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 616
INTRODUCER:	Senator Ring
SUBJECT:	Prescription Drug Monitoring Program
DATE:	February 11, 2010
REVISED:	

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

Summary:

The bill requires any disclosures of confidential information from the electronic prescription drug database maintained by the Department of Health (DOH) to the Attorney General for Medicaid fraud cases or law enforcement agencies during active investigations to be done pursuant to a search warrant based upon probable cause.

This bill amends sections 893.055 and 893.0551, Florida Statutes.

I. Present Situation:

Prescription-Drug-Monitoring Programs

In an effort to control the diversion of controlled substances, 39 states have enacted legislation establishing prescription-drug-monitoring programs (34 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 law enforcement 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.

[1] United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control. See "State Prescription Drug Monitoring Programs," at <http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm> (Last visited on February 11, 2010).

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 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.

Florida's Prescription-Drug-Monitoring Program

During the 2009 Regular Legislative Session, legislation passed to create a prescription-drug-monitoring program in Florida.[2] The DOH is required, by December 1, 2010, to design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient's health care practitioner and pharmacist who inform the DOH that they wish for the patient advisory report provided to them. "Patient advisory reports" are information provided by the DOH in writing, or as determined by the DOH, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances listed in Schedule II, Schedule III, or Schedule IV.

Under s. 893.055, F.S., a practitioner or pharmacist who dispenses a controlled substance must submit specified information regarding the prescription for inclusion in the database.

The following entities may not be allowed direct access to information in the prescription-drug-monitoring program database, but may request information that is otherwise confidential and exempt under s. 893.0551, F.S., from the program manager and when authorized by the program manager, the program manager's program and support staff. Before the release of information, the request must be verified as authentic and authorized with the requesting organization by the program manager, the program manager's staff, or as determined in rules by the DOH as being authentic and as having been authorized by the requesting entity:

- The DOH or its relevant health care regulatory boards responsible for licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances;
- The Attorney General for Medicaid fraud cases involving prescribed controlled substances;
- A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances; or
- A patient or legal guardian or designated health care surrogate of an incapacitated patient who for verifying the accuracy of the database information, submits a written notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health surrogate submits the request. The DOH must validate and verify specified information to honor the request.

A similar procedure is outlined in s. 893.0551, F.S., relating to the public records exemption for the prescription-drug-monitoring program, for the DOH to verify the legitimacy of requests from the Attorney General and his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs; or a law enforcement agency that has initiated an

[2] See sections 893.055 and 893.0551, F.S.

active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substance. Law enforcement agencies may disclose confidential and exempt information received from the DOH to a criminal justice agency as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law for controlled substances.

Pharmacy Records

Chapter 465, F.S., provides for the regulation of the practice of pharmacy. Section 465.017(2), F.S., specifies that except as permitted by law (specifically ch. 465, F.S., relating to pharmacy; ch. 406, F.S., relating to the Medical Examiners Act; ch. 409, F.S., relating to the Medicaid program; ch. 456, F.S., relating to the general regulatory provisions for professions; ch. 499, F.S., relating to drugs, devices and household products; and ch. 893, F.S., relating to controlled substances) records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs may not be furnished to any person other than to the patient for whom the drugs were dispensed, or his or her legal representative, or to the Department of Health pursuant to existing law, or, in the event that the patient is incapacitated or unable to request the records, his or her spouse, except upon written authorization of such patient. Section 465.017(2), F.S., also provides that the records may be furnished in any civil or criminal proceeding upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or his or her legal representative by the party seeking such records.

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.

The chapter 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. Section 893.07(4), F.S., provides that every record required by the chapter, including prescription records be kept and made available for at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of the state relating to controlled substances.[3] The Second District Court of Appeal upheld a warrantless search and seizure of prescription records pursuant to s. 893.07, F.S.[4]

[3] See *Gettel v. State* 449 So.2d 413 (2nd DCA 1984).
[4] *Id.*

The First District Court of Appeal recently held that s. 893.07(4), F.S., which requires pharmacies to produce, for inspection and copying by law enforcement officers, records of controlled substances sold and dispensed does not require a subpoena, warrant, or prior notice to the patient.[5] The First District Court of Appeal also held that the provision of records to law enforcement in compliance with state law did not violate the federal Health Insurance Portability and Accountability Act (HIPAA) and the pharmacy's provision of the defendant's state constitutional right to privacy.[6] In *State v. Carter*, a police investigator obtained patient pharmacy records while investigating a "doctor shopping" violation as described in s. 893.13(7)(a)8., F.S.[7] The records were obtained under s. 893.07(4), F.S. In *Carter*, the defendant filed a motion to suppress, arguing that the warrantless seizure of her prescription records violated her constitutional rights to privacy and due process. The defendant also alleged that her pharmacy records could not legally be transmitted to law enforcement.

Health Insurance Portability and Accountability Act of 1996

The 1996 Health Insurance Portability and Accountability Act (HIPAA)[8] required the Administration to issue regulations protecting the privacy of health information. The United States Department of Health and Human Services 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.[9] Exceptions for state law are provided for public health and state regulatory reporting.[10] The HIPAA regulations permit covered entities to use or disclose protected health information as required by law.[11]

Probable Cause

Fourth Amendment searches are unlawful unless accompanied by "probable cause." The Florida Supreme Court has defined [p]robable cause [to mean] a reasonable ground of suspicion supported by circumstances strong enough in themselves to warrant a cautious person in belief that the named suspect is guilty of the offense charged.[12] When a warrant is secured in advance of an arrest or search, the initial probable cause determination is made by a judge.[13] Under s. 933.01, F.S., a search warrant authorized by law may be issued by any judge, including the

[5] See *State v. Carter*, 23 So.3d 798 (1st DCA 2009).
[6] *Id.*
[7] *Id.*
[8] 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.
[9] Sections 160.201, 160.203, 160.204, and 160.205, C.F.R.
[10] 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.
[11] See 45 C.F.R. s. 164.512 and 45 C.F.R. s. 164.103 which defines "required by law" to mean a mandate contained in law that compels an entity to make a use or disclosure of protected health information and that is enforceable in a court of law.
[12] See *Dunnavant v. State*, 46 So.2d 871 (Fla.1950) as quoted in *Johnson v. State* 660 So.2d 648, at 654 (internal quotation omitted).
[13] See Fla.R.Crim P. 3.120.

committing judge of the trial court having jurisdiction where the place, vehicle, or thing to be searched may be. The judge, upon examination of the application and proofs submitted, if satisfied that probable cause exists for the issuing of the search warrant, shall thereupon issue a search warrant signed by him or her with his or her name of office, to any sheriff and the sheriff's deputies or any police officer or other person authorized by law to execute process, commanding the officer or person forthwith to search the property described in the warrant or the person named, for the property specified, and to bring the property and any person arrested in connection therewith before the judge or some other court having jurisdiction of the offense.[14]

II. Effect of Proposed Changes:

The bill requires any disclosures of confidential information from the electronic prescription drug database maintained by the DOH to the Attorney General for Medicaid fraud cases or law enforcement agencies during active investigations to be done pursuant to a search warrant based upon probable cause.

The bill provides an effective date of July 1, 2010.

III. 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:

The provisions of this bill have no impact on public records or open meetings issues under the requirements of Article I, Section 24(a) and (b) of the Florida Constitution.

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.

IV. Fiscal Impact Statement:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

None.

[14] See s. 933.07, F.S.

C. Government Sector Impact:

None.

V. Technical Deficiencies:

The bill requires any disclosures to the Attorney General for Medicaid fraud cases or law enforcement agencies from the electronic prescription drug database maintained by DOH to be done pursuant to a search warrant based upon probable cause. The bill does not state that the search warrant must be issued by a court of competent jurisdiction that determines probable cause exists for the issuance of the search warrant.

VI. Related Issues:

The bill's requirement for law enforcement agencies to obtain a search warrant to obtain information from the electronic prescription drug database appears to be in conflict with the requirements for disclosure of controlled substance records maintained by pharmacists under s. 893.07(4), F.S.

VII. 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.

This Senate Bill Analysis does not reflect the intent or official position of the bill's introducer or the Florida Senate.