The Florida Senate

Interim Project Report 2005-139 *November 2004*

Committee on Health Care Senator Durell Peaden, Jr., Chair

REVIEW OF STATUTES REGULATING HOSPITALS

SUMMARY

It has been 12 years since the Legislature comprehensively reviewed ch. 395, F.S., which governs hospital licensure. This report provides an overview of selected statutes that hospital representatives and staff of the Agency for Health Care Administration (AHCA) identified for possible revision.

The selected statutes include those governing the internal risk management program in hospitals, access to patients' protected health information, access to emergency care, certification of organ procurement organizations, reports of adult abuse in hospitals, and the ability of hospitals to accept lab orders from out-of-state physicians. Many of the proposed changes are policy decisions regarding the provision of health care that must be made in a forum where all parties involved would have an opportunity to discuss the effects of the proposed changes. Such changes involve the safety of patients and their access to care in the daily operations of hospitals.

This report gives an overview of the statutes for which changes were proposed and makes recommendations as follows:

1. Proposed changes to the internal risk management program for licensed health care facilities should be examined in the context of AHCA's emphasis on patient safety.
2. The state should continue to license organ procurement organizations.
3. Any change in state requirements for the provision of emergency services should be considered in a public forum with participation by all affected parties.
4. The Legislature should amend s. 395.1023, F.S., to require hospital staff to report any actual or suspected case of abuse, abandonment or neglect of a vulnerable adult to the Department of Children and Family Services.
5. Due to the complexities of HIPAA preemption analysis, it is recommended that the state encourage collaborative efforts between stakeholders to complete a comprehensive analysis of the effect of HIPAA on state law. Such collaborative efforts in Florida would require consensus building among stakeholders to ensure that consistent interpretation occurs regarding HIPAA preemption of state law. The Legislature may consider the following options for conducting a comprehensive HIPAA preemption analysis:
   - Encourage voluntary collaborative efforts between stakeholders to make recommendations for any revisions to the Legislature in an informal manner.
   - Create an advisory council whose duties would include an examination of state law and the Privacy Rule, and the completion of a comprehensive HIPAA preemption analysis that includes recommendations to the Legislature for any revisions of incompatible state laws for harmonization with HIPAA.
   - Require the State Privacy Officer, by statute, to coordinate efforts with interested stakeholders, including those in the private sector, to complete a comprehensive HIPAA preemption analysis that includes recommendations to the Legislature for any revisions of incompatible state laws for harmonization with HIPAA and to make electronically available a matrix of state laws preempted by HIPAA for educational use. The State Privacy Officer could be required to update the matrix as needed to accommodate any changes in state and federal law.
6. The Legislature should amend s. 483.041(7), F.S., to permit a hospital to accept a lab order from a duly licensed practitioner in another state who writes the order for a patient in that same state or an adjacent state.

BACKGROUND

Hospital Licensure and Regulation

The State of Florida has licensed and regulated hospitals since 1947. Chapter 395, F.S., which governs hospital licensure, was reviewed in 1982 and in 1991 under Florida's former Regulatory Sunset Act. During the 12 years since the Legislature last reviewed ch. 395, F.S., federal laws have changed, state agencies have been created, and programs have been moved from one agency to another or have ceased to exist. Amendments to ch. 395, F.S., have accommodated many, but not all, of these changes.

Chapter 395, F.S., requires AHCA to inspect hospitals, or to cause inspections to be made, to ensure compliance with licensure and safety requirements. Surveys or inspections of accrediting organizations such the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) are accepted as licensure surveys by the state. AHCA performs licensure surveys for hospitals that are not accredited. Of 273 licensed hospitals in Florida, 252 are accredited.

Significant federal legislation governs hospitals, including Medicare certification, Health Information Portability and Accountability Act (HIPAA) compliance, and responsibilities under the Emergency Medical Treatment and Active Labor Act (EMTALA). Hospitals must comply with an ever-changing, complex mix of state and federal laws and regulations.

The construction of a new hospital and the provision of certain services are regulated by a certificate-of-need (CON) process under ch. 408, F.S. Revisions to the CON statutes in 2004 made adult open-heart surgery subject to licensure rather than CON review and required the Secretary of Health Care Administration to appoint a technical advisory panel to develop procedures and standards for measuring outcomes of interventional cardiac programs.

The legislation required two advisory groups to study:

- The issue of replacing CON review of organ transplant programs operating under ch. 408, F.S., with licensure regulation of organ transplant programs under ch. 395, F.S., with a report to the Governor, the Secretary of Health Care Administration, and the Legislature by July 1, 2005.
- Certificate-of-need regulations and changing market conditions related to the supply and distribution of hospital beds, with a report to the Secretary and the Legislature by January 1, 2005.

During the 2004 Session, AHCA proposed the development of a common statutory basis for licensure of health care facilities, including hospitals. The proposal would have eliminated duplication and variation of certain basic licensing standards for the various health care providers regulated by AHCA. The proposed new standards included the application process, changes of ownership, licensure categories, background screening, changes of administrator, right of inspection, inspection reports, unlicensed activity, administrative fines, moratoriums, and license denial and revocation.

A proposal for core licensure standards for facilities licensed by AHCA and recommendations regarding the certificate-of-need program likely will be considered by the 2005 Legislature. This report does not address core licensure standards or certificate of need but rather provides an overview of selected statutes that hospital representatives and AHCA staff identified for possible revision.

METHODOLOGY

Staff reviewed selected statutes with the goal of reducing the regulatory burden on hospitals while maintaining the quality of health care. Staff consulted hospital compliance officers and staff from the Agency for Health Care Administration, Department of Health, and Florida Hospital Association to identify hospital regulatory statutes that should be changed or repealed and to assemble documents and data to support proposed statutory changes.

FINDINGS

The statutes identified by the hospital compliance officers, AHCA, Department of Health, and Florida Hospital Association address a range of issues including the requirements for internal risk managers; updating of the statutes to conform them to changes made in other statutes or to federal laws and regulations; the release of protected medical information for various purposes; and future recommendations relating to trauma care. Many of the proposed changes are policy decisions regarding the provision of health care that must be made in a forum where all parties involved would have an opportunity

to discuss the effects of the proposed changes. Such changes involve the safety of patients and their access to care in the daily operations of hospitals.

Requirements for Internal Risk Managers

S. 395.0197, F.S., requires every licensed hospital, ambulatory surgical enter, and mobile surgical facility to have an internal risk management program that includes the following components:

- The investigation and analysis of the frequency and causes of general categories and specific types of adverse incidents to patients.
- The development of appropriate measures to minimize the risk of adverse incidents to patients.
- The analysis of patient grievances that relate to patient care and the quality of medical services.
- A system for informing a patient or the patient's health care proxy according to s. 765.401(1), F.S., that the patient was the subject of an adverse incident.
- The development and implementation of an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed health care facility to report adverse incidents to the risk manager, or to his or her designee, within 3 business days after their occurrence.

While the internal risk management program applies to all facilities licensed under ch. 395, F.S., for this report discussion of the program will be limited to hospitals.

For purposes of submitting an annual report to AHCA, the statute defines adverse incident to be:

- An event over which health care personnel could exercise control, which is associated with the medical intervention rather than the condition for which the intervention was performed, and which resulted in one of the following:
  - Death;
  - Brain or spinal damage;
  - Permanent disfigurement;
  - Fracture or dislocation of bones or joints;
  - Limitation of neurological, physical, or sensory functioning;
  - Any condition that required specialized medical attention or surgical intervention; or
  - Any condition that required transfer of the patient to another facility or a unit providing a more acute level of care.
- 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;
- 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
- A procedure to remove unplanned foreign objects remaining from a surgical procedure.

A hospital must report to AHCA within 15 days of the occurrence of any of the following incidents:

- The death of a patient;
- Brain or spinal damage to a patient;
- The performance of a surgical procedure on the wrong patient;
- The performance of a wrong-site surgical procedure;
- The performance of a wrong surgical procedure;
- The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;
- The surgical repair of damage resulting to a patient from a planned surgical procedure, where the damage is not a recognized specific risk, as disclosed to the patient and documented through the informed-consent process; or
- The performance of procedures to remove unplanned foreign objects remaining from a surgical procedure.

This 15-day report is popularly known as a "Code 15 report". AHCA may investigate these code 15 incidents as it deems appropriate and prescribe measures that must be taken, or may be taken, in response to the incident.

The internal risk management program is the responsibility of the hospital's governing board. Each licensed facility must hire a risk manager, licensed under s. 395.10974, F.S., who is responsible for implementation and oversight of the facility's internal risk management program. A risk manager must not be made responsible for more than four internal risk management programs in separate licensed facilities, unless the facilities are under one corporate ownership or the risk management programs are in rural hospitals. The qualifications of a risk manager, procedures for licensure, and fees are established in s. 395.10974, F.S.

When an allegation of sexual misconduct is made against a member of a hospital's personnel who has direct patient contact, and the allegation is that the sexual misconduct occurred at the facility or on the grounds of the facility, the hospital's internal risk manager must:

- Investigate the allegation of sexual misconduct;
- Report every allegation of sexual misconduct to the hospital's administrator;
- Notify the family or guardian of the victim, if a minor, that an allegation of sexual misconduct has been made and that an investigation is being conducted; and
- Report to the Department of Health every allegation of sexual misconduct, as defined in ch. 456, F.S., and the respective practice act, by a licensed health care practitioner that involves a patient.

The statute requires any witness who witnessed or who possesses actual knowledge of the act that is the basis of an allegation of sexual abuse to:

- Notify the local police; and
- Notify the hospital risk manager and the administrator.

The statute defines sexual abuse and provides that it is a second degree misdemeanor to make a false claim of sexual abuse with malice or with the intent of harming a licensed facility or a person.

Senate staff received seven suggested statutory changes concerning the internal risk management program. The Florida Hospital Association asked for deregulation of the program while AHCA asked for strengthening of the requirements for the internal risk manager and the program.

Hospital compliance officers reported that under **s. 395.0197(7), F.S.,** when an adverse incident occurs for which a 15-day report is required, AHCA makes an unannounced visit which disrupts the hospital's routine for one or two days. The compliance officers suggested that AHCA schedule the visits ahead of time. According to AHCA, the Agency treats code 15 incidents as complaints and investigates in an unannounced visit. There is no statutory requirement that AHCA's investigations of code 15 incidents be either announced or unannounced; therefore, changing this policy would not require a change in **s. 395.0197, F.S.**

The Florida Hospital Association recommended amending the requirement in **s. 395.0197(9)(d), F.S.**, for facilities to report alleged sexual misconduct by a member of the hospital's staff to the Department of Health (DOH) to require instead the reporting of any *substantiated* allegation of misconduct. This proposal presumably would leave to the hospital the determination of whether or not a claim was substantiated. Under s. 456.053, F.S., each licensed health care professional must report allegations of sexual misconduct to DOH. Requiring a health care professional to report an allegation to DOH and requiring that the same allegation be substantiated by the hospital would set in motion two separate and potentially conflicting investigations of the same allegation. Under s. 456.072, F.S., engaging in or attempting to engage in sexual misconduct as defined in s. 456.063, F.S., constitutes grounds for discipline which could include suspension or permanent revocation of a practitioner's license.

The Florida Hospital Association recommended amending **s. 395.0197(2), F.S.,** to remove the 4-facility limit on the number of programs a single risk manager can oversee. This recommendation must be viewed in light of the application of ch. 395, F.S., to ambulatory surgical centers and mobile surgical facilities as well as hospitals. Having a risk manager be responsible for more than four facilities would not be in keeping with the state's and the hospital industry's emphasis on improving patient safety.

According to AHCA, the current provision in **s. 395.0197(1)(e), F.S.,** permits adverse incident reporting to be directed to a "designee" of the Risk Manager. This option has permitted facilities to operate with a reporting system that includes untrained staff receiving reports on behalf of a risk manager who may only be in the hospital infrequently.

Under **s. 395.01917(19), F.S.**, coercing, intimidating, or precluding a risk manager from executing his or her reporting obligations is unlawful and is punishable by monetary penalties not to exceed $10,000 per violation. According to AHCA, reporting of adverse incidents to risk managers should be "non-punitive" to encourage more complete reporting and subsequent response to, and resolution of, problems that precipitate those incidents. Amending this statute to prohibit coercion or intimidation of staff who report to a risk manager could help to create an atmosphere in which an employee reporting an incident to the risk manager would not feel threatened.

Under **s. 395.10974, F.S.**, risk managers are not subject to the Level 2 background screening requirements as specified in ch. 435, F.S. The current requirement for "fingerprinting", does not give AHCA the authority to require Level 2/FBI screening, with the result that no information on out-of-state violations is obtained on applicants for licensure as internal risk managers.

The licensing criteria for risk managers in **s. 395.10974(2)(c)3, F.S.**, authorize the issuance of a license on the basis of "1 year of practical experience in health care risk management." AHCA points out that this provision does not require any structured learning program or supervision of the experience.

The internal risk manager performs an important function in a hospital's quest to improve patient safety. Thus, reducing the regulatory burden imposed on hospitals by the internal risk management program should only be done if the changes would not adversely affect the quality of health care provided by the hospital.

Updating Florida Statutes to Conform Them to Other State and Federal Laws and Regulations

Centers for Medicare and Medicaid Services/Organ Procurement Organizations

Medicaid is a health care program that is jointly funded by the federal, state, and county governments to provide medical care to eligible individuals. Medicaid is the largest program providing medical and health-related services to the nation's poorest citizens. Medicare is the national health insurance program for:

- People age 65 or older,
- Some people under age 65 with disabilities, and
- People with End-Stage Renal Disease (ESRD), which is permanent kidney failure requiring dialysis or a kidney transplant.

The Centers for Medicare and /Medicaid Services (CMS) is the federal agency administering the Medicare Program.

According to hospital compliance officers, **ss. 395.2050 and 765.542, F.S.,** duplicate CMS regulations for organ procurement organizations (OPOs). S. 395.2050, F.S., requires licensed hospitals that engage in procurement of organs, tissue, and eyes, to comply with the certification requirements of ss. 765.541-765.546, F.S., which require both certification by AHCA and designation as an OPO by the U.S. Secretary of Health and Human Services. According to hospital representatives, these two surveys/certification processes have the same effect and are duplicative of each other. Tissue banks and eye banks are not certified by CMS and should therefore not be excluded from the state certification. However, the state's ability to intervene when a problem occurs could be limited, or impossible, if state licensure were eliminated.

The Emergency Medical Treatment and Active Labor Act (EMTALA)

Hospitals that participate in the Medicare and Medicaid programs are subject to the federal Emergency Medical Treatment and Active Labor Act (EMTALA), which governs when and how a patient may be refused treatment or transferred from one hospital to another when he or she is in an unstable medical condition. Hospitals that participate in Medicare and have an emergency department must medically screen anyone who comes to the emergency department seeking treatment for a medical condition to determine whether an emergency medical condition exists. If an emergency medical condition exists, the hospital must provide treatment to stabilize the patient's condition and may not transfer the patient except in certain specified circumstances.

S. 395.1041, F.S., governs access to emergency services and care. Patterned after EMTALA, Florida's statute requires AHCA to maintain an inventory of hospitals with emergency services, requires every general hospital with an emergency department to provide emergency services and care. A patient, whether stabilized or not, may be transferred to another hospital if:

- The patient or the person legally responsible for the patient requests the transfer,
- A physician has signed a certification that the medical benefits that might be expected by treatment at another hospital outweigh the potential risk transfer might pose to the patient's medical condition, or
- A physician is not physically present in the emergency department and a qualified medical person signs a certification that a physician, in consultation with the personnel, has determined that the medical benefits that might be expected by treatment at another hospital outweigh the potential risk transfer might pose to the patient's medical condition.

Every hospital must ensure the provision of services within the service capability of the hospital at all times

either by directly providing the service or by arranging for another hospital or a group of physicians to provide the service. In recent years, hospitals have experienced difficulty finding available specialists to be on call to treat patients in the hospital's emergency department seven days per week, twenty-four hours per day, as required by this statute.

In regulations, the federal government has interpreted EMTALA to apply only to hospitals that have a dedicated emergency department, and obligations for physicians apply only in the context of a hospital's provision of emergency services. Hospitals are required to maintain a list of physicians who are on call in such a manner that best meets the needs of hospital patients receiving required EMTALA services, taking into account the services offered by the hospital and the availability of specialty physicians who take calls. The Florida Hospital Association proposed that the Legislature review s. 395.1041, F.S., in light of these federal regulatory revisions and taking into consideration the difficulty hospitals have in securing physicians to be on call for emergency services. However, there is a public expectation that emergency services will be available at all hours of the day and night, every day of the week. If Florida's statute were changed to match federal EMTALA regulations, the public would no longer be able to expect to have access to emergency services at all times. Proposed changes to s. 395.1041, F.S., should be discussed in a public forum with participation by all affected parties.

S. 395.1046, F.S., requires AHCA to investigate any complaint against a hospital for any violation of s. 395.1041, F.S., that AHCA believes to be reasonably sufficient. The statute has not been revised since 1996, and AHCA suggests that it should be updated to match current agency authority.

Changes to Florida's emergency access statute should be done in a forum where all interested parties have an opportunity to discuss proposed changes. Participants in such a forum should include representatives of AHCA, the Florida Hospital Association, the College of Emergency Physicians, and the Florida Medical Association.

Requirements to Report Adult Abuse

S. 395.1023, F.S., requires every hospital to have a policy that every staff member has an affirmative duty to report any actual or suspected case of child abuse, abandonment or neglect. There is no comparable requirement in ch. 395, F.S., for reporting of adult abuse. While hospital personnel are required to report abuse, neglect, or exploitation of vulnerable adults under s. 415.1034, F.S., AHCA reports that the agency's authority to specify reporting of adult abuse in administrative rule has been questioned. AHCA recommends adding a requirement to report adult abuse in s. 395.1023, F.S.

Access to Patients' Protected Health Information

In Florida, patients have a constitutional right to privacy under Article I, Section 23 of the State Constitution, and judicial decisions. Although Florida courts have recognized patients' rights to secure the confidentiality of their health information (medical records) under the right to privacy under the State Constitution, that right must be balanced with and yields to any compelling state interest.

Since 1951, Florida law (ch. 26684, L.O.F.) has granted a patient access to his or her own medical records and has required the health care practitioner who created the records to maintain the confidentiality of the records. Two primary sections of Florida law address medical records and grant patients access to their health information. S. 456.057, F.S., deals with the confidentiality of, and patient's access to, medical records created by specified health care practitioners, including medical physicians. S. 395.3025, F.S., addresses the confidentiality of, and patient's access to, medical records held by a Florida hospital. In addition to ss. 456.057 and 395.3025, F.S., a number of statutory provisions and administrative agency rules provide additional confidentiality and patient access for specialized individual health information.

The federal Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, (HIPAA) protects the privacy of certain health information. The United States Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information (Privacy Rule) on December 28, 2000, which were originally scheduled to go into effect on February 26, 2001.[1] The effective date for the Privacy Rule was delayed and the rule took effect on April 14, 2003. The regulations only apply to covered entities (health providers who engage in certain electronic transactions, health plans, and health care clearinghouses). HHS issued transaction and code sets rules for which the compliance date was October 16, 2003. Compliance with a security rule under HIPAA is not mandated until April 2005.

[1] See 45 C.F.R. Parts 160 and 164.

In order to comply with HIPAA and with state laws regarding access to and privacy of protected health information, a hospital must conduct a HIPAA preemption analysis to determine whether the state law is in part or wholly preempted by HIPAA. This is a complex and difficult legal task.[2]

The following statutes were identified by hospital representatives as requiring a HIPAA preemption analysis to be conducted.

Clinical Records for Mental Health Patients

S. 394.4615(9), F.S., provides that nothing in this section is intended to prohibit the parent or next of kin of a person who is held in or treated under a mental health facility or program from requesting and receiving information limited to a summary of that person's treatment plan and current physical and mental condition. Release of such information must be in accordance with the code of ethics of the profession involved.

S. 394.4615(10), F.S., provides patients access to their clinical records unless the physician determines that release would be harmful to the patient; if so determined, the physician must give notice to the patient, guardian, attorney, etc., which is good for 7 days and is renewable.

Protected Health Information Provided to Poison Control Centers

S. 395.1027(2), F.S., requires each regional poison control center to provide the following services:

- Toll-free access by the public for poison information.
- Case management of poison cases.
- Professional consultation to health care practitioners.
- Prevention education to the public.
- Data collection and reporting.

In 2004, subsection (3) was added to this statute to provide that "upon request, a licensed facility shall release to a regional poison control center any patient information that is necessary for case management of poison cases." Hospital representatives asked that this subsection be amended to specify that facilities may collect and report patients' protected health information to a poison control center for purposes of professional consultation with providers, without express authorization by the patient.

Hospitals' Patient and Personnel Records

S. 395.3025, F.S., governs hospitals' patient and personnel records. According to AHCA, agency requests for access to hospital employee personnel and credentialing files have been based on s. 395.3025, F.S., and hospitals have challenged AHCA's ability to access those records citing HIPAA provisions.

Hospital compliance officers cited the need for clarification and updating of **s. 395.3025(4)(a), F.S.**, which authorizes release of patient medical records to licensed facility personnel and attending physicians without patient consent. Suggested changes to this statute included:

- Broadening the authorization to permit release of records to licensed health care providers for use in treatment of a patient,
- Allowing disclosure of patient medical information for purposes of medical research, and
- Allowing disclosure to poison control centers.

S. 395.3025(4)(b), F.S., permits release of patient medical records to licensed facility personnel only for administrative purposes or risk management and quality assurance functions. Hospital compliance officers requested clarification that they could release a patient's health information to a covered entity for payment activities, i.e., to an insurance company in order to receive payment.

S. 395.3025(4)(c), F.S., permits release of patient medical records to AHCA for purposes of cost containment. The Florida Hospital Association requested the ability to release records to oversight agencies in addition to AHCA, not just for cost containment but for any purpose required by law.

S. 395.3025(7)(b), F.S., prohibits the use of patient information for solicitation or marketing the sale of goods or services. Hospital-based fundraising units would like to use patient demographic information to create mailing lists and solicit contributions, which they believe are permissible under the federal privacy rule. Definitions of "solicitation" and "marketing" added to this section would enable hospitals to use patient demographic information for fundraising purposes. Hospital compliance officers also believe the use of patient information to communicate information (a) about the hospital's services or treatment alternatives, (b) for further treatment of the patient, or

[2] See "*Review of Statutes Regulating Access to Patient Medical Records*". Senate Interim Project 2005-142. 2004.

(c) for case management and care coordination are federally permitted and suggest changes to this section to permit such uses of patient information.

Ss. 405.01-405.03, F.S., permit the disclosure of medical information for research to reduce morbidity and mortality. Revising these sections to allow disclosures for research purposes when certain requirements have been met would permit hospitals to disclose medical information to researchers for a broader range of subjects than reduction of morbidity and mortality.

S. 395.3025(1), F.S., establishes maximum fees for furnishing a patient or a representative of the patient a complete copy of all patient records, provided the person requesting the records agrees to pay a charge. The charge may include sales tax and actual postage and, except for nonpaper records that are subject to a charge not to exceed $2, the charge may not exceed $1 per page. The Florida Hospital Association requested an increase in the fees to $3 and $2, respectively.

Clinical Laboratory Orders from Out-of-State Physicians

Under Part I of ch. 483, F.S., which governs clinical laboratories, **s. 483.041(7), F.S.,** defines *licensed practitioner* to mean a physician licensed under ch. 458, 459, 460, or 461, F.S.; a dentist licensed under ch. 466, F.S.; a person licensed under ch. 462, F.S.; or an advanced registered nurse practitioner licensed under part I of ch. 464, F.S.; or a duly licensed practitioner from another state licensed under similar statutes who orders examinations on materials or specimens for nonresidents of the State of Florida, but who reside in the same state as the requesting licensed practitioner.

Hospital compliance officers requested that this definition be revised to allow a hospital to accept a lab order from any licensed out-of-state practitioner, and delete any mention of where the practitioner resides. Such a change would be designed to permit temporary residents who spend a portion of the year in Florida to present a Florida hospital with a lab order from their own out-of-state practitioner even if the practitioner lived in an adjacent state. However, an amendment to this statute should strike a balance between accommodating the needs of a seasonal visitors and preventing a situation in which patients in essence ordered their own lab test through a practitioner whose only relationship with the patient was writing the lab order. Amending the statute to permit a hospital to accept a lab order from a duly licensed practitioner in another state who writes the order for a patient in that same state or an adjacent state could address the hospital officers' concerns.

Trauma Care

The 2004 Legislature passed CS/SB 1762, which requires the Department of Health (DOH) to update the state trauma system plan under Part II of ch. 395, F.S., by February 2005 and annually thereafter. The DOH is required to complete an assessment of the trauma system in Florida and report its findings to the Governor, the President of the Senate, the Speaker of the House of Representatives and the substantive legislative committees by February 1, 2005. The department must review the existing trauma system and determine whether it is effective in providing trauma care uniformly throughout Florida. It is possible that revisions to Part II of ch. 395, F.S., could be proposed.

Patients' Right to Know about Adverse Medical Incidents

In November 2004, Florida voters amended Article X of the State Constitution to permit an individual who seeks, undergoes, or has undergone treatment in a health care facility or by a health care provider to have access to any records made or received in the course of business by a health care facility or provider relating to any adverse medical incident or potential adverse incident. Because the amendment does not specify who holds the record, it could be presumed that any holder of such a record would have to make it available upon request. The amendment says that the right to know about adverse medical incidents must be balanced against an individual patient's right to privacy and dignity. The amendment took effect the day it was approved by the voters, November 2, 2004.

The amendment does not require the Legislature to enact legislation relating to patients' right to know about adverse medical incidents. However, statutes governing the investigating and reporting of adverse incidents in licensed health care facilities and those governing peer review of physicians provide for confidential records that would be made public by this constitutional amendment, and legislative action would be required to conform those statutes to the amendment. Private businesses, including physician practices, hospitals, and third-party administrators of insurance plans, would have to make records public

under this amendment, and legislation could provide guidelines for making such records available while observing federal privacy requirements.

RECOMMENDATIONS

1. Proposed changes to the internal risk management program for licensed health care facilities should be examined in the context of AHCA's emphasis on patient safety.
2. The state should continue to license organ procurement organizations.
3. Any change in state requirements for the provision of emergency services should be considered in a public forum with participation by representatives of those who would be affected.
4. The Legislature should amend s. 395.1023, F.S., to require hospital staff to report any actual or suspected case of abuse, abandonment or neglect of a vulnerable adult to the Department of Children and Family Services.
5. Due to the complexities of HIPAA preemption analysis, it is recommended that the state encourage collaborative efforts between stakeholders to complete a comprehensive analysis of the effect of HIPAA on state law. Such collaborative efforts in Florida would require consensus building among stakeholders to ensure that consistent interpretation occurs regarding HIPAA preemption of state law. The Legislature may consider the following options for conducting a comprehensive HIPAA preemption analysis:

- Encourage voluntary collaborative efforts between stakeholders to make recommendations for any revisions to the Legislature in an informal manner.
- Create an advisory council whose duties would include an examination of state law and the Privacy Rule and the completion of a comprehensive HIPAA preemption analysis that includes recommendations to the Legislature for any revisions of incompatible state laws for harmonization with HIPAA.
- Require the State Privacy Officer, by statute, to coordinate efforts with interested stakeholders, including those in the private sector, to complete a comprehensive HIPAA preemption analysis that includes recommendations to the Legislature for any revisions of incompatible state laws for harmonization with HIPAA and to make electronically available a matrix of state laws preempted by HIPAA for educational use. The State Privacy Officer could be required to update the matrix as needed to accommodate any changes in state and federal law.[3]

6. The Legislature should amend s. 483.041(7), F.S., to permit a hospital to accept a lab order from a duly licensed practitioner in another state who writes the order for a patient in that same state or an adjacent state.

[3] The State Privacy Officer pursuant to s. 282.102, F.S., is working on the development of a Privacy Workgroup made up of HIPAA privacy officers and representatives from other interested state executive branch agencies to identify privacy issues. One immediate goal of the workgroup will be to finalize an inventory of statutes, rules and agency practices impacting privacy, along with legislative recommendations. The workgroup could also identify what types of information are stored in databases and how such information should be shared with other state agencies, shared with third parties and provided online. Also, the group could assist in the development of risk assessment tools and methodologies to identify risks to privacy, work with state agencies to implement the appropriate operational controls and ensure the existence and effectiveness of operational controls (audits).