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 Judiciary Committee

BILL:	CS/SB's 1550 & 2724
INTRODUCER:	Health Regulation Committee and Senators Saunders and Atwater
SUBJECT:	Patients' Medication History Website
DATE:	April 20, 2008 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Fav/Combined CS**
2.	Maclure	Maclure	JU	**Pre-meeting**
3.			GO	
4.			CJ	
5.			HA	
6.				

Please see Section VIII. for Additional Information:

A. COMMITTEE SUBSTITUTE.....	X	Statement of Substantial Changes
B. AMENDMENTS.....		Technical amendments were recommended
		Amendments were recommended
		Significant amendments were recommended

I. Summary:

The bill requires the Agency for Health Care Administration (AHCA), by June 30, 2009, to contract with a vendor to design and operate a secure, privacy-protected website that provides a health care practitioner, pharmacy, or pharmacist access to a comprehensive patient medication history. In order to provide a comprehensive patient medication history, AHCA must require the contracted vendor to subcontract with private-sector organizations that currently operate electronic prescribing networks that provide such medication histories.

The bill provides definitions, requirements for the vendor who is contracted to design and operate the website that provides a health care practitioner, pharmacy, or pharmacist access to a comprehensive patient medication history, and limitations on the use of the website by health care practitioners, pharmacies, and pharmacists. The bill provides that a person may not recover damages against a health care practitioner, pharmacy, or pharmacist for accessing or failing to access information through the website. A violation of the provisions of the bill subjects a health care practitioner, pharmacy, or pharmacist to disciplinary action.

A contractor entering into a contract under the section created in the bill is liable in tort for the improper release of any confidential information received, in addition to any breach of contract

liability. The contractor and the contractor's insurer may not raise sovereign immunity as a defense.

This bill creates section 893.055, Florida Statutes.

II. Present Situation:

Prescription-Monitoring Systems

In an effort to control the diversion of controlled substances, over 30 states have established prescription-monitoring systems.[1] Prescription-monitoring systems collect prescription data from pharmacies in either paper or electronic format. The data may be reviewed and analyzed for educational, public health, and investigational purposes. The goals of prescription-monitoring systems are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a prescription-monitoring program has its own set of goals for its program.

Prescription-monitoring systems may cover a specified number of controlled substances. Several states cover only controlled substances listed in Schedule II; while others cover a range of controlled substances listed in Schedules II through V. Prescription-monitoring systems may combine the use of serialized prescription forms by prescribing practitioners that are tracked by state officials and an electronic data system that tracks the prescriptions. California and Texas are the only states to require the use of a serialized triplicate prescription form. Effective June 1, 2001, New York moved from the use of a triplicate prescription form to a serialized single copy. Each program achieves different objectives and offers advantages for drug diversion control efforts that cannot be achieved through either program acting alone. A multiple-copy prescription or single-copy prescription serialized form program provides the opportunity, through analysis of the data, to identify the prescribers who may be involved in inappropriate prescribing and patients who may be "doctor shopping" for prescription drugs. A multiple-copy prescription or single-copy serialized form program discourages "doctor shopping" by persons who visit several unsuspecting physicians during a short period of time and obtain prescriptions for controlled substances by feigning illness and other illegal behavior.

Electronic Prescribing Clearinghouse

Section 408.0611, F.S., requires the Agency for Health Care Administration (AHCA or the agency) to develop an electronic prescribing clearinghouse and provide information regarding electronic prescribing on the agency's website. The agency must monitor public and private sector initiatives on the subject and report to the Governor and the Legislature by January 31 of each year on the progress of implementation of electronic prescribing.

[1] Office of Diversion Control, Drug Enforcement Adm., U.S. Dep't of Justice, *A Closer Look at State Prescription Monitoring Programs, Questions and Answers*, http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm (last visited on April 19, 2008).

Agency Efforts to Prevent Drug Diversion

The agency, in collaboration with other stakeholders, recently developed a proposal to conduct a pilot project that would demonstrate the patient safety benefits of the electronic prescribing of controlled substances. As proposed, the partnership of stakeholders including AHCA, Broward Health, RxHub, SureScripts, and the Florida Office of Drug Control will demonstrate the patient safety effects of electronic prescribing among a select population of Florida clinicians who are active in using electronic prescribing and clinics connected to Broward Health who will have e-prescribing software installed during the study period. The study will measure the effects of the presence of the medication history at the point of care in preventing prescription drug abuse and reducing medication errors. The project is also designed to demonstrate that the prescribing of controlled substances can be made systematically safer and more secure using electronic prescribing.

The Board of Medicine, the Board of Osteopathic Medicine, the Board of Nursing, and the Board of Pharmacy recently held a joint board meeting to discuss issues relating to drug diversion.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Section 893.02, F.S., defines practitioner to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number. The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

"Prescription" is defined under s. 893.02(20), F.S., to mean and include an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04, F.S. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional

judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may direct the administration of a controlled substance by a licensed nurse or an intern practitioner under his or her direction and supervision.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only, to dispense controlled substances upon a written or oral prescription under specified conditions. The pharmacist must promptly reduce an oral prescription for controlled substances to writing. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. The following must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and the initials of the pharmacist filling the prescription and the date filled. Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of two years. The section requires the original container in which a controlled substance is dispensed to bear a label with specified information.

Health Insurance Portability and Accountability Act of 1996

The 1996 Health Insurance Portability and Accountability Act (HIPAA)[2] required the Administration to issue regulations protecting the privacy of health information. The U.S. Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which took effect on April 14, 2003. The regulations only apply to health plans, health care clearinghouses, and certain health care providers. The regulations permit states to afford greater privacy protections to health information.[3] Exceptions for state law are provided for public health and state regulatory reporting.[4]

[2] Section 262 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, enacted on August 21, 1996, directed the United States Department of Health and Human Services to develop standards to protect the security, including the confidentiality and integrity, of health information.
[3] Sections 160.201, 160.203, 160.204, and 160.205, C.F.R.
[4] The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally preempts state health information privacy laws, unless they provide a higher level of protection than the act. (Pub. L. No.104-191, s. 62, 110 Stat. 1936, 2029). However, these state privacy provisions may not be preempted if the Secretary of Health and Human Services determines that the state law has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. s. 802), or that is deemed a controlled substance by state law. (45 C.F.R. s. 160.203 (a)(2)). *See also* 42 U.S.C. s. 1320d-7.

Sovereign Immunity

Article X, s. 13, of the State Constitution, authorized the Florida Legislature in 1868 to waive sovereign immunity by stating that, "Provision may be made by general law for bringing suit against the state as to all liabilities now existing or hereafter originating." The doctrine of sovereign immunity prohibits lawsuits in state court against a state government, and its agencies and subdivisions without the government's consent. Section 768.28, F.S., provides that sovereign immunity for tort liability is waived for the state, and its agencies and subdivisions, but imposes a $100,000 limit on the government's liability to a single person and the limit is $200,000 for claims arising out of a single incident. Section 768.28, F.S., outlines requirements for claimants alleging an injury by the state or its agencies. Section 11.066, F.S., requires a claimant to petition the Legislature in accordance with its rules, to seek an appropriation to enforce a judgment against the state or state agency. The exclusive remedy to enforce damage awards that exceed the recovery cap is by an act of the Legislature through the claims bill process. A claim bill is a bill that compensates an individual or entity for injuries or losses occasioned by the negligence or error of a public officer or agency.

III. Effect of Proposed Changes:

The bill creates s. 893.055, F.S., to require the Agency for Health Care Administration (AHCA or the agency), by June 30, 2009, to contract with a vendor to design and operate a secure, privacy-protected website that provides a health care practitioner, pharmacy, or pharmacist access to a comprehensive patient medication history. In order to provide a comprehensive patient medication history, AHCA must require the contracted vendor to subcontract with private-sector organizations that currently operate electronic prescribing networks that provide such medication histories.

Subsection (1) of s. 893.055, F.S., as created in the bill, provides definitions. "Agency" means the Agency for Health Care Administration. "Department" means the Department of Health. "Federal privacy laws" means the provisions related to the disclosure of patient privacy information under federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, and its implementing regulations, the Federal Privacy Act, 5 U.S.C. s. 552a, and its implementing regulations, and any other federal law, including, but not limited to, federal common law and decisional law that would prohibit the disclosure of patient privacy information. "Health care practitioner" means with the exception of a pharmacist, a practitioner licensed under chapter 456, F.S., and authorized by law to prescribe drugs. "Pharmacy" means a pharmacy subject to licensure or regulation by the department under chapter 465, F.S., which dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a patient in Florida.

The contracted vendor must comply with all applicable state and federal privacy laws and maintain the website within the United States. The contracted vendor must create a system to verify with the Department of Health (DOH or the department) that each health care practitioner, pharmacy, or pharmacist requesting access to the website holds a valid, active license.

A health care practitioner authorized to access the website may use the website only to obtain medication history for a current patient for prescribing purposes with the written permission of the patient.

A pharmacy or pharmacist authorized to access the website may use the website only to obtain medication history in dispensing a current prescription for Schedule II, Schedule III, or Schedule IV medicinal drugs with the written permission of the patient. The pharmacy or pharmacist may not have access to pharmacy-identifying information within a patient's medication history.

A person may not recover damages against a health care practitioner, pharmacy, or pharmacist authorized to obtain medication history information under this bill for accessing or failing to access such information. A violation of this bill by a health care practitioner, pharmacy, or pharmacist constitutes grounds for disciplinary action under each respective licensing chapter and chapter 456, F.S., the general regulatory provisions for health care professions under DOH.

Any contractor entering into a contract under this section is liable in tort for the improper release of any confidential information received, in addition to any breach of contract liability. Sovereign immunity may not be raised by the contractor, or the insurer of that contractor on the contractor's behalf, as a defense in any action arising out of the performance of any contract entered into under this bill, as a defense in tort, in any other application regarding the maintenance of confidentiality of information, or for any breach of contract.

The bill takes effect on July 1, 2008, if CS/SB 1540 and 2782, or similar legislation, is adopted in the same legislative session or an extension thereof and becomes law.

IV. Constitutional Issues:

A. Municipality/County Mandates Restrictions:

None.

B. Public Records/Open Meetings Issues:

An exemption to the Public Records Law for identifying information of patients, practitioners, and pharmacists in the information and reports held by certain agencies is being addressed in separate legislation (CS/SB's 1540 and 2782).

C. Trust Funds Restrictions:

None.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

This bill will not affect Floridians access to health care directly. However, there could be an indirect impact if the pharmacy refuses to dispense medications to patients who do not give written permission for access to the medical history.

The bill also requires that practitioners obtain written permission from the patients. Whether this requirement changes existing practices is unclear. Dispensing practitioners and pharmacies may incur some costs to incorporate changes in their procedures for patient written authorization to obtain patients' medication histories as provided in the bill.

C. Government Sector Impact:

The bill would have a fiscal impact on the Agency for Health Care Administration (AHCA or the agency) requiring two FTEs and contracted services. The first year impact would be $8,753,673 and the estimated recurring impact is $7,402,673 for development and implementation of the patients' medication history website. The first year contract includes $2,392,000 for the development of the website interface and certification functions. The agency estimates the on-going transaction fees per year at $6,125,331. The cost for automated background checks is estimated by AHCA at $50.00 per requesting patient or $100,000 per year for this contracted service.

VI. Technical Deficiencies:

None.

VII. Related Issues:

The bill requires the contracted vendor who designs and operates a secure, privacy-protected website that provides a health care practitioner, pharmacy, or pharmacist access to comprehensive patient medication history, to maintain the website within the United States. However, it is unclear whether that is a prohibition on hiring components of the design or maintenance of the website to overseas operations or employees.

The bill defines "health care practitioner" with the exception of pharmacist as a practitioner licensed under chapter 456, F.S., and authorized by law to prescribe drugs. Florida law authorizes pharmacists to dispense controlled substances based on an order of drugs or medicinal supplies written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state outside of Florida, but only if the pharmacist determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the pharmacist does not know the physician writing the prescription, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription.

VIII. Additional Information:

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

CS by Health Regulation on April 1, 2008:

The committee substitute no longer repeals s. 408.0611, F.S., which requires the Agency for Health Care Administration to develop an electronic prescribing clearinghouse and provide information regarding electronic prescribing on its website. It combines SB 1550 and SB 2724, but contains the substantive provisions that originally were in SB 1550. Senate Bill 2724 required the Department of Health, by June 30, 2009, to design and establish an electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedules II, III, and IV by health care practitioners within Florida and the dispensing of such controlled substances to an individual within Florida by a pharmacy permitted or registered by the Board of Pharmacy.

B. Amendments:

None.