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.)

SB 1600 BILL: SPONSOR: Senator Clary Public Records Exemption/Physician Adverse Incident Notification SUBJECT: February 7, 2002 DATE: **REVISED:** ANALYST STAFF DIRECTOR REFERENCE ACTION 1. Munroe Wilson HC Favorable GO 2. RC 3. 4. 5. 6.

I. Summary:

The bill creates exemptions from chapter 119, Florida Statutes, relating to the Public Records Law, and Section 24(a), Article I of the State Constitution, for information contained in the notification of adverse incidents involving physician office surgery and makes such information confidential. Such information may not be made available to the public as part of the record of investigation or prosecution in disciplinary proceedings by the Department of Health or a regulatory board. The bill makes the exemptions subject to a future review and repeal date of October 2, 2007, as required by s. 119.15, F.S., the Open Government Sunset Review Act of 1995. The bill provides findings and statements of public necessity to justify the creation of the public records exemptions.

This bill creates one undesignated section of law and ss. 458.353 and 459.028, Florida Statutes.

II. Present Situation:

Public Records Law

The Public Records Law, ch. 119, F.S., and the Public Meetings Law, s. 286.011, F.S., specify the conditions under which public access must be provided to governmental records and meetings of the executive branch and other governmental agencies. While the state constitution provides that records and meetings of public bodies are to be open to the public, it also provides that the Legislature may create exemptions to these requirements by general law if a public need exists and certain procedural requirements are met. Article I, s. 24, Fla. Const. governs the creation and expansion of exemptions to provide, in effect, that any legislation that creates a new exemption or that substantially amends an existing exemption must also contain a statement of the public necessity that justifies the exemption. Article I, s. 24, Fla. Const. provides that any bill

Chapter 95-217, Laws of Florida, repealed the Open Government Sunset Review Act, contained in s. 19.14, F. S., and enacted in its place s. 119.15, F.S., the Open Government Sunset Review Act of 1995. The Open Government Sunset Review Act of 1995 provides for the repeal and prior review of any public records or public meetings exemptions that are created or substantially amended in 1996 and subsequently. The review cycle begins in 2001. The chapter defines the term "substantial amendment" for purposes of triggering a repeal and prior review of an exemption to include an amendment that expands the scope of the exemption to include more records or information or to include meetings as well as records. The law clarifies that an exemption is not substantially amended if an amendment limits or narrows the scope of an existing exemption.

Hospital Adverse Incident Reporting

Ambulatory surgical centers and hospitals must be licensed under ch. 395, F.S.

Chapter 395, F.S., imposes requirements on ambulatory surgical centers and hospitals which 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 the Agency for Health Care Administration:

- < 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.

Pursuant to s. 395.0197(8), F.S., the incident reports filed with the Agency for Health Care Administration 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 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. The Department of Health (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. The 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.

Nursing Home and Assisted Living Facility Adverse Incident Reporting

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. Each nursing facility must develop and implement an incident reporting system based upon the affirmative duty of all health care providers and all agents and employees of the licensed facility to report adverse incidents to the risk manager or his or her designee, within 3 business days after their occurrence. "Adverse incident" is defined as an event over which the facility staff could have exercised control and which is associated in whole or in part with the facility's intervention, rather than the condition for which the intervention occurred. Adverse incidents are those events which result in death; brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; a limitation of neurological, physical, or sensory function; any condition requiring medical attention to which the resident has not given his or her informed consent, including failure to honor advance directives; any condition that requires 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; abuse, neglect, or exploitation; resident elopement; or an event that is reported to law enforcement.

The facility is required to notify the Agency for Health Care Administration within 1 business day after the risk manager or his or her designee receives the report of an adverse incident. The Agency for Health Care Administration may investigate any such incident, as it deems appropriate, and is allowed to prescribe measures that must or may be taken in response to the incident. The Agency for Health Care Administration must review each incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action. If this is the case, the provisions related to disciplinary proceedings of s. 456.073, F.S., apply. The notification is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the Agency for Health Care Administration or a regulatory board.

Each facility must complete the investigation and submit an adverse incident report to the Agency for Health Care Administration for each adverse incident within 15 calendar days after its occurrence, on a form developed by the agency. The Agency for Health Care Administration must review the information, and determine whether the incident potentially involved conduct subject to the disciplinary proceedings of s. 456.073, F.S. The adverse incident report must contain the name and license number of the risk manager. The report is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the agency or a professional board.

Section 400.119, F.S., makes records of meetings of the risk management and quality assurance committee of a long-term care facility under part II or part III of ch. 400, F.S.,¹ as well as the adverse incident reports filed with the facility's risk manager and administrator, notifications of

¹ The exemption to the Public Records Law in s. 400.119, F.S., also applies to adverse incidents reported in assisted living facilities that are regulated under part III, ch. 400, F.S.

the occurrence of an adverse incident, and adverse incident reports from the facility confidential and exempt from the Public Records Law and unavailable to the public.

Assisted living facilities, pursuant to s. 400.423, F.S., may establish a voluntary risk management program, but must report adverse incidents. Each facility is required to maintain adverse incident reports. "Adverse incident" is defined as an event over which the facility staff could have exercised control and which is associated in whole or in part with the facility's intervention, rather than the condition for which the intervention occurred. Adverse incidents are those events which result in death; brain or spinal damage; permanent disfigurement; fracture or dislocation of bones or joints; any condition requiring medical attention to which the resident has not given his or her informed consent, including failure to honor advance directives; any condition that requires the transfer of the resident from 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; abuse, neglect, or exploitation; resident elopement; or an event that is reported to law enforcement.

The facility, regardless of the number of beds, is required to notify the Agency for Health Care Administration within 1 business day after the occurrence of an adverse incident. The Agency for Health Care Administration must review each incident and determine whether the incident potentially involved conduct by a health care professional who is subject to disciplinary action. If this is the case, the provisions related to disciplinary proceedings of s. 456.073, F.S., apply. The notification is confidential and not discoverable or admissible in any civil or administrative action, except disciplinary proceedings by the Agency for Health Care Administration or regulatory boards.

Patient Confidentiality under Disciplinary Procedures

Section 456.073, F.S., provides procedures to be used for the discipline of health care practitioners. Disciplinary complaints and all information obtained by the DOH are confidential and exempt from the public records and meetings laws until 10 days after probable cause is found or the subject of the complaint waives confidentiality. Section 456.057(8), F.S., provides that all patient records obtained by the DOH and any other documents maintained by the department which identify the patient by name are confidential and exempt from the public records and meetings laws, and may be used solely by the department and the appropriate regulatory board in their investigation, prosecution, and appeal of disciplinary proceedings. The patient records may not be made available to the public as part of the record of investigation for and prosecution in disciplinary proceedings.

Physician Office Surgery Adverse Incident Reporting

Licensed medical physicians may perform surgery in their medical offices, ambulatory surgical centers, or hospitals. Sections 458.351 and 459.026, F.S., require any medical physician, osteopathic physician, or physician assistant to notify the DOH of any adverse incident that involved the physician or physician assistant which occurred on or after January 1, 2000, in any office maintained by the physician for the practice of medicine that is not licensed under ch. 395, F.S., relating to licensure for hospitals and ambulatory surgical centers. The sections require any medical physician, osteopathic physician, or physician assistant to notify the

department in writing and by certified mail of the adverse incident within 15 days after the adverse incident occurred. The notice must be postmarked within 15 days after the adverse incident occurred.

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

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

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

III. Effect of Proposed Changes:

Section 1. Creates s. 458.353, F.S., to make the information contained in the notification of an adverse incident that occurred in a physician's office as a result of surgery confidential and exempt from the Public Records Law. Such information may not be released to the public as part of the records relating to the disciplinary proceeding. The exemption is subject to the Open Government Sunset Review Act of 1995 and stands repealed on October 2, 2007, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. Creates s. 459.028, F.S., to make the information contained in the notification of an adverse incident which occurred in an osteopathic physician's office as a result of surgery confidential and exempt from the Public Records Law. Such information may not be released to the public as part of the records relating to the disciplinary proceeding. The exemption is subject to the Open Government Sunset Review Act of 1995 and stands repealed on October 2, 2007, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 3. Creates an undesignated section, to provide legislative findings and a statement of public necessity for the exemptions from the Public Records Law provided in the bill for information contained in the notification of an adverse incident involving physician office

surgery. The section provides that the exemptions are a public necessity and that it would be an invasion of a patient's privacy for such personal, sensitive information contained in the notification of an adverse incident to be publicly available. The section states that failure to protect the confidentiality of any information submitted or collected by the DOH regarding an adverse incident, such as the identity of the patient, the type of adverse incident, and the fact that a disciplinary investigation is being conducted would deter the collection and reporting of this information to the department. Without the exemptions from the Public Records Law, the section indicates, the DOH and the appropriate regulatory boards would be prevented from effectively carrying out their responsibility to enforce safe patient care and take necessary disciplinary action for practice violations. Release of the information. The bill states that these exemptions apply the same exemption accorded under other sections of the Florida Statutes for similar information.

Section 4. Provides that this 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 Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

The bill creates exemptions from ch. 119, F.S., relating to the Public Records Law, and s. 24(a), Art. I of the State Constitution, for specified records maintained by the DOH and provides findings of necessity to justify the creation of the exemptions.

The bill states that it is a public necessity to make adverse incident reports confidential and exempt because it would be an invasion of a patient's privacy for personal, sensitive information contained in the report to be publicly available. Under the requirements of the s. 24(a), Art. I of the State Constitution, exemptions must be narrowly tailored and be no broader than necessary to effect the public necessity. Typically, if an individual's privacy is affected because information about the person is contained in a document, the narrowest means of protecting the individual is to make only identifying information about the individual in the report confidential and exempt. Instead, the bill makes the entire report confidential and exempt.

C. Trust Funds Restrictions:

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

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

C. Government Sector Impact:

None.

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.