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.)

Prepared By: Health Regulation Committee

BILL:	SB 518
INTRODUCER:	Senators Saunders and Bennett
SUBJECT:	Controlled Substances
DATE:	February 15, 2007 REVISED: 02/21/07

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HR	**Fav/4 amendments**
2.			CJ	
3.			HA	
4.				
5.				
6.				

Please see last section for Summary of Amendments

- [x] Technical amendments were recommended
- [x] Amendments were recommended
- [ ] Significant amendments were recommended

I. Summary:

The bill creates a third-degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of specified prohibited acts under the Florida Comprehensive Drug Abuse Prevention and Control Act, sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blanks for controlled substances.

The bill amends existing law relating to the dispensing of controlled substances by a pharmacist to: limit the dispensing of a Schedule II drug in an emergency upon an oral prescription to a 72-hour supply; limit the dispensing of a Schedule III drug upon an oral prescription to a 30-day supply; specify procedures for a pharmacist to verify the validity of prescriptions for controlled substances listed in Schedule II, Schedule III, or Schedule IV and the identity of the individual obtaining any controlled substance; authorize a pharmacist to record a prescription electronically if permitted by federal law for certain controlled substances; and impose additional requirements on prescriptions for controlled substances in Schedule II, Schedule III, or Schedule IV to prevent diversion.

The bill requires the Department of Health (department or DOH), by June 30, 2008, to design and establish an electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedule II, Schedule III, and Schedule IV by health care practitioners within Florida and the dispensing of such controlled substances to an individual at a specific

address within Florida by a pharmacy permitted or registered by the Board of Pharmacy. 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 exemptions from the data reporting requirements for controlled substances that are administered, dispensed, or ordered in specified settings or for specified categories of patients. The department must determine by rule the data required to be reported under the prescription-monitoring system. Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV commits a first-degree misdemeanor.

The bill requires the DOH to develop and adopt by rule the form and content for a counterfeit-resistant prescription blank, which may be used by practitioners to prescribe a controlled substance listed in Schedule II, Schedule III, or Schedule IV. The department may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances.

The bill appropriates $2,564,670, in recurring general revenue and $1,837,677 in nonrecurring general revenue to the DOH and authorizes three positions to implement the electronic monitoring system and the counterfeit-resistant prescription blanks. The Medical Quality Assurance Trust Fund may not be used to implement or fund the system.

The bill amends s. 893.04, F.S.

The bill creates ss. 831.311, 893.055 and 893.065, F.S., and two undesignated sections of law.

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

[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 February 6, 2007).

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.

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.

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.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by regulation of the DOH, when such controlled substance may be dispensed upon oral prescription. No prescription for a Schedule II controlled substance may be refilled.[2] No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.[3] A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II.[4]

Health Insurance Portability and Accountability Act of 1996

The 1996 Health Insurance Portability and Accountability Act (HIPAA)[5] 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.[6] Exceptions for state law are provided for public health and state regulatory reporting.[7]

Senate Bill 520

Senate Bill 520 makes confidential and exempt identifying information of a patient, patient's agent, health care practitioner, pharmacist, pharmacist's agent, or pharmacy that is contained in any record held by the DOH under the prescription-monitoring system. The department is

[2] Section 893.04(1)(f), F.S.
[3] Section 893.04(1)(g), F.S.
[4] See 21 CFR 1306.11(d)(1) which provides that in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.
[5] 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.
[6] Sections 160.201, 160.203, 160.204, and 160.205, C.F.R.
[7] 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.

required to give specific entities or person's access to the confidential and exempt information in particular instances.

III. Effect of Proposed Changes:

Section 1. Creates s. 831.311, F.S., to create a third-degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of specified prohibited acts under the Florida Comprehensive Drug Abuse Prevention and Control Act[8], sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blanks for controlled substances, the form and content of which are adopted by rule of the DOH pursuant to s. 893.065, F.S. A third-degree felony is punishable by imprisonment up to 5 years, and a fine up to $5,000 may also be imposed.

Section 2. Amends s. 893.04, F.S., to authorize a pharmacist to record an oral prescription for controlled substances electronically if permitted by federal law. The bill limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply.

A pharmacist is prohibited from dispensing a controlled substance in Schedule II, Schedule III, or Schedule IV to any patient or the patient's agent without first determining, in the exercise of her or his professional judgment, that the order is valid. The pharmacist or pharmacist's agent must obtain a government-issued identification card or other form of documentary identification substantiating the identity of a patient or patient's agent prior to dispensing any controlled substance and must make a record of the type of documentary identification provided. If the patient or patient's agent does not have appropriate identification, the pharmacist may dispense the controlled substance only when the pharmacist determines, using his or her professional judgment, that the order is valid and includes such information in the patient's record. The Board of Pharmacy is authorized to adopt, by administrative rule, required patient identification information for controlled substances and procedures for a pharmacist to verify the validity of a prescription for controlled substances in circumstances in which the pharmacist was not provided required identification information.

Any pharmacist, who dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV, is exempt from the requirement to obtain suitable identification for the prescription dispensed by mail if the pharmacist has obtained the patient's identification through the patient's prescription benefit plan.

Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon oral prescription if, before filling the prescription, the pharmacist reduces the prescription to writing or records the prescription electronically if permitted by federal law. These prescriptions must contain the date of the oral authorization.

Each written prescription prescribed by a practitioner in Florida for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and numerical notation of the quantity and a notation of the date with the abbreviated month written out on the face of

[8] Section 893.13, F.S.

the prescription. A pharmacist is permitted, upon verification by the prescriber, to document any of this required information on the prescription.

A pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription issued in Florida. A pharmacist may not knowingly fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

Section 3. Creates s. 893.055, F.S., to require the DOH, by June 30, 2008, 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 at a specific address within Florida by a pharmacy permitted or registered by the Board of Pharmacy or subject to licensure by the DOH. The design of the electronic prescription-monitoring system must be consistent with the American Society for Automation in Pharmacy standards. 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 such controlled substance is dispensed. Reporting requirements for a pharmacy or dispensing practitioner are specified. The department must 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.

Exceptions to the reporting requirements under the electronic-monitoring system are created for controlled substances that are: (1) administered by a health care practitioner directly to a patient; (2) 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; (3) dispensed by a health care practitioner or pharmacist to an in-patient of a facility that holds an institutional pharmacy permit; (4) ordered from an institutional pharmacy permitted under s. 465.019, F.S., in accordance with the institutional policy for such controlled substances or drugs; (5) 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; or (6) prescribed by a health care practitioner for a patient less than 16 years of age.

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 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 section 1 of SB_____ (SB 518), 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. The department must cover all costs for the prescription monitoring system, and an amount necessary to cover such costs is to be appropriated annually, subject to the availability of funds, out of the Grants and Donations Trust Fund. The Medical Quality Assurance Trust Fund may not be used to implement or otherwise fund the electronic prescription-monitoring program.

Section 4. Creates s. 893.065, F.S., to require the DOH to develop and adopt by rule the form and content for a counterfeit-resistant prescription blank, which may be used by practitioners for prescribing a controlled substance listed in Schedule II, Schedule III, or Schedule IV. The department may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

Section 5. Appropriates $2,564,670, in recurring general revenue and $1,837,677 in nonrecurring general revenue to the DOH and authorizes three positions to implement the electronic-monitoring system and the counterfeit-resistant prescription blanks for FY 2007-08.

Section 6. Provides that the penalties created in ss. 831.311(2) and 893.055(6), F.S., are effective only upon the adoption by the DOH and each applicable professional regulatory board of the rules required pursuant to ss. 893.055(7) and 893.065, F.S., as created in the bill.

Section 7. Provides that, except as otherwise provided in this act, this act shall take effect on July 1, 2007, if SB_____ (SB 520), 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:

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 520).

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. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

Schedule III controlled substance prescriptions intended to cover more than a 30-day supply must be in writing under the bill. Consumers who currently may obtain such drugs through an oral prescription may bear additional costs for medical visits to obtain prescriptions beyond a 30-day supply.

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

C. Government Sector Impact:

The department will incur costs to design and establish an electronic prescription-monitoring system and to develop counterfeit-resistant prescription blanks in Florida for

controlled substances listed in Schedules II, III, and IV. The department estimates the fiscal impact of the bill to be: $5,064,253 in FY 2007-08; $3,488,743 in FY 2008-09 and $3,963,791 in FY 2009-10 for three positions, costs associated with a private vendor to develop the electronic monitoring system, costs associated with data collection, systems staff, and software and hardware for the controlled substances monitoring system. There may be a fiscal impact on other state agencies that are required by the bill to comply with certain reporting standards.

Section 5 of the bill appropriates $2,564,670 in recurring general revenue funds and $1,837,677 in nonrecurring general revenue funds to the DOH to implement the bill. The bill authorizes three additional positions.

The Harold Rogers Prescription Monitoring grant program, which is administered by the U.S. Department of Justice, provides financial assistance to states that want to create, enhance, or plan a Prescription Monitoring Program. State governments are eligible to apply under this program for implementation or enhancement grant funds when the state has legislation or regulations that require the submission of dispensing data to a centralized database and authorize or designate a state agency to implement and administer the program. State governments are eligible for planning grant funds even if they have not adopted enabling statutes or regulations. During fiscal year 2003, the Florida Office of Drug Control within the Executive Office of the Governor was awarded $300,000. For fiscal year 2007, the President's budget request is $9.9 million for the program and the application deadline for States to apply for grants for federal fiscal year 2007 was January 11, 2007.

The National All Schedules Prescription Electronic Report Act of 2005 (NASPER) is administered by the HHS. The NASPER grant program is authorized for $60 million over 5 years, with $15 million allocated for 2006 and 2007, and $10 million for 2008, 2009, and 2010. However, HHS did not receive an appropriation in its fiscal year 2006 budget for this program. Funding for NASPER in federal fiscal year 2007 has not yet been determined.

VI. Technical Deficiencies:

On page 2, lines 20-21, the bill refers to controlled substances "listed in Schedules II, III, and IV" in the catch line, however, the criminal violation created in the bill applies to unlawful acts involving prescription blanks for "all" controlled substances. The reference to "listed in Schedules II, III, and IV" on page 2, lines 20-21 should be deleted from the bill.

On page 9, line 11 and on page 11, line 5 the bill refers to Senate Bill _____. The bill should be amended to refer to Senate Bill 520, which creates an exemption to the Public Records Law and establishes requirements for identifying information obtained under the implementation of the electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedules II, III, and IV.

VII. Related Issues:

None.

VIII. Summary of Amendments:

Barcode 224420 by Health Regulation:
Technical. Deletes the reference to "listed in Schedules II, III, and IV" in the catch line of the a criminal violation created in the bill that applies to unlawful acts involving prescription blanks for "all" controlled substances.

Barcode 065834 by Health Regulation:
Revises the requirements for pharmacists to dispense certain controlled substances so that they would not be required to obtain a government-issued identification from the patient or patient's agent. (WITH TITLE AMENMENT)

Barcode 532830 by Health Regulation:
Technical. Amends the contingent effective date of the bill to refer to Senate Bill 520, which creates an exemption to the Public Records Law and establishes requirements for identifying information obtained under the implementation of the electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedules II, III, and IV.

Barcode 470738 by Health Regulation:
Provides immunity to a practitioner or pharmacist who is authorized to access information in the prescription drug monitoring-system created in the bill for obtaining or failing to obtain access to such information.