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:	CS/SB 614
INTRODUCER:	Health Regulation Committee and Senator Aronberg
SUBJECT:	Monitoring the Dispensing of Controlled Substances
DATE:	April 6, 2009 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Fav/CS**
2.			CJ	
3.			GO	
4.			HA	
5.				
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 Department of Health (DOH), by March 1, 2011, to adopt an electronic monitoring system to monitor the collection of biometric identifiers and to record and store, in a secure database:

- The dispensing of controlled substances listed in Schedule II, Schedule III, and Schedule IV by health care practitioners within Florida; and
- The dispensing or delivering of controlled substances listed in Schedule II, Schedule III, and Schedule IV to individuals in Florida by any Florida-licensed pharmacy or Florida-registered dispensing health care practitioner.

The bill requires any health care practitioner who, and any pharmacy that, dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to have in the practitioner's office or pharmacy an active and operational biometric scanning device connected to the database. Prior to dispensing or delivering such a controlled substance to a person in Florida, the practitioner or pharmacy must obtain a biometric scan of an approved biometric identifier of the person and submit the same to the database. The bill specifies additional information that must be submitted to the database before such a controlled substance may be dispensed or delivered to a person.

After receiving the required information, the database must assign the prescription a unique identifying number and immediately provide certain information to the prescribing practitioner, pharmacy, or dispensing practitioner.

The bill establishes exceptions to the reporting requirements of the database.

For each Schedule II, III, or IV controlled substance dispensed, dispensing practitioners or pharmacists must submit the required information specified in the bill in an electronic format approved by the DOH. The DOH, together with the Board of Pharmacy and the Board of Medicine, must by March 1, 2010, adopt rules governing the administration of the bill, including rules governing access to the database by practitioners and pharmacists and implementing procedures to be employed when a biometric scanning device is inoperable or the database is inaccessible.

Any person who fails to comply with any provision of the bill, commits a first-degree misdemeanor, punishable by jail up to 1 year, and a fine up to $1,000 may be imposed. The penalties take effect March 1, 2011, or upon the adoption of rules, whichever occurs first, and apply to acts or omissions on or after that date

This bill creates section 893.055, Florida Statutes, and one undesignated section of law.

II. Present Situation:

Prescription-Drug-Monitoring Programs

In an effort to control the diversion of controlled substances, 38 states have enacted legislation establishing prescription-drug-monitoring programs (32 of the programs are currently operational).[1] Prescription-drug-monitoring programs 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-drug-monitoring programs are dependent on the mission of the state agency that operates the program or uses the data. Each state that has implemented a prescription-drug-monitoring program has its own set of goals for its program.

Prescription-drug-monitoring programs 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-drug-monitoring programs 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, New York, and Texas are the only states to require the use of a single-copy, serialized prescription form.

[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 April 3, 2009).

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, dentist, veterinarian, osteopathic physician, naturopathic physician, or 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 893.04, 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 filled; 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 a controlled substance 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.

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.

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:

The bill requires the DOH, by March 1, 2011, to adopt an electronic monitoring system to monitor the collection of biometric identifiers and to record and store, in a secure database, the dispensing of controlled substances listed in Schedule II, Schedule III, and Schedule IV by health care practitioners within Florida. The system must also monitor the collection of biometric identifiers and record and store, in a secure database, the dispensing or delivering of controlled substances listed in Schedule II, Schedule III, and Schedule IV to individuals in Florida by any Florida-licensed pharmacy or Florida-registered dispensing health care practitioner.

Section 287.057(5)(f)6., F.S., provides an exemption for contractual services and commodities that are otherwise subject to the competitive-bid requirements of that section of law if the services or commodities are health services involving examination, diagnosis, treatment, prevention, medical consultation, or administration. The bill provides that, notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(5)(f), F.S., if the DOH determines that it is cost-effective to contract for any system components or services, the DOH

[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.

must comply with the competitive-solicitation requirements for the procurement of any goods or services required under the bill. The DOH may not award a contract for any components or services related to biometrics unless it receives a minimum of three responses to its competitive solicitation for such components or services.

The bill requires any health care practitioner who dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to have in the practitioner's office an active and operational biometric scanning device connected to the database. Any practitioner who dispenses or delivers a controlled substance in Schedule II, Schedule III, or Schedule IV to a person in Florida must first obtain a biometric scan of an approved biometric identifier of the person and submit the same to the database. The bill creates the same requirements for a pharmacy.

Before dispensing or delivering a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a person in Florida, every health care practitioner and dispensing pharmacy must submit the following information to the database: the biometric scan of the person's biometric identifier; the full name and address of the prescribing practitioner; the date of the each prescription; and the name of the controlled substance prescribed and the strength, quantity, and directions for use.

The database must assign each prescription a unique identifying number and must immediately transmit to the prescribing practitioner: the unique identifying number; the names of controlled substances that have been prescribed in connection with the biometric scan submitted that may conflict with or overlap the prescribing practitioner's prescription; the full name and address of the practitioner whose prescription may conflict with or overlap the prescribing practitioner's prescription and the full name and address of the practitioner or pharmacy that dispensed or delivered the conflicting or overlapping prescription.

Before dispensing or delivering a prescription for a Schedule II, Schedule III, or Schedule IV controlled substance, the pharmacist or dispensing health care practitioner must submit the biometric scan of the person's biometric identifier to the database and the database must immediately transmit the following to the pharmacy or dispensing practitioner: names of the Schedule II, Schedule III, or Schedule IV controlled substances that have been prescribed in connection with the biometric scan submitted that may conflict with or overlap the prescription to be dispensed or delivered; the full name and address of the practitioner whose prescription may conflict with or overlap the prescription to be dispensed or delivered and the full name and address of the practitioner or pharmacy that dispensed or delivered the conflicting or overlapping prescription.

Personal protected health care information other than the biometric scans and the prescription information provided to the database may not be retained in the database. The bill does not preclude health care practitioners and pharmacies from retaining personal information on their patients.

The reporting requirements of the database do not apply to controlled substances:

- Administered by a health care practitioner directly to his or her patient;

- Dispensed or delivered 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 period no more than 72 hours;
- Dispensed or delivered by a health care practitioner or a pharmacist to an inpatient of a facility that holds an institutional pharmacy permit;
- Ordered from an institutional pharmacy in accordance with internal policy and procedure for controlled substances;
- Dispensed or delivered by a pharmacist or administered by a health care practitioner to a patient or resident receiving care from a Florida-licensed hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled;
- Prescribed by a health care practitioner for a patient younger than 16 years of age;
- Prescribed or dispensed pursuant to rule adopted by the DOH; or
- Administered, prescribed dispensed, or delivered under circumstances in which the pharmacist or practitioner cannot, in good faith, comply with the bill's requirements.

Dispensing practitioners or pharmacists must submit the required information in an electronic format approved by the DOH. The DOH, or the person or agency authorized by the DOH, must maintain the information for no longer than 24 months from the date of receipt and must expunge the information unless otherwise directed by a court of competent jurisdiction. The transmissions required by the bill must comply with relevant federal and state privacy and security laws.

The DOH, together with the Board of Pharmacy and the Board of Medicine, must by March 1, 2010, adopt rules governing the administration of the bill, including rules governing access to the database by practitioners and pharmacists and implementing procedures to be employed when a biometric scanning device is inoperable or the database is inaccessible.

Any person who fails to comply with any provision of the bill, commits a first-degree misdemeanor, punishable by jail up to 1 year, and a fine up to $1,000 may be imposed. The penalties created in the bill take effect March 1, 2011, or upon the adoption of rules, whichever occurs first, and apply to acts or omissions on or after that date.

The bill provides an effective date of July 1, 2009.

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 612).

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.

V. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Health care practitioners and pharmacies that prescribe or dispense controlled substances may be required to obtain and maintain biometric scanning devices to comply with the provisions of the bill.

The bill may result in a reduction of overall health care costs if the monitoring system helps control fraudulent prescriptions and reduces health care costs related to the abuse of controlled substances.

C. Government Sector Impact:

The DOH will incur costs related to the development, deployment and maintenance of the proposed system under the bill. Officials at the DOH report that the fiscal impact of this bill is expected to be considerable, although currently indeterminate. Due to the technical complexity and rarity of the proposed system, extensive research would need to be performed to determine a solution and estimate costs. The DOH staff indicate that the time required to research, develop, contract for, and deploy the proposed system is unknown.

The DOH staff note that in addition to the initial set-up costs, there will be significant on-going costs associated with system maintenance and costs associated with prosecution of administrative cases in which licensed health practitioners have been found guilty of violations.

County health departments and other clinics or pharmacies funded by the State of Florida that prescribe or dispense controlled substances may be required to obtain and maintain biometric scanning devices to comply with the provisions of the bill.

VI. Technical Deficiencies:

On line 88, the reference to “prescribing pharmacy” should be changed to “dispensing pharmacy.”

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.)

CS by Health Regulation on April 6, 2008:
The committee substitute requires the DOH to comply with statutory competitive bidding requirements. The DOH is prohibited from awarding a contract for any components or services related to biometrics unless it receives a minimum of three responses to its competitive solicitation.

B. Amendments:

None.