

Under s. 395.0197(8), F.S., the incident reports filed with AHCA may not be made available to the public under s. 119.07(1), F.S., or any other law providing access to public records, nor be discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the Department of Health (DOH) or the appropriate regulatory board. The incident reports may not be made available to the public as part of the records of investigation for and prosecution in disciplinary proceedings that are made available to the public. DOH or the appropriate regulatory board must make available, upon written request by a health care professional against whom probable cause has been found, any such records which form the basis of the determination of probable cause. DOH must review each incident and determine whether it potentially involved conduct by the health care professional who is subject to disciplinary action under the provisions of s. 456.073, F.S.

Section 400.147, F.S., requires nursing homes to have an internal risk management and quality assurance program and report adverse incidents to the Agency for Health Care Administration.

Sections 458.351 and 459.026, F.S., require any medical physician, osteopathic physician, or physician assistant to notify the Department of Health 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 chapter 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.

Confidentiality of Patient Records

Section 456.057, F.S., provides that medical records are confidential and, absent certain exceptions, they cannot be shared with or provided to anyone without the consent of the patient. Subsection (5) identifies the circumstances when medical records may be released without written authorization from the patient. The circumstances are as follows:

- To any person, firm, or corporation that has procured or furnished such examination or treatment with the patient's consent;
- When compulsory physical examination is made pursuant to Rule 1.360, Florida Rules of Civil Procedure, in which case copies of the medical records shall be furnished to both the defendant and the plaintiff;
- In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or the patient's legal representative by the party seeking such records; or
- For statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient's legal representative.

The Florida Supreme Court has addressed the issue of whether a health care provider, absent any of the above-referenced circumstances, can disclose confidential information contained in a patient's medical records as part of a medical malpractice action.¹⁷ The court ruled that, pursuant to s. 455.241, F.S., (the predecessor to current s. 456.057(6), F.S.), only a health care provider who is a defendant, or reasonably expects to become a defendant, in a medical malpractice action can discuss a patient's medical condition. The court also held that the health care provider can only discuss the patient's medical condition with his or her attorney in conjunction with the defense of the action. The court determined that a defendant's attorney cannot have ex parte discussions about the patient's medical condition with any other treating health care provider.

Under s. 456.057(7), F.S., the Department of Health may obtain patient records pursuant to a subpoena without written authorization from the patient, if the department and the probable cause panel of the appropriate board find reasonable cause to believe that a health care

¹⁷ *Acosta v. Richter*, 671 So.2d 149 (Fla. 1996).

practitioner has excessively or inappropriately prescribed any controlled substance violating ch. 893, F.S., relating to controlled substances or any professional practice act or that a health care practitioner has practiced his or her profession below that level of care, skill, and treatment required by law and also find that reasonable attempts were made to obtain a patient release.

The department may obtain patient records and insurance information pursuant to a subpoena without written authorization from a patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has provided inadequate medical care based on the termination of insurance and also find that reasonable attempts were made to obtain a patient release.

The department may obtain patient records, billing records, insurance information, and provider contracts pursuant to a subpoena without written authorization from the patient if the department and probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has submitted a claim, statement, or bill using a billing code that would result in payment greater in amount than would be paid using the appropriate billing code; used information derived from an automobile accident report to solicit or obtain patients personally or through an agent; solicited patients fraudulently; received a kickback; violated patient brokering provisions; presented a false or fraudulent insurance claim; or patient authorization cannot be obtained because the patient cannot be located or is deceased, incapacitated, or suspected of being a participant in the fraud or scheme; and if the subpoena is issued for specific and relevant records.

Financial Responsibility and Closed Claims

Sections 458.320 and 459.0085, F.S., require Florida-licensed allopathic and osteopathic physicians to maintain professional liability insurance or other specified financial responsibility to cover potential claims for medical malpractice as a condition of licensure, with specified exemptions. Physicians who have hospital privileges must maintain professional liability insurance or other financial responsibility to cover an amount not less than \$250,000 per claim. Physicians without hospital privileges must carry sufficient insurance or other financial responsibility in coverage amounts of not less than \$100,000 per claim. Physicians who do not carry professional liability insurance must provide notice to their patients. A physician is said to be “going bare” when that physician has elected not to carry professional liability insurance. Physicians who go bare must either provide notice by posting a sign which is prominently displayed in the reception area and clearly noticeable by all parties or provide a written statement to each patient. Such sign or statement must state:

“Under Florida law, physicians are generally required to carry medical malpractice insurance or otherwise demonstrate financial responsibility to cover potential claims for medical malpractice. YOUR DOCTOR HAS DECIDED NOT TO CARRY MEDICAL MALPRACTICE INSURANCE. This is permitted under Florida law subject to certain conditions. Florida imposes penalties against noninsured physicians who fail to satisfy adverse judgments arising from claims of medical malpractice. This notice is provided pursuant to Florida law.”

With specified exceptions, the Department of Health must suspend on an emergency basis, any licensed allopathic or osteopathic physician who fails to satisfy a medical malpractice claim against him or her within specified time frames.

Section 627.912, F.S., requires insurers to report “closed claims” that involve any action for damage for personal injuries in the performance of professional services by a Florida-licensed medical physician, osteopathic physician, podiatric physician, dentist, hospital, crisis stabilization unit, health maintenance organization, ambulatory surgical center, or attorney to the Department of Insurance. DOH must review each closed claim involving a Florida-licensed medical physician, osteopathic physician, podiatric physician, or dentist and determine whether any of the incidents that resulted in the claim involved conduct by the licensed health care practitioner that is subject to disciplinary action.

Section 456.049, F.S., requires medical physicians, osteopathic physicians, physician assistants, podiatric physicians, and dentists to report “closed claims” for damages for personal injury that are alleged to have been caused by the negligence of the practitioner that are not covered by an insurer and reported as a closed claim under s. 627.912, F.S., to DOH. Section 456.051, F.S., specifies that “closed claims” reported under s. 456.049 and s. 627.912, F.S., to DOH are public information except for the name of the claimant or injured person. Any information that DOH possesses that relates to a bankruptcy proceeding by a medical physician, osteopathic physician, physician assistant, podiatric physician, or dentist is public information.

Sections 458.331 and 459.015, F.S., provide grounds for which an allopathic or osteopathic physician may be subject to discipline by his or her board. Allopathic and osteopathic physicians may be subject to discipline for gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances. “Repeated malpractice” includes, but is not limited to, three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$25,000. If it is reported that a physician has had three or more claims with indemnities exceeding \$25,000 each within the previous 5-year period, DOH must investigate the occurrences upon which the claims were based and determine if action by the department against the physician is warranted.

Similarly, s. 461.013, F.S., provides that a podiatric physician may be subject to discipline for gross or repeated malpractice or the failure to practice podiatric medicine at a level of care, skill, and treatment which is recognized by a reasonably prudent podiatric physician as being acceptable under similar circumstances and conditions. “Repeated malpractice” includes but is not limited to, three or more claims for medical malpractice within the previous 5-year period resulting in indemnities being paid in excess of \$10,000. A dentist is subject to discipline for “dental malpractice” which includes but is not limited to, three or more claims within the previous 5-year period which resulted in indemnity being paid, or any single indemnity paid in excess of \$5,000 in a judgment or settlement, as a result of negligent conduct on behalf of the dentist.

III. Effect of Proposed Changes:

Section 1. Amends s. 120.57(1)(l), F.S., relating to limitations on the ability of state agencies to reject or modify recommended orders from administrative hearings, to provide that, as a matter of law, any decision involving the standard of care of a health care profession regulated by any board within the Department of Health is infused with overriding policy considerations that are best left to the regulatory board that has jurisdiction over that profession. When rejecting or modifying a recommended finding of fact in standard-of-care cases, the appropriate board within the Department of Health may reassess and resolve conflicting evidence in a recommended order based on the record in the case.

Section 2. Amends s. 120.80, F.S., to revise an exception to the Administrative Procedure Act that prohibits the Secretary of Health, the Secretary of Health Care Administration, or a board or member of a board within the Department of Health or the Agency for Health Care Administration from conducting formal hearings for matters relating to the regulation of professions, to allow a board within the Department of Health to appoint an administrative law judge or hearing officer who has expertise in the profession regulated by the board to conduct hearings involving standard-of-care cases.

Section 3. Creates s. 381.0409, F.S., to establish the Florida Center for Excellence in Health Care (Center) which shall be responsible for performing activities and functions that are designed to improve the quality of health care delivered by health care facilities and health care practitioners. The principal goals of the center are the improvement of health care quality and patient safety.

This effectiveness of this section is contingent on the enactment of a companion public records exemption, (now found in CS/CS/SB 566) in this session or an extension thereof.

The bill defines the terms “center,” “health care practitioner,” “health research entity,” “patient safety data,” and “patient safety event.”

The Center must, either directly or by contract:

- Analyze patient safety data for the purpose of recommending changes in practices and procedures which may be implemented by health care practitioners and health care facilities to prevent future adverse incidents;
- Collect, analyze, and evaluate patient safety data voluntarily submitted by a health care practitioner or health care facility. The Center must recommend to health care practitioners and facilities any changes in practices and procedures that may be implemented for the purpose of improving patient safety and preventing patient safety events.
- Foster the development of a statewide electronic infrastructure to improve patient care and the delivery and quality of health care services by health care practitioners and facilities. The electronic infrastructure must be a secure platform for communication and the sharing of clinical and other data among providers and between providers and patients. The electronic infrastructure must include a “core” electronic medical record. Health care practitioners and health care facilities must have access to individual electronic medical records subject to consent of the individual. Health insurers must have

- access to the electronic medical records of their policy holders and to other data with limitations. Such access must be for the sole purpose of conducting research to identify diagnostic tests and treatments that are medically effective. Health research entities must have access to electronic medical records of individuals subject to the consent of the individual other data subject to other limitations. Such access must be for the sole purpose of conducting research to identify diagnostic tests and treatments that are medically effective.
- Foster the use of computerized physician medication ordering systems by hospitals which do not have such systems and develop protocols for these systems.
 - Establish a simulation center for high technology intervention surgery and intensive care for use by all hospitals.
 - Identify best practices and share this information with health care providers.

The Center may release information contained in patient safety data to any health care practitioner or health care facility when recommending changes in practice and procedures which may be implemented by such practitioner or facility to prevent patient safety events and adverse incidents. All information related to adverse incident reports and all patient safety data received by the Center may not be subject to discovery or introduction into evidence in any civil or administrative action. Individuals in attendance at meetings held for the purpose of discussing patient safety data and held to formulate recommendations to prevent future adverse incidents or patient safety events may not be permitted or required to testify in any civil or administrative action related to such events.

Employees or agents of the Center are immune from liability for any lawful action taken by such individuals in advising health care practitioners or facilities when carrying out the duties of the Center. There shall be no liability on the part of, and no cause of action of any nature shall arise against a health care practitioner or facility, its agents or employees when acting in reliance on any advice or information provided by the Center.

The Center shall be a nonprofit corporation registered, incorporated, organized, and operated in compliance with ch. 617, F.S., and shall have all powers necessary to carry out the purposes of the Center, including the power to receive and accept contributions of money, property, labor, or any other thing of value to be applied to its purpose. The Center must be designed and operated with demonstrated expertise in health care quality data and systems analysis, health information management, systems thinking and analysis, human factors analysis, and identification of latent and active errors. The Center must include systems for ensuring its confidentiality, timeliness, and independence that are consistent with state and federal law.

The Center shall be governed by a 10-member board of directors appointed by the Governor to 2-year terms. The Secretary of Health and the Secretary of Health Care Administration or their respective designees shall be members of the board. The board members must serve without compensation but may be reimbursed for travel expenses pursuant to s. 112.061, F.S.

Notwithstanding any law to the contrary, the Center shall be financed by requiring an assessment on various regulated individuals or entities. In each case, the assessment described below may be collected by the regulated party from the individual who is served. The assessment is applied as follows:

- Each insurer that is issued a certificate of authority under part VI, VII, or VIII, of ch. 627, F.S., as a condition of maintaining the certificate must pay to the Center an amount equal to \$1 for each individual included in every insurance policy issued during the previous calendar year.
- Each HMO issued a certificate of authority under part I, ch. 641, F.S., and each prepaid clinic issued a certificate of authority under part II of ch. 641, F.S., as a condition of maintaining the certificate of authority must pay to the Center an amount equal to \$1 for each individual who is eligible to receive services pursuant to a contract with the HMO or prepaid clinic during the previous calendar year.
- Each hospital and ambulatory surgical center licensed under ch. 395, F.S., as a condition of licensure, must pay to the Center an amount equal to \$1 for each individual during the previous 12 months who was an inpatient discharged by a hospital or who was a patient in an ambulatory surgical center.
- Each nursing home licensed under part II, ch. 400, F.S., assisted living facility licensed under part III, ch. 400, F.S., home health agency licensed under part IV, ch. 400, F.S., hospice licensed under part VI, ch. 400, F.S., prescribed pediatric extended care center licensed under part IX, ch. 400, F.S., and health care services pool licensed under part XII, ch. 400, F.S., must pay to the Center an amount equal to \$1 for each individual served by each aforementioned entity during the previous 12 months.
- Each application and renewal fee for each license and each fee for certification or recertification for each person licensed or certified under ch. 401, F.S., (emergency medical services or personnel) or under ch. 404, F.S., (radiological technicians) and each person licensed as a health care practitioner under the Division of Medical Quality Assurance in the Department of Health shall be increased by the amount of \$1 for each year for which the license or certification is issued.

The payment is due on April 1 of each year and must be accompanied by a certification under oath by the chief executive officer that states the number of individuals that payment is based on. The Department of Health must make payment to the Center on April 1 of each year in the amount of the total received from the additional fee assessed on health care professional licensees during the preceding 12 months. The entity may be directed by the Center to provide an independent audit of the certification within 90 days. An interest rate at the annualized rate of 18 percent is charged on any amount due that is not received by the Center within 30 days after April 1. If payment is not received within 60 days after interest is charged, the Center must notify the agency regulating having regulatory jurisdiction over the entity that payment has not been received. Any entity that refuses to make the payment is subject to forfeiture of certificate of authority or license, as appropriate.

The Center must develop a business and financing plan to accomplish its objectives and may enter into affiliations with universities for any purpose. State agencies may contract with the Center for projects to improve the quality of program administration, such as the implementation of an electronic medical record for Medicaid program recipients. Travel and per diem paid with Center funds must be in accordance with s. 112.061, F.S. The Center may use state purchasing and travel contracts and the state communications system in accordance with s. 282.105(3), F.S. The Center may acquire, enjoy, use and dispose of patents, copyrights, trademarks, and any licenses, royalties, and other rights or interests thereunder or therein.

The Center must submit an annual report to the Governor and the presiding officers of the Legislature no later than October 1 of each year. The initial report must include any recommendations regarding revisions in the definition of adverse incidents in s. 395.0197, F.S., and the reporting of such adverse incidents by licensed facilities.

The Center may establish and manage an operating fund for the fiscal management of the corporation. Upon dissolution of the corporation, any remaining cash balances of any state funds revert to the General Revenue Fund, or other state funds as provided by law. All books, records, and audits of the Center shall be open to the public unless exempted by law. The Center must furnish an annual audited report to the Governor and Legislature by March 1 of each year. The Center must consult with various parties, as appropriate within the health care industry and educational institutions.

Section 4. Creates s. 395.1012, F.S., to require each licensed hospital and ambulatory surgical center to adopt a patient safety plan. Any plan adopted to implement the requirements of 42 CFR 482.21¹⁸ shall be deemed to comply with this requirement. Each licensed facility must appoint a patient safety officer and a patient safety committee. The officer and committee shall promote the health and safety of patients, review and evaluate the quality of patient safety measures used by the facility, and assist in the implementation of the facility safety plan.

Section 5. Amends s. 395.004, F.S., to provide that a facility licensed under chapter 395, F.S., may apply for certification of a program that reduces patient adverse incidents. The Agency for Health Care Administration and the Office of Insurance Regulation are to develop criteria for such certification. Insurers are to submit rates that reflect a discount for implementing such a program. The Office of Insurance Regulation is to review these adjusted rates and is to consider whether the implemented program is otherwise part of a risk management program offered by an insurance company or self-insurance plan providing medical malpractice coverage.

Section 6. Amends s. 766.106, F.S., to provide that copies of complaints alleging medical malpractice received by the Department of Health that involve a facility licensed under ch. 395, F.S., are to be provided to the Agency for Health Care Administration.

Section 7. Creates s. 395.0056, F.S., to provide that when the Agency for Health Care Administration receives pursuant to s. 766.106, F.S., a complaint alleging medical malpractice filed against a hospital, it is to review its files to determine whether the hospital has complied with the requirements of s. 395.0197, F.S., relating to hospital licensing and regulation, and whether the incident that is the basis for the complaint can be the subject of a disciplinary proceeding.

Section 8. Amends s. 395.0193, F.S., relating to peer review, to add mental or physical abuse of a nurse or other staff member as grounds for discipline of a staff member or physician who

¹⁸ 42 CFR 482.21 requires hospitals, as a condition of participation in the Medicare program, to develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program. The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.

delivers health care services at a hospital, ambulatory surgical center, or mobile surgical facility. Also provides that a defendant's monetary liability under this section must not exceed \$250,000.

Section 9. Amends s. 395.0197, F.S., to require copies of all reports of adverse incidents submitted to the Agency for Health Care Administration by hospitals and ambulatory surgical centers to be forwarded to the Center for Health Care Excellence for analysis by experts who may make recommendations regarding the prevention of such incidents. Such information shall remain confidential as otherwise provided by law. Revises the requirements for the internal risk management program that every hospital, ambulatory surgical center, or mobile surgical facility must implement. Requires a facility to have a system by which the patient, patient's family member, or patient's designated representative is notified that the patient was the subject of an adverse incident. Provides that a person who had the duty to file an incident report and who failed to do so subject to disciplinary action by the facility and the appropriate regulatory board and subject to a fine of up to \$1,000 per day for each day the report was not timely submitted. Requires a facility at which an incident of sexual abuse occurs to offer the victim of the abuse testing for sexually transmissible diseases, if appropriate, and provide all such testing at no cost to the victim.

Section 10. Amends s. 456.025, F.S., relating to the Department of Health's or board's authority to set license renewal fees for health care practitioners within the department's Division of Medical Quality Assurance, to delete provisions that limit the department's or board's authority to set license renewal fees which are no more than 10 percent greater than the fee imposed during the previous 2-year licensure period and that are no more than 10 percent greater than the actual cost to regulate a profession.

Section 11. Creates an undesignated section of law, to require the Agency for Health Care Administration to conduct or contract for a study to determine if it is feasible to provide information to the public that will help them make better health care decisions regarding their choice of a hospital based on that facility's patient safety and quality performance. This study must be conducted in cooperation with hospitals, physicians, other health care providers, and the agency. The agency must submit the final report to the Governor and the presiding officers of the Legislature by January 1, 2004.

Section 12. Creates s. 395.1051, F.S., to require that every facility licensed under ch. 395, F.S., must inform each person or person representative of adverse incidents that result in harm to the individual. Such notice does not constitute acknowledgement or admission of liability nor can it be introduced as evidence.

Section 13. Creates s. 456.0575, F.S., to require that every healthcare practitioner licensed identified pursuant to s. 765.401(1), F.S., must inform each person or person representative of adverse incidents that result in harm to the individual. Such notice does not constitute acknowledgement or admission of liability nor can it be introduced as evidence.

Section 14. Amends s. 456.026, F.S., relating to the annual report of the Department of Health's Division of Medical Quality Assurance, to require the department to publish the report to its website simultaneous with delivery of the report to the presiding officers of the Legislature. The report must be directly accessible on the department's Internet homepage highlighted by easily

identifiable links. The report must also include additional statistics and relevant information detailing: the number of health care practitioners licensed by the department or otherwise authorized to provide services in Florida, if known to the department; information on the professional liability claims and actions reported by insurers as closed claims for medical physicians, osteopathic physicians, podiatric physicians or dentists; and closed claims for health maintenance organizations licensed under pt. I, ch. 641, F.S

Section 15. Amends s. 456.041, F.S., relating to practitioner profiles, to require the Department of Health to develop a format to compile uniformly any information submitted by certain health care practitioners. Medical physicians and osteopathic physicians are required to report to the department and their board, all final disciplinary actions, sanctions by governmental agencies or facilities licensed by state law, and claims or actions for personal injury reported under s. 456.051, F.S., no later than 15 calendar days after such action or sanction is imposed. Failure to submit the information within the 15 calendar days subjects the physician to discipline by their board and a fine of \$100 per day that the information is not submitted following the expiration of the 15-day reporting period.

The Department of Health must update the practitioner profile with disciplinary actions, sanctions and claims for personal injury within 45 business days. Criminal history information must indicate on each profile whether the criminal history information included in the practitioner profile is, or is not, corroborated by a criminal history check. The department or the board having regulatory authority over the practitioner must investigate any information received and limitations under current law which narrow such investigations to “reasonable grounds to believe that the practitioner has violated any law that relates to the practitioner’s practice”.

The department must provide in each practitioner profile, a narrative description of every final disciplinary action taken against the practitioner that explains the administrative complaint and the final discipline imposed on the practitioner. The department must include a hyperlink to each final order listed in its website report of dispositions of recent disciplinary actions taken against practitioners. The department must include a hyperlink to comparison reports of closed claims filed against a practitioner in the practitioner’s profile. The department must include in the practitioner profiles the date of any disciplinary action taken by a licensed hospital or ambulatory surgical center against a practitioner. Any practitioner who is disciplined for failing to report disciplinary actions, sanctions or claims of personal injury as required by the bill must report the date the disciplinary action was imposed. The department must state whether the action related to professional competence and whether it related to the delivery of services to a patient.

The Department of Health would no longer have to consult with board having jurisdiction over a practitioner to include information in his or her profile that is a public record and relates to the practitioner’s ability to competently practice his or her profession. The department must make a practitioner’s profile available at the end of a 30-day period under which the practitioner may review and verify the factual accuracy of the contents of the profile. The practitioner is required to review and verify the accuracy of his or her profile and is made subject to a fine of up to \$100 per day for a failure to verify the profile contents and to correct any factual errors in his or her profile within the 30-day period.

The department must include a statement in each profile that has not been reviewed by the practitioner, the fact that the practitioner has not verified the information contained in the profile. Each profile must contain an easy-to-read explanation of any disciplinary action taken and the reason that sanctions were imposed. The department may provide one link in each profile to a practitioner's professional website if the practitioner requests that such a link be included in his or her profile.

Section 16. Amends s. 456.042, F.S., to revise requirements for a practitioner submit updates of required information within 15 days after the final activity that renders such information a fact. An updated profile is subject to the same requirements as an original profile.

Section 17. Amends s. 456.049, F.S., to require medical physicians, osteopathic physicians, podiatric physicians, or dentists to report all claims or actions for damages for personal injury alleged to have been caused by the licensee rather than just those claim that are not reported by insurers as "closed claims" under s. 627.912, F.S. The practitioner's board, or department when there is no board, must fine the practitioner up to \$500 for the failure to comply with reporting requirements within 60 days after the payment of a claim or disposition of action for damages has been determined. The failure of the claimant to comply within 90 days subjects the practitioner to a fine of up to an additional \$1,000. Any practitioner who has not reported the claims or actions as required by this section, and who is the subject of a subsequent action for damages at which time it is determined that he or she paid or had paid on his or her behalf a claim for damages, shall be subject to discovery of all such unreported information during the subsequent action.

Section 18. Amends s. 456.051, F.S., to require the Department of Health, within 45 calendar days of its receipt, to make available as part of a practitioner's profile, any report of a claim for damages filed with the department by a practitioner or his or her insurer as a closed claim or any bankruptcy proceeding involving the practitioner that the department has obtained.

Section 19. Amends s. 458.320, F.S., relating to the financial responsibility requirements for medical physicians to provide that notwithstanding any other provision of this section, the Department of Health must suspend the license of any physician against whom has been entered a final judgment, arbitration award, or other order or who has entered into a settlement agreement to pay damages arising out of a claim for medical malpractice, if all appellate remedies have been exhausted and payment up to amounts required by this section has not been made within 30 days after the entering of such judgment, award, or order or agreement, until proof of payment is received by the department. This requirement does not apply to a physician who has met the financial responsibility requirements by obtaining medical malpractice insurance.

Section 20. Amends s. 459.0085, F.S., relating to the financial responsibility requirements for osteopathic physicians, to provide, notwithstanding any other provision of this section, that the Department of Health must suspend the license of any osteopathic physician against whom has been entered a final judgment, arbitration award, or other order or who has entered into a settlement agreement to pay damages arising out of a claim for medical malpractice, if all appellate remedies have been exhausted and payment up to amounts required by this section has not been made within 30 days after the entering of such judgment, award, or order or agreement,

until proof of payment is received by the department. This requirement does not apply to a physician who has met the financial responsibility requirements by obtaining medical malpractice insurance.

Section 21. Creates an undesignated section of law, to make each member of, or health care professional consultant to, any committee, board, group, commission, or other entity immune from civil liability for any act, decision, omission, or utterance done or made in the performance of his or her duties while serving as a member or consultant to such committee, board, group, commission, or other entity established and operated for purposes of quality improvement review, evaluation, and planning in a state licensed health care facility. The act, decision, omission, or utterance may not be made or done in bad faith or with malicious intent. Such entities must function primarily to review, evaluate, or make recommendations relating to:

- The duration of patient stays in health care facilities;
- The professional services furnished with respect to the medical, dental, psychological, podiatric, chiropractic, or optometric necessity for such services;
- The purpose of promoting efficient use of available health care facilities and services;
- The adequacy or quality of professional services;
- The competency and qualifications for professional staff privileges;
- The reasonableness or appropriateness of charges made by or on behalf of health care facilities; and
- Patient safety.

The committee, board, group, commission, or other entity must be established in accordance with requirements of the Joint Commission on Accreditation of Healthcare Organizations, established and duly constituted by one or more public or licensed private hospitals or behavioral health agencies, or established by a governmental agency.

Section 22. Creates an undesignated section, to establish a privilege from disclosure or discovery for all communications, both oral and written, of any medical staff committee, utilization review committee, or other committee, board, group, commission, or other entity, as specified in ch. 395, F.S., relating to hospitals or ch. 641, F.S., relating to health maintenance organizations, which originate in the course of such committees' deliberation, investigation, or analysis. Such communications are privileged and may not be disclosed or obtained by legal discovery proceedings unless a circuit court, after a hearing and for good cause, orders the disclosure of such proceedings, minutes, records, reports, or communications. For purposes of this section, accreditation and peer review records are considered privileged communications.

Definitions for the terms "patient safety data" and "patient safety organization" are provided.

Any documents and communications pertaining to the professional conduct of a physician or staff member of the facility or pertaining to service delivered by a physician or staff member of the facility which are not generated during the course of deliberation, investigation, and analysis of a patient safety organization are not considered privileged. In response to a request for discovery, a claim of privilege by a patient safety organization must be accompanied by a list identifying all documents or communications for which the privilege is asserted. The list and a document or communication, must be reviewed in camera by a court for a determination of

whether the document or communication is privileged. Patient identifying information shall be redacted or otherwise excluded from the list, unless a court of competent jurisdiction orders disclosure of such information.

A list of documents or communications for which privilege is asserted must include: the date of creation of the document or communication; the name and address of the document's author or communication's originator, unless a patient; name and address of the party from whom the document was received; the date the document or communication was received; the name and address of the original document's custodian or communication's originator; and the statutory or case law on which the privilege is asserted.

The section does not provide any additional privilege to a hospital, physician, or behavioral health provider with respect to any medical record kept for any patient in the ordinary course of business of operating a hospital, licensed physician's office, or behavioral health provider or to any facts or information in such records. The section does not preclude or affect discovery of or production of evidence relating to hospitalization or treatment of any patient in the ordinary course of hospitalization or treatment.

A patient safety organization must promptly remove all patient-identifying information after receipt of a complete patient safety data report unless such organization is otherwise permitted by state or federal law to maintain such information. The exchange of patient safety data among health care providers or patient safety organizations which does not identify any patient shall not constitute a waiver of any privilege established under this section. Reports of patient safety data to patient safety organizations does not abrogate obligations to make reports to the Department of Health, the Agency for Health Care Administration, or other state or federal law regulatory agencies. Employers are prohibited from taking retaliatory actions against an employee who in good faith makes a report of patient safety data to a patient safety organization. Each patient safety organization convened under this section must quarterly submit statistical reports of its findings to the Department of Health, the Agency for Health Care Administration, and the Department of Financial Services. Each department must use such statistics for comparison to information the department generates from its regulatory operations and to improve its regulation of health care providers.

Section 23. Creates an undesignated section of law to require each final settlement relating to medical malpractice to include the following statement: "The decision to settle a case may reflect the economic practicalities pertaining to the cost of litigation and is not, alone, an admission that the insured failed to meet the required standard of care applicable to the patient's treatment. The decision to settle a case may be made by the insurance company without consulting its client for input unless otherwise provided by the insurance policy."

Section 24. Creates an undesignated section of law, to require the Department of Financial Services to revise its closed claim form for readability at the 9th grade level. The department must compile annual statistical reports that provide data summaries of all closed claims, including the number of closed claim files pertaining to the referent health care professional or health care entity, the nature of the errant conduct, the size of payments, and the frequency and size of noneconomic damage awards. The department must develop annualized historical statistical summaries beginning with the 1976 state fiscal year and publish these reports on its

website no later than the 2005 state fiscal year. Medical physicians, osteopathic physicians, and physician assistants must report to the Department of Financial Services and the Department of Health any claim or action for damages for personal injury alleged to have been caused by error, omission, or negligence in the performance of such licensee's professional services or based on a claimed performance of professional services without consent if the claim was not covered by an insurer required to report under s. 627.912, F.S., is not a claim for medical malpractice, subject to s. 766.106, F.S., and resulted in: a final judgment, settlement, or final disposition not resulting in payment. Reports must be filed with the Department of Financial Services no later than 60 days following the occurrence of any final judgment, settlement, or disposition.

Health professional reports must include information specified in the bill and any other information that the Department of Financial Services requires to analyze and evaluate the nature, causes, location, cost, and damages involved in professional liability cases.

Section 25. Amends s. 456.039, F.S., to require licensed physicians to provide relevant professional qualifications to be included in that physician's profile.

Section 26. Amends s. 456.057, F.S., to authorize the Department of Health to obtain patient records pursuant to subpoena without written authorization from the patient, if the patient refuses to cooperate, is unavailable, or fails to execute a patient release. The department's access is conditioned on the department and the probable cause panel of the appropriate board having reasonable cause to believe that a health care practitioner has committed certain specified acts.

Section 27. Amends s. 456.063, F.S., to authorize the Department of Health and each board to adopt rules to implement the requirements for reporting allegations of sexual misconduct, including rules to determine the sufficiency of the allegations.

Section 28. Creates an undesignated section of law to provide rulemaking authority to each health care practitioner licensing board within the department to adopt rules governing the prescribing of drugs to patients via the internet or other electronic means.

Section 29. Amends s. 456.072, F.S., to authorize health care practitioner regulatory boards or the Department of Health to determine the amount of costs to be assessed in disciplinary cases of health care practitioners. The burden of proof in the administrative hearing under ch. 120, F.S., regarding a case of disciplining health care practitioners that the Department of Health and each board must meet to prove a violation is changed from a "clear and convincing evidence" standard to the "greater weight of the evidence" standard, which is the same burden of proof for a medical malpractice case before a court of competent jurisdiction.

Section 30. Amends s. 456.073, F.S., to authorize the use of formal administrative hearings conducted by an administrative law judge or hearing officer appointed by the appropriate health care practitioner regulatory board who has expertise in the profession regulated by the board in cases involving violations of the standard of care in that profession. The right of a licensed health care practitioner to elect a formal hearing is revised from any circumstance during a proceeding in which a party raises an issue of disputed fact during an informal hearing to affirmatively require the licensee to dispute an issue of material fact and request a formal hearing within 45 days after service of the administrative complaint.

The section is also amended to provide that the department may investigate paid claims information obtained by reporting requirements on medical and osteopathic physicians where the indemnity paid is greater than \$50,000.

Section 31. Amends s. 456.077, F.S., to specify that each citation issued to a licensed health care practitioner by the Department of Health for a first offense and not contested by the practitioner does not constitute discipline for a first offense.

Section 32. Amends s. 456.078, F.S., to require each health care practitioner regulatory board or the Department of Health to designate violations, including standard of care violations, that are appropriate for mediation.

Section 33. Amends s. 458.331, F.S., to increase the threshold amount from \$25,000 to \$50,000 of indemnities paid within a 5-year period for purposes of the violation of gross or repeated malpractice applicable to medical physicians. To conform, the threshold amount for physician closed claims reported and investigated by the Department of Health is increased from \$25,000 to \$50,000. Requirements for the burden of proof in the discipline of physicians and physician assistants that the Department of Health must meet to prove a violation is revised from a “clear and convincing evidence” standard to the “greater weight of the evidence” standard, when revoking or suspending the license of a medical physician or physician assistant.

Section 34. Amends s. 459.015, F.S., to increase the threshold amount from \$25,000 to \$50,000 of indemnities paid within a 5-year period for purposes of the violation of gross or repeated malpractice applicable to osteopathic physicians. To conform, the threshold amount for physician closed claims reported and investigated by the Department of Health is increased from \$25,000 to \$50,000. Requirements for the burden of proof in the discipline of osteopathic physicians and physician assistants that the Department of Health must meet to prove a violation is revised from a “clear and convincing evidence” standard to the “greater weight of the evidence” standard, when revoking or suspending the license of an osteopathic physician or physician assistant.

Section 35. Amends s. 461.013, F.S., to increase the threshold amount from \$10,000 to \$50,000 of indemnities paid within a 5-year period for purposes of the violation of gross or repeated malpractice applicable to podiatric physicians. To conform, the threshold amount for physician closed claims reported and investigated by the Department of Health is increased from \$25,000 to \$50,000.

Section 36. Amends s. 466.028, F.S., to increase the threshold amount from \$5,000 to \$25,000 of indemnities paid within a 5-year period for purposes of defining “dental malpractice”.

Section 37. Amends s. 627.912, F.S., to increase the threshold amount to \$50,000 or more for closed claims reported to Department of Health for medical physicians, osteopathic physicians, or podiatric physicians. The threshold amount is increased to \$25,000 or more for closed claims reported to the Department of Health for dentists.

Section 38. Creates an undesignated section of law, to require the Office of Program Policy Analysis and Government Accountability and the Office of the Auditor General to jointly conduct an audit of the Department of Health's health care practitioner disciplinary process and closed claims that are filed with the Department of Health. The Office of Program Policy Analysis and Government Accountability and the Office of Auditor General must submit a report to the Legislature by January 1, 2004.

Section 39. Creates s. 1004.08, F.S., to require each public school, college, and university that offers degrees in medicine, nursing, or allied health to include in the curricula applicable to such degrees material on patient safety, including patient safety improvement. Material must include, but need not be limited to, effective communication and teamwork; epidemiology of patient injuries and medical errors; medical injuries; vigilance, attention and fatigue; checklists and inspections; automation, technological, and computer support; psychological factors in human error; and reporting systems.

Section 40. Creates s. 1005.07, F.S., to require each private school, college, and university that offers degrees in medicine, nursing, or allied health to include in the curricula applicable to such degrees material on patient safety, including patient safety improvement. Material must include, but need not be limited to, effective communication and teamwork; epidemiology of patient injuries and medical errors; medical injuries; vigilance, attention and fatigue; checklists and inspections; automation, technological, and computer support; psychological factors in human error; and reporting systems.

Section 41. Provides for severability of the provisions of bill.

Section 42. Creates an undesignated section of law to create a workgroup to study the current healthcare practitioner disciplinary process. Provides for membership and that the sponsoring organization is to assume the costs of its member's participation in the workgroup. Provides that the workgroup is to submit its report no later than September 1, 2003, to the Governor, the President of the Senate and Speaker of the House of Representatives.

Section 43. Provides that unless otherwise provided within, the bill takes effect upon becoming law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

CS/CS/SB 566 makes information contained in patient safety data, as defined in s. 381.0409, F.S., which is held by the Florida Center for Excellence in Health Care and all patient records obtained by the center and any other documents maintained by the center which identify the patient by name confidential and exempt from the Public Records Law. Any portion of a meeting held by the Florida Center for Excellence in

Health Care at which such information is discussed is made exempt from the Public Meetings Law requirements. The bill specifies the conditions under which the confidential and exempt information may be disclosed.

C. Trust Funds Restrictions:

None.

D. Other Constitutional Issues:

The Florida Supreme Court has held that licensure revocation proceedings are penal in nature and has adopted the clear and convincing standard as the correct burden of proof in proceedings involving the imposition of administrative fines, license suspension, and license revocation. See *Dept. of Banking and Finance, Division of Securities & Investor Protection v. Osborne Stern & Co.*, 670 So.2d 932 (Fla. 1996); *Ferris v. Turlington*, 510 So.2d 292 (Fla. 1987). But also see *Borrego v. Agency for Health Care Administration*, 675 So.2d 666, 667 (Fla. 1st DCA 1996).

The bill requires an assessment on health care insurers, health maintenance organizations, prepaid health clinics, hospitals, ambulatory surgical centers, nursing homes, assisted living facilities, home health agencies, hospices, prescribed pediatric extended care centers, health care services pools and health care professionals licensed by the Department of Health. The bill requires, with the exception of the health care professionals, for the funds to be paid directly to the Florida Center for Excellence in Health Care without being deposited into a trust fund and appropriated by the state. This flow of moneys, through the power of the state to tax such entities, raises questions of whether this is in violation of the State Constitution's prohibitions against the state pledging any money to the benefit of any private corporation under Art. VII, section 10 of the State Constitution. Art. VII, Section 10 of the State Constitution, provides that "[n]either the state nor any county, school district, municipality, special district, or agency of any of them, shall become a joint owner with, or stockholder of, or give, lend or use its taxing power or credit to aid any corporation, association, partnership or person." The authority to pass on this assessment to individuals who are served by the regulated entity does not necessarily change this analysis.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

The bill, requires the assessment of a tax on health care insurers, health maintenance organizations, prepaid health clinics, hospitals, ambulatory surgical centers, nursing homes, assisted living facilities, home health agencies, hospices, prescribed pediatric extended care centers, health care services pools and health care professionals licensed by the Department of Health. The amount of revenue generated is indeterminate.

B. Private Sector Impact:

Hospitals will incur costs to report adverse incidents to the Florida Center for Excellence in Health Care, to implement a patient safety plan, and to inform patients of unanticipated outcomes.

The entity or individual responsible for implementing the duties and responsibilities of the Florida Center for Excellence in Health Care will incur costs. Such costs are currently indeterminate. Those individuals and entities (and those served by these individuals and entities who will pay the assessment as a pass-through) will be required to pay an assessment to fund the operation of the Center as a licensure requirement.

C. Government Sector Impact:**Government Sector Impact for Those Portions of the CS Derived From CS/SB 562:**

The Department of Health will incur costs associated with appointing administrative law judges and holding formal administrative hearings for disciplinary cases of health care practitioners; revising the practitioner profiles to accommodate additional information; and to adopt rules regarding sexual misconduct and Internet prescribing standards.

The bill requires health insurers to make a payment of \$1 for each individual included in every insurance policy issued during the previous calendar year. To the extent such insurers are doing business in multiple states they may be able to obtain a credit for a retaliatory tax which would generate a loss in General Revenue funds. Under the concept of a retaliatory tax the insurers subject to the assessment or tax in the bill would receive a credit for the sum of revenue equal to that assessment.

The Office of Program Policy Analysis and Government Accountability and the Office of the Auditor General will incur costs to jointly conduct an audit of the Department of Health's disciplinary process and the closed claims filed with the department.

Public schools, colleges, and universities offering degrees in medicine, nursing, or allied health will incur costs to include material in curricula on patient safety.

Government Sector Impact for Those Portions of the CS Derived From SB 1912:

AHCA would incur costs for implementing and regulating the certification for a quality improvement program, determining whether facilities filed adverse incident reports, working with each licensed facility to determine acceptable variations from nurse staffing ratios, revising the format for adverse incident reports, and publishing an annual report card for each facility.

The Department of Health will incur costs to comply with the provisions of this bill. These provisions include: publishing the Medical Quality Assurance Division's annual report for health care practitioners to its website and include additional statistics and information specified in the bill, including the required timely updates of such

information; to develop a format to uniformly compile any information submitted by certain health care practitioners; to complete narrative descriptions of disciplinary actions and provide hyperlinks to websites; to update the information in the practitioner profiles within 45 days; to impose additional disciplinary fines and actions on physicians for failure to timely report specified information.

The Department of Financial Services will incur costs to implement its responsibilities for revising the handling of closed claims data and the reporting of such information.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Amendments:

None.

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