The Florida Senate

BILL ANALYSIS AND FISCAL IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: The Professional Staff of the Health Regulation Committee

BILL:	SB 2646
INTRODUCER:	Senator Jones
SUBJECT:	Medical quality assurance
DATE:	March 17, 2008 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Stovall	Wilson	HR	**Pre-meeting**
2.			JU	
3.			HA	
4.				
5.				
6.				

I. Summary:

This bill provides technical corrections to align responsibilities between the Agency for Health Care Administration (Agency) and the Department of Health (DOH or department) with the statutory assignment of regulatory oversight for medical practitioners to the DOH. It requires the Agency to forward copies of adverse incident reports received from a health care facility or nursing home that relate to a health care practitioner to the Division of Medical Quality Assurance (MQA) within the DOH, and deletes responsibility for the Agency or appropriate regulatory board to provide records that form the basis of a determination of probable cause to the affected health care professional, since provisions for accessing this information are contained within the chapter dealing with health professionals.

The bill requires an administrator or records custodian in a licensed health care facility or nursing home to certify the accuracy and completeness of records produced in response to a request for records from the DOH, assigns the responsibility of medical record ownership to an employer or clinic in the case of abandoned records or closure of a clinic or facility, and authorizes the DOH to subpoena patient records without obtaining a patient release if the patient refuses to cooperate or if attempting to obtain a patient release would be detrimental to completing an investigation.

The bill removes authority for the Board of Medicine and Board of Osteopathic Medicine to approve an accrediting organization that is not nationally recognized to conduct inspections of physician offices registered to perform level 2 or level 3 surgical procedures.

This bill substantially amends the following sections of the Florida Statutes: 395.0193, 395.0197, 395.3025, 400.141, 400.145, 400.147, 456.057, 458.309, and 459.005.

II. Present Situation:

Medical Facility and Professional Regulation

The DOH is created in s. 20.43, F.S., and is responsible for, among other things, the regulation of health care professionals through the MQA. The Agency is created in s. 20.42, F.S., and is responsible for, among other things, the licensure, inspection, and regulatory enforcement related to health care facilities and nursing homes.

In 1996[1], the Legislature created the DOH, and transferred most of the medical practice boards to the DOH. At that time, the department was required to contract with the Agency for consumer complaint, investigative, and prosecutorial services related to professionals regulated by those boards. Effective July 1, 2002, the consumer complaint services, investigations, and prosecutorial services were transferred from the Agency to the DOH.[2]

In 1997, the Legislature created ch. 456, F.S., to address general regulatory provisions for health professions and occupations. Much of this chapter was transferred from another chapter that provided for general regulatory provisions for both business and professional regulation and medical professional regulation.

Health care providers are required to be licensed and are regulated under the general provisions for the regulation of health professions and occupations in ch. 456, F.S., the specific provisions for the applicable discipline through the professional boards under the DOH/MQA, and rules developed for the health care professions. The practice of medicine is regulated under ch. 458, F.S., and the practice of osteopathic medicine is regulated under ch. 459, F.S.

Health care facilities[3] are licensed and regulated under ch. 395, F.S., and ch. 408, F.S. Nursing homes are licensed and regulated by the Agency under part II of ch. 400, F.S., part II of ch. 408, F.S. Administrative rules also govern the operation of health care facilities and nursing homes.

Adverse Incidents

Hospitals
An adverse incident is defined in s. 395.0197, F.S., as an event over which health care personnel could exercise control and which is associated in whole or in part with medical intervention rather than the condition for which such intervention occurred, and which:

- Results in one of the following injuries:
  - Death;*
  - Brain or spinal damage;*
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - A resulting limitation of neurological, physical, or sensory function which continues after discharge from the facility;

[1] CS/HB 555 (1996).
[2] Section 44 of Chapter 2002-400, Laws of Florida.
[3] Hospitals, ambulatory surgical centers, and mobile surgical facilities.

- Any condition that required specialized medical attention or surgical intervention resulting from non-emergency medical intervention, other than an emergency medical condition, to which the patient has not given his or her informed consent; or
- Any condition that required the transfer of the patient, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the patient's condition prior to the adverse incident;

- Was the performance of a surgical procedure on the wrong patient, a wrong surgical procedure, a wrong-site surgical procedure, or a surgical procedure otherwise unrelated to the patient's diagnosis or medical condition;*
- Required the surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage was not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process;* or
- Was a procedure to remove unplanned foreign objects remaining from a surgical procedure.[4]*

If any condition identified above with an asterisk (*) occurs, a licensed facility must report it to the Agency within 15 calendar days after its occurrence. These are commonly known as "Code 15" incidents. Additionally facilities are required to annually report to the Agency all adverse incidents as well as information related to all malpractice claims filed against a licensed facility. The Agency sends copies of the Code 15 reports, the annual summaries, and malpractice reports related to licensed medical physicians, osteopathic physicians, podiatrists, and dentists to the DOH so that the department can review the information for possible practitioner disciplinary action.

The internal risk manager at a licensed health care facility must also report to the DOH every allegation of sexual misconduct by a licensed health care practitioner that involves a patient.[5]

Nursing Homes
An adverse incident is defined in s. 400.147(5), F.S., as:

- An event over which facility personnel could exercise control and which is associated in whole or in part with the facility's intervention, rather than the condition for which such intervention occurred, and which results in one of the following:
  - Death,
  - Brain or spinal damage,
  - Permanent disfigurement,
  - Fracture or dislocation of bones or joints,
  - A limitation of neurological, physical, or sensory function,
  - Any condition that required medical attention to which the resident has not given his or her informed consent, including failure to honor advanced directives, or
  - Any condition that required the transfer of the resident, within or outside the facility, to a unit providing a more acute level of care due to the adverse incident, rather than the resident's condition prior to the adverse incident;

[4] S. 395.0197(5), F.S.
[5] S. 395.0197(9), F.S.

- Abuse, neglect, or exploitation as defined in s. 415.102, F.S.;
- Abuse, neglect and harm as defined in s. 39.01, F.S.;
- Resident elopement; or
- An event that is reported to law enforcement.

A facility must initiate an investigation and notify the Agency of minimal information about an incident within one business day after the risk manager has received an incident report from a health care provider, agent, or employee of the nursing home. The minimal information reported includes, but is not limited to, whether the events causing or resulting in the adverse incident represent a potential risk to any other resident. The facility is to complete an investigation into the incident and submit an adverse incident report to the Agency for each adverse incident within 15 calendar days after the occurrence. If, after investigation, the risk manager determines that the incident was not an adverse incident as defined, this determination must be reported to the Agency. The Agency forwards adverse incident reports from nursing homes related to licensed medical physicians, osteopathic physicians, podiatrists, and dentists to the DOH so that the department can review the information for possible practitioner disciplinary action.

Records

Several sections of law authorize a licensed health care professional to inspect or request a copy of an investigative file when the department finds probable cause related to a practitioner's conduct.[6]

Generally patient medical records in a licensed hospital, ambulatory surgical center, and mobile surgical facility are confidential and must not be disclosed without the consent of the patient.[7] One exception, in s. 395.3025, F.S., provides that the Agency may subpoena records pursuant to the general provisions related to the regulation of health care professionals for the purpose of disciplinary proceedings; however the Agency is no longer responsible for the regulation of health care professionals. Facilities are authorized to charge for the actual copying costs, including reasonable staff time. The DOH indicated that the fees charged to the DOH in fiscal year 2006-07 totaled $273,000 for copies of medical records and that facilities interpret charging for reasonable staff time differently.

The DOH also subpoenas records related to health care practitioners for disciplinary purposes from nursing homes since they maintain medical records on residents.

Generally, the owner of a patient medical record is the health care practitioner who generates a medical record after making a physical or mental examination of, or administering treatment or dispensing legend drugs to, any person.[8] A record owner may also be a health care practitioner to whom records are transferred by a previous records owner, or any health care practitioner's employer, including, but not limited to, group practices and staff-model health maintenance organizations, provided the employment contract or agreement between the employer and the health care practitioner designates the employer as the records owner. The DOH has indicated

[6] S. 395.0197(6), F.S., s. 395.0197(7), s. 395.0197(13), F.S., and s. 456.073(19), F.S.
[7] S. 395.3025(4), F.S.
[8] S. 456.057, F.S.

that there is significant confusion about who is responsible when a physician leaves the employ of a clinic or a clinic closes and the medical records of patients are subsequently abandoned. Frequently, the treating physician and the clinic owner maintain that the other is the responsible party. Storage and maintenance of abandoned records has, in several instances, been taken on as a responsibility of the department.[9]

According to the DOH, when the department needs to obtain patient records in an investigation where a patient may be complicit in the alleged violation, the department has no recourse if a patient release cannot be obtained. In a serious case, such as drug diversion where a practitioner has a willing patient accomplice, it is not uncommon for the patient to refuse to execute a release of records. The department is often unable to successfully prosecute such cases.

Surgeries in a Physician's Office

Physicians performing office surgical procedures which require certain levels of anesthesia, referred to as level 2 and level 3 surgical procedures, are required to demonstrate compliance with patient safety standards established by board rule. Physician offices may demonstrate compliance with the standards in one of three ways:

- Accreditation by national organizations,
- Accreditation by entities approved by the Board of Medicine or the Board of Osteopathic Medicine, or
- Annual inspection by the department.

Three nationally recognized accrediting organizations are approved by the Board of Medicine and the Board of Osteopathic Medicine. The Board of Medicine previously approved one state level private entity as an accrediting organization, but subsequently denied renewal of the approval. The Board of Osteopathic Medicine previously approved one state level private entity as an accrediting organization.[10]

III. Effect of Proposed Changes:

Section 1. Amends s. 395.0193, F.S., to substitute references to the MQA and the DOH as the regulatory bodies associated with licensed facilities reporting discipline or peer review action against a licensed practitioner.

Section 2. Amends s. 395.0197, F.S., to require the Agency to review the annual adverse incident reports from licensed hospitals, ambulatory surgical centers, or mobile surgical facilities as well as malpractice claims filed against the facility and forward a copy of reports that relate to a health care practitioner as defined in s. 456.001, F.S.,[11] to the MQA. This requires the Agency

[9] Department of Health Bill Analysis, Economic Statement and Fiscal Note for SB 2646, dated March 13, 2008.
[10] *Ibid.*
[11] Section 465.001, F.S., defines health care practitioners as any person licensed under chapter 457 (acupuncture); chapter 458 (medical practice); chapter 459 (osteopathic medicine); chapter 460 (chiropractic medicine); chapter 461 (podiatric medicine); chapter 462 (naturopathy); chapter 463 (optometry); chapter 464 (nursing); chapter 465 (pharmacy); chapter 466 (dentistry); chapter 467 (midwifery); part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468 (speech-language pathology and audiology; nursing home administration; occupational therapy; respiratory therapy; dietetics and nutrition practice; athletic trainers; and orthotics, prosthetics, and pedorthics); chapter 478 (electrolysis); chapter 480 (massage practice); part III or part IV of chapter 483 (clinical laboratory personnel and medical physicists); chapter 484

to send reports concerning essentially all health care practitioners, where previously this provision only related to reports involving medical physicians, osteopathic physicians, podiatric physicians, and dentists.

The bill also strikes provisions related to:

- Requiring the Agency or the appropriate regulatory board to provide a health care professional against whom probable cause has been found with the records forming the basis for the determination of probable cause. Health care professionals can obtain copies of records pertaining to a probable cause action pursuant to s. 456.073(10), F.S., and
- The Agency reviewing facility adverse incident reports to assess a health care professional's conduct for disciplinary action.

Section 3. Amends s. 395.3025, F.S., relating to patient and personnel records to substitute the department for the Agency for subpoenaing patient records pursuant to the general provisions for health professions and occupations in s. 456.071, F.S. An administrator or records custodian in a licensed hospital, ambulatory surgical center, or mobile surgical facility must certify that a true and complete copy of records requested pursuant to a subpoena or patient release has been provided to the department or shall otherwise identify those documents that were not provided. The department is authorized to adopt a rule setting a reasonable fee that a licensed facility may charge for producing copies of requested records.

Section 4. Amends s. 400.141, F.S., to require a nursing home to provide a certified true and complete copy of records to the department which were subpoenaed for the purpose of investigating whether a health care practitioner excessively or inappropriately prescribed controlled substances, provided inadequate medical care based on termination of insurance, submitted a false billing claim, or for other investigations or proceedings by the department. The bill provides that ch. 456, F.S., which relates to health professions and occupations, applies to the records obtained pursuant to the entire section. This may be overly broad since s. 400.141, F.S., addresses the administration and management of nursing home facilities which is under the regulatory responsibility of the Agency, not the DOH.

Section 5. Amends s. 400.145, F.S., to require an administrator or records custodian of a facility licensed under ch. 400, F.S., to certify that a true and complete copy of records subpoenaed by the department or requested by patient release have been provided to the department or identify those records that were not provided. Facilities licensed under ch. 400, F.S., include: nursing homes; home health agencies; hospices; intermediate, special services, and transitional living facilities; prescribed pediatric extended care centers; home medical equipment providers; intermediate care facilities for developmentally disabled persons; health care services pools, and health care clinics.

Section 6. Amends s. 400.147, F.S., relating to an internal risk management and quality assurance program for nursing homes to:

(dispensing of optical devices and hearing aids); chapter 486 (physical therapy practice); chapter 490 (psychological services); or chapter 491 (clinical, counseling, and psychotherapy services).

- Provide that the initial notification to the Agency of a potential adverse incident is confidential and is not discoverable or admissible in any civil or administrative action, except in disciplinary proceedings by the DOH or the appropriate regulatory board. The DOH is substituted for Agency. With this substitution, the bill eliminates the ability of the Agency to use the record in a disciplinary proceeding. The DOH is required to review each incident to assess whether a health care professional is subject to disciplinary action, and
- Requires the Agency to forward a copy of an adverse incident report that relates to a health care practitioner as defined in s. 456.001, F.S.,[12] essentially all health care practitioners, to the MQA to determine whether the health care professional's conduct is subject to disciplinary action.

Section 7. Amends s. 456.057, F.S., to designate the employer or clinic as the medical records owner for records that have been abandoned by a health care practitioner or upon the closure of a clinic or facility, regardless of contractual provisions that might assign responsibility of the records owner elsewhere. The bill authorizes the department or appropriate probable cause panel to subpoena patient records without written authorization from the patient if the patient refuses to cooperate or if an attempt to obtain a patient release would be detrimental to completing the investigation. Reasonable cause is necessary to subpoena the records without a patient's written authorization. It is within the department's discretion to determine whether an attempt to obtain a patient release would be detrimental to the investigation.

Section 8. Amends s. 458.309, F.S., to eliminate the Board of Medicine's rulemaking authority to approve accrediting organizations that are not nationally recognized to conduct an inspection that may be used to satisfy the inspection requirements of a physician's office where level 2 procedures lasting more than 5 minutes and all level 3 surgical procedures are performed.

Section 9. Amends s. 459.005, F.S., to eliminate the Board of Osteopathic Medicine's rulemaking authority to approve accrediting organizations that are not nationally recognized to conduct an inspection that may be used to satisfy the inspection requirements of an osteopathic physician's office where level 2 procedures lasting more than 5 minutes and all level 3 surgical procedures are performed.

Section 10. Provides that the act shall take effect upon becoming a law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

[12] *Ibid.*

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

The rule the department adopts setting fees that a facility licensed under ch. 395, F.S., may charge the DOH for records could favorably or adversely impact a health care facility depending upon its current procedures for assessing costs to the department for the production of records.

Local accrediting organizations will not be approved by the Boards of Medicine and Osteopathic Medicine to conduct inspections of physicians' offices where level 2 and level 3 surgeries occur and as a result could be adversely affected.

C. Government Sector Impact:

The DOH is required to adopt a rule related to the fees a facility may charge the department for providing patient records. The department indicates the bill has no fiscal impact on it.[13]

VI. Technical Deficiencies:

Line 225. The new language within s. 400.141, F.S., relating to the administration and management of nursing home facilities, states that ch. 456, F.S., applies to the records obtained pursuant to this section. It should be limited to the subsection.

Line 237. The new language within s. 400.145, F.S., requires the administrator or records custodian in a facility licensed under ch. 400, F.S., to certify records that are subpoenaed by the DOH. Section 400.145, F.S., is in part II of ch. 400, F.S., which relates to nursing homes. If the intent is to apply this provision only to nursing homes, the new provision should refer to part II of ch. 400, F.S., not the entire chapter. If the intent is for this provision to apply to all facilities licensed under ch. 400, F.S., the provision could be placed in part II of ch. 408, F.S., the Agency's general licensing provisions.

VII. Related Issues:

Line 258 should retain the Agency as a governmental entity authorized to use the nursing home notification for disciplinary purposes.

[13] *Supra 9.*

The bill does not include a provision in s. 400.147(7), F.S., (lines 244-265) authorizing the Agency to provide copies of the one-day notification to the DOH despite requirements for the DOH to review the records.

The DOH has requested two amendments:

- To eliminate the requirement for the Agency to provide copies of the hospital adverse incident annual reports to the DOH since it contains only aggregate and coded data, and
- The Agency needs specific authority to transfer the individual hospital adverse incident reports to the DOH.

VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

None.

B. Amendments:

None.