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 Health Regulation Committee

BILL:	SB 2724
INTRODUCER:	Senator Atwater
SUBJECT:	Controlled Substances
DATE:	March 31, 2008
REVISED:	

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Pre-meeting**
2.			CJ	
3.			GO	
4.			HA	
5.				
6.				

I. Summary:

Senate Bill 2724 requires the Department of Health (DOH), 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. Phase one of the system must be implemented in two geographic areas. One site must include only Broward County and the second site must include Palm Beach County. By June 30, 2010, the DOH must implement expansion of the program to include the remaining counties of Florida in accordance with a plan developed by the DOH.

Data regarding controlled substances subject to the requirements of the monitoring system must be reported to the DOH as soon as possible, but not more than 35 days after the date the controlled substance is dispensed, each time that such controlled substance is dispensed. The bill provides that a pharmacy or dispensing practitioner may meet the reporting requirements by providing the DOH an electronic or magnetic disc or tape, or via the Internet of each controlled substance listed in Schedules II, III, and IV, which it dispenses.

The bill creates a first-degree misdemeanor offense for any person who knowingly fails to report the dispensing of controlled substances listed in Schedules II, III, and IV. All costs incurred by the DOH for the prescription monitoring system, shall be through a grant applied for by the county or the State of Florida. The DOH and local governments must cooperate in seeking grant funds at no cost to the DOH.

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 thirty 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. New York recently moved from the use of a triplicate prescription form to a serialized single copy, effective June 1, 2001. 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 AHCA to develop an electronic prescribing clearinghouse and provide information regarding electronic prescribing on the agency's website. The AHCA 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.

Agency Efforts to Prevent Drug Diversion

The AHCA, 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 the 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

[1] United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control. See "A Closer Look at State Prescription Monitoring Programs," at <http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm> (Last visited on March 31, 2008).

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. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There 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 2 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]

III. Effect of Proposed Changes:

Senate Bill 2724 creates s. 893.055, F.S., to require the DOH, 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

[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. 262, 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.A s. 1320d-7.

such controlled substances to an individual within Florida by a pharmacy permitted or registered by the Board of Pharmacy. Phase one of the system must be implemented in two geographic areas. One site must include only Broward County and the second site must include Palm Beach County. By June 30, 2010, the DOH must implement expansion of the program to include the remaining counties of Florida in accordance with a plan developed by the DOH. Data regarding controlled substances subject to the requirements of the monitoring system must be reported to the DOH as soon as possible, but not more than 35 days after the date the controlled substance is dispensed, each time that such controlled substance is dispensed. The bill provides that a pharmacy may meet the reporting requirements by providing the DOH, an electronic or magnetic disc or tape, or via the Internet of each controlled substance listed in Schedules II, III, and IV, which it dispenses.

Exceptions to the reporting requirements under the electronic-monitoring system are created for controlled substances that are:

- Administered by a health care practitioner directly to a patient;
- Dispensed by a health care practitioner authorized to prescribe controlled substances directly to a patient and limited to an amount adequate to treat the patient for a period of no more than 72 hours;
- Dispensed by a health care practitioner or pharmacist to an in-patient of a facility that holds an institutional pharmacy permit;
- Ordered from an institutional pharmacy permitted under s. 465.019, F.S., in accordance with the institutional policy for such controlled substances or drugs; or
- Dispensed by a pharmacist or administered by a health care practitioner to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled which is licensed in Florida.

A practitioner or pharmacist who dispenses a controlled substance must transmit the information required under the prescription-monitoring system in an electronic or other format approved by the DOH rule. The bill requires the DOH to determine by rule the data required to be reported under the prescription monitoring system, and such data may include any data required under s. 893.04, F.S.

The bill provides that the cost to the dispenser in submitting the required information may not be material or extraordinary as specified in the bill. The information submitted to the DOH under the prescription-monitoring system may be transmitted to any person or agency authorized to receive it pursuant to ch. 119, F.S., (section 1 of SB 2782), or similar legislation, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All required transmissions must comply with relevant federal and state privacy and security laws. However, any authorized agency receiving such information may maintain it for a period longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this section commits a first-degree misdemeanor, punishable by jail up to 1 year, and a fine up to $1,000 may be imposed.

The department and the regulatory boards for the health care practitioners must adopt rules to implement and administer this section. All costs incurred by the DOH for the prescription monitoring system, shall be through a grant applied for by the county or the State of Florida. The DOH and local governments must cooperate in seeking grant funds at no cost to the DOH.

The bill provides an effective date of July 1, 2008.

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 Article VII, Section 18 of the Florida Constitution.

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 the DOH is being addressed in separate legislation (SB 2782).

C. Trust Funds Restrictions:

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

D. Other Constitutional Issues:

The bill requires the DOH to determine by rule the data required to be reported under the prescription monitoring system, and such data may include any data required under s. 893.04, F.S., and must include the category of professional licensure of the prescribing practitioner. The bill imposes criminal penalties for any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this bill. Such persons are liable for a first-degree misdemeanor. To the extent the bill does not state what data must be reported and delegates that function to the DOH, it, arguably, may raise an issue as to whether the legislative delegation to the department constitutes a proper delegation. The delegation also, arguably, may raise an issue as to whether such delegation allows an administrative agency to define the elements of a crime. Article I, section 18 of the Florida Constitution provides that:

> No administrative agency, except the Department of Military Affairs in an appropriately convened court-martial action as provided by law, shall impose a sentence of imprisonment, nor shall it impose any other penalty except as provided by law.

In addressing the question as to "how much of a role may administrative agencies take in defining the elements of a crime," the Florida Supreme Court has declared that Article I,

Section 18 of the Florida Constitution, though speaking only to quasi-adjudicatory powers of some administrative agencies, nevertheless embodies an overall constitutional policy that administrative agencies may not create a criminal statute or its equivalent and prescribe the penalty. See *B.H. v. State*, 645 So.2d 987, 46 A.L.R. 5th 877 (1994), certiorari denied 115 S.Ct. 2559, 515 U.S. 1132, 132 L.Ed.2d 812.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Pharmacies and other dispensers will incur costs to comply with the reporting requirements under the prescription-monitoring system.

C. Government Sector Impact:

The DOH will incur costs to implement the bill, however, the bill requires all costs incurred by the DOH for the prescription monitoring system, to be paid through a grant applied for by the county or the State of Florida. The DOH and local governments must cooperate in seeking grant funds at no cost to the DOH.

VI. Technical Deficiencies:

None.

VII. Related Issues:

None.

VIII. Additional Information:

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

None.

B. Amendments:

None.