

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

The bill does not appear to implicate any of the House Principles.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Transfer of Medical Quality Assurance

In 1997, the regulation of certain boards by the Division of Health Quality Assurance at the Agency for Health Care Administration (AHCA) was transferred by a type two transfer and assigned to the Division of Medical Quality Assurance (MQA) within the newly-created Department of Health (DOH).¹ However, DOH continued to contract with AHCA for consumer complaint, investigative, and prosecutorial services required by MQA, councils, or boards.

In 2002, the consumer complaint, investigative, and prosecutorial services provided by AHCA under a contract with DOH were transferred from AHCA to DOH. The interagency agreement between DOH and AHCA terminated on June 30, 2002.²

Adverse Incident Reports

An adverse incident is 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;
 - 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.^{3*}

If any condition identified above with an asterisk (*) occurs, a licensed facility must report it to AHCA within 15 calendar days after its occurrence. These are commonly known as "Code 15" incidents. Additionally, facilities are required to annually report to AHCA all adverse incidents as well as

¹ Chapter 1997-261, L.O.F.

² Section 44, Chapter 2002-300, L.O.F.

³ Section 395.0197(5), F.S.

information related to all malpractice claims filed against a licensed facility. AHCA publishes on its website a summary and trend analysis of “Code 15” incidents quarterly and an annual summary and trend analysis of all adverse incident reports and malpractice claims information. These publications do not include identifying information of any of the parties or entities involved.

Right to Obtain Complaint Documents

Under s. 456.073(10), F.S., a healthcare professional may obtain copies of complaint investigation records pertaining to any probable cause action by petitioning the DOH.

Fees Charged for Medical Records Subpoenaed by DOH

DOH is authorized under s. 456.071, F.S., to issue a subpoena for purposes of an investigation or proceeding. Section 395.3025(4)(e), F.S., authorizes patient medical records from a licensed facility to be released without patient consent to “the agency” upon subpoena in the course of an investigation or proceeding. Though the current statute references “the agency”, it is the DOH that currently issues subpoenas for a patient’s medical records to be used for purpose of the department and the appropriate professional board’s investigation, prosecution, and appeal of disciplinary proceedings.

According to DOH, the fees charged to the department for receiving such medical records are “significant”. In Fiscal Year 2006-2007, DOH paid \$273,000 for copies of medical records.

Board Approval of Local or State Accrediting Organizations

Physicians performing office surgical procedures which require certain levels of anesthesia (referred to as Level 2 and Level 3 surgical procedures) are required to register that office with DOH, unless the office is licensed as a facility pursuant to chapter 395, F.S.⁴ In addition to registration with DOH, the physician’s office is subject to an annual inspection by DOH unless the physician provides written notification of current accreditation by a nationally recognized or Board-approved organization.

There are currently three nationally recognized accrediting organizations approved by the Board of Medicine: American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care, and Joint Commission on Accreditation of Healthcare Organizations.⁵

There are currently five nationally recognized accrediting organizations approved by the Board of Osteopathic Medicine: American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care, Joint Commission on Accreditation of Healthcare Organizations, American Osteopathic Association, and American Osteopathic Association Healthcare Facilities Accreditation Program.⁶

No local or state accrediting organization is approved by the Board of Medicine or the Board of Osteopathic Medicine at this time.

Effect of Proposed Changes

The bill deletes obsolete references to AHCA and inserts references to DOH to reflect the transfer of regulation of healthcare practitioners from AHCA to DOH. The authority for disciplining licensed healthcare practitioners has always resided with the regulatory boards, which are administered by the DOH’s Division of Medical Quality Assurance (MQA). However, when the enforcement program of MQA was transferred from AHCA to DOH in 2002, this language was not revised to reflect that transfer.

The bill clarifies that the information contained in facility annual adverse incident reports received by AHCA that relate to health care practitioners must be sent to DOH for review. However, the entire

⁴ Section 458.309(3), F.S.

⁵ Rule 64B8-9.0091, F.A.C.

⁶ Rule 64B15-14.0077, F.A.C.

annual adverse incident report does not have to be forwarded by AHCA to DOH. By citing to the definition of "health care practitioner" found in s. 456.001, F.S., all licensed healthcare practitioners who may be involved in an adverse incident are subject to review by DOH.

The bill deletes obsolete references to AHCA regarding the rights of healthcare professionals to obtain copies of the records pertaining to any probable cause action.

The bill clarifies that each adverse incident report received by AHCA must be forwarded to DOH for review of possible violations by healthcare licensees.

The bill requires DOH to establish by rule the reasonable fee that a facility may charge DOH for subpoenaed hospital medical records. The cost of obtaining these records may be reduced by creating a uniform fee in rule.

The bill deletes the authority of the Boards of Medicine and Osteopathic Medicine to approve state or local level organizations as accrediting entities for physician offices registered to perform Level II or Level III surgery.

C. SECTION DIRECTORY:

Section 1: Amends s. 395.0193, F.S., relating to licensed facilities; peer review; disciplinary powers; agency or partnership with physicians.

Section 2: Amends s. 395.0197, F.S., relating to internal risk management program.

Section 3: Amends s. 395.3025, F.S., relating to patient and personnel records; copies; examination.

Section 4: Amends s. 400.147, F.S., relating to internal risk management and quality assurance program.

Section 5: Amends s. 458.309, F.S., relating to rulemaking authority.

Section 6: Amends s. 459.005, F.S., relating to rulemaking authority.

Section 7: Provides an effective date of July 1, 2008.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The department appears to have sufficient rulemaking authority to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

None.

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES