

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: SB 76

SPONSOR: Senator Campbell

SUBJECT: Public Records

DATE: January 17, 2003

REVISED: _____

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|----|-----------------------------|-----------------------------|-----------------------------|-----------------------------|
| 1. | <u>Munroe</u> | <u>Wilson</u> | <u>HC</u> | <u>Favorable</u> |
| 2. | <u> </u> | <u> </u> | <u>GO</u> | <u> </u> |
| 3. | <u> </u> | <u> </u> | <u>RC</u> | <u> </u> |
| 4. | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| 5. | <u> </u> | <u> </u> | <u> </u> | <u> </u> |
| 6. | <u> </u> | <u> </u> | <u> </u> | <u> </u> |

I. Summary:

The bill creates an exemption from chapter 119, Florida Statutes, relating to the Public Records Law, and Section 24(a), Article I of the State Constitution, and makes certain information contained in the notification of a pharmaceutical adverse incident provided to the Department of Health confidential until 10 days after probable cause has been found that a violation of law occurred. Such information may be used by the Department of Health or the appropriate regulatory board only in a disciplinary proceeding brought against a pharmacist or by the department in any study of pharmaceutical adverse incidents without identifying the patient, pharmacist, pharmacy, office, or entity by name, location, or other identifier. The bill makes the exemptions subject to a future review and repeal date of October 2, 2008, 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 two undesignated sections of law.

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 that contains an exemption may not contain other substantive provisions, although it may contain multiple exemptions.

Chapter 95-217, Laws of Florida, repealed the Open Government Sunset Review Act, contained in s. 119.14, 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.

The Practice of Pharmacy and Medication Errors

Chapter 465, F.S., authorizes the regulation of the practice of pharmacy by the Florida Board of Pharmacy. Section 465.0276, F.S., requires any person who is not a licensed pharmacist to register with her or his regulatory board and meet other specified requirements in order to dispense drugs to her or his patients in the regular course of her or his practice for a fee or remuneration. Under s. 465.0276(5), F.S., an exception to these requirements allows a practitioner to dispense drug samples to his or her patients. Under the exception, the practitioner must confine her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner’s own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind.

The Florida Board of Pharmacy, pursuant to s. 465.0155, F.S., must adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and must be applied by such agencies when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state. The Florida Board of Pharmacy has adopted an administrative rule¹ relating to pharmacy practice standards that provides requirements for institutional pharmacies to implement a system to identify and evaluate quality-related events and improve patient care.

According to a recent survey developed by the United States Department of Health and Human Services, prescription errors by physicians and pharmacists could cause up to 7,000 deaths this year. In 1983, prescription errors accounted for 2,900 deaths. Some experts are calling for more education, focusing on understanding why medication errors occur, instead of trying to cover up

¹ The Florida Board of Pharmacy has adopted 64B16-27.300, Florida Administrative Code. The rule requires each institutional pharmacy to establish a “Continuous Quality Improvement Program,” which must be described in the pharmacy’s policy and procedure manual and which must include a process for review of events relating to the inappropriate dispensing of prescribed medication. Records maintained as a component of the Continuous Quality Improvement Program are confidential as medical-review activities under s. 766.101, F.S., and are not discoverable or admissible in any disciplinary proceeding against a licensed health care practitioner. Licensed health care practitioners who furnish information to a medical review committee, hospital internal risk management program, the Department of Health or the Agency for Health Care Administration under s. 766.101, F.S., are granted limited immunity to a civil action, if the information is not intentionally fraudulent and is within the scope of the functions of such entities.

the errors or punishing pharmacists for reporting individual mistakes. In an effort to end the silence surrounding medical errors, 56 of the nation's 6,000 hospitals -- recently joined by more than 200 additional facilities -- have "openly report[ed]" pharmaceutical "blunders" in a "first-of-its-kind" database called MedMARx®, providing a "glimpse into causes of medication errors." During the first year of the program, designed to "curb the miscues" in prescribing and administering drugs, the hospitals reported 6,224 drug therapy errors that injured 187 patients and killed one. During 2001, 368 facilities reported 105,603 medication errors to MedMarx® that resulted in 2,539 patient injuries and 14 deaths.²

Public Records Status of Adverse Incident Reports

Hospitals, ambulatory surgical centers, mobile surgical facilities, nursing homes, assisted living facilities, and physicians performing office surgery are required to report adverse incidents under similar circumstances to state regulatory entities. Such health care providers must generally report adverse incidents within 15 days after their occurrence. Except for physician office surgery adverse incident reports, adverse incident reports by hospitals, ambulatory surgical centers, mobile surgical facilities, nursing homes and assisted living facilities are exempt under the Public Records Law.

Disciplinary Procedures for Health Care Practitioners

Section 456.073, F.S., sets forth procedures the Department of Health must follow in conducting 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.

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.

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. Section 456.073(10), F.S., provides that complaints and information obtained by the department during its investigations are exempt from the Public Records Law until 10 days after probable cause has

² See "Administering Drugs Using Wrong Technique Harmful to Patients and Costly to Insurers," U.S. Pharmacopeia at <<http://www.onlinepressroom.net/uspharm/>>.

been found to exist by the probable cause panel or the department, or until the subject of the investigation waives confidentiality. If the case is dismissed prior to a finding of probable cause, the complaints and information remain confidential in perpetuity under s. 456.073(2), F.S. Under s. 456.073(4), F.S., all proceedings of a probable cause panel are exempt from the open meetings requirements of ch. 286, F.S., until 10 days after probable cause has been found to exist or until the subject of an investigation of a disciplinary complaint waives confidentiality.

The Department of Health's clerk is the custodian designated for orders and related information regarding the discipline of a licensed health care practitioner under s. 456.073, F.S. The Department of Health and its agents may share information with law enforcement agencies or other regulatory agencies that are investigating an individual for activity within such agency's regulatory jurisdiction which may be related to activities being investigated by the department. The information provided by the department retains its confidential status in the hands of those other agencies.

Under s. 456.057(8)(a), F.S., all patient records obtained by the Department of Health and any other documents maintained by the department that identify the patient by name are confidential and exempt from the Public Records Law and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

As used in s. 456.057, F.S., "records owner" is defined to mean any 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; any health care practitioner to whom records are transferred by a previous records owner; or to any health care practitioner's employer, if the contract or agreement between the employer and the health care practitioner designates the employer as the records owner. The following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of s. 456.057, F.S., to maintain those documents required by regulations under which they are regulated: certified nursing assistants, *pharmacists and pharmacies*, nursing home administrators, respiratory therapists, athletic trainers, electrologists, clinical laboratory personnel, medical physicists, opticians and optical establishments, persons or entities making physical examinations for an injured person as part of personal injury protection claim, or hospitals and ambulatory surgical centers.

III. Effect of Proposed Changes:

Section 1. Creates an undesignated section of law, to make the information contained in the notification of a pharmaceutical adverse incident which identifies a patient, pharmacist, pharmacy, office, or entity by name, location, or other identifier and which is provided to the Department of Health confidential and exempt from the Public Records Law until 10 days after probable cause has been found that a violation of law occurred. Such information may be used by the Department of Health or the appropriate regulatory board only in a disciplinary proceeding brought against a pharmacist or by the department in any study of adverse incidents without identifying the patient, pharmacist, pharmacy, office, or entity by name, location, or

other identifier. The exemption is subject to the Open Government Sunset Review Act of 1995 and stands repealed on October 2, 2008, unless reviewed and saved from repeal through reenactment by the Legislature.

Section 2. 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 a pharmaceutical adverse incident provided to the Department of Health. The section provides that it would be an invasion of a patient's privacy for personal, sensitive information contained in the notification of a pharmaceutical adverse incident to be publicly available. The section provides legislative findings that failure to protect the confidentiality of any information submitted to or collected by the Department of Health regarding a pharmaceutical adverse incident, including the identity of the patient, pharmacist, pharmacy, entity, or office, and the fact that an investigation is being conducted, would deter the collection and reporting of this information to the department and would prevent the department and the appropriate regulatory boards from effectively carrying out their responsibility to enforce safe patient care and take necessary disciplinary actions for practice violations. The section states that release of such personal information before the completion of the investigation and before a finding of probable cause would deter Florida-licensed pharmacists and other health care practitioners from reporting adverse incidents, leading to the deterioration of services and care rendered to the detriment of the health of those served. The bill states that these exemptions apply the same exemption accorded under other sections of the Florida Statutes for similar information.

Section 3. The bill provides an effective date of July 1, 2003.

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 exemption to the Public Records Law for specified information contained in the notification of a pharmaceutical adverse incident created in the bill is tied to legislation filed this session (SB 74) that contains provisions requiring pharmaceutical adverse incident reporting. The provisions in that legislation will become effective only upon passage of a separate public records exemption bill.

Senate Bill 74 provides that section two of that bill must take effect only upon the effective date of legislation that makes pharmaceutical adverse incident information provided to the Department of Health confidential and exempt from disclosure under the Public Records Law, until 10 days after probable cause is found that a violation of law occurred. Such legislation must also provide that information be used by the department or the Board of Pharmacy only in a disciplinary proceeding brought against the pharmacist or by the department in any study of adverse incidents without identifying the patient, pharmacist, pharmacy, office, or entity by name, location, or other identifier.

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.
