The Florida Senate

PROFESSIONAL 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: Criminal Justice Committee

BILL:	CS/SB 518
INTRODUCER:	Criminal Justice Committee and Senator Saunders and others
SUBJECT:	Controlled Substances
DATE:	April 10, 2007 REVISED:

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

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; preclude a pharmacist from dispensing a controlled substance listed in Schedules II, III, and IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the order is valid, but authorize a pharmacist to dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent; exempt any pharmacist who dispenses by mail a controlled substance listed in Schedules II, III, and IV 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; 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 provides that, by June 30, 2008, the Agency for Health Care Administration (AHCA) must contract with a vendor for the design and operation of a secure, privacy-protected website that provides a health care practitioner, pharmacy, or pharmacist access to comprehensive patient

medication history, which is provided by the AHCA requiring the contracted vendor to subcontract with private-sector organizations that currently operate electronic prescribing networks that provide such medication history. The contracted vendor must comply with all applicable state and federal privacy laws and maintain the website within the United States, and create a system to verify with the Department of Health (department or DOH) 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 only the website to obtain medication history for a current patient for prescribing purposes with the written permission of the patient. A pharmacy or pharmacist with this authorization may use only the website to obtain medication history in dispensing a current prescription for Schedule II, III, or 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.

The bill disallows recovery in any Florida court against a health care practitioner, pharmacy, or pharmacist authorized to obtain information for accessing or failing to access such information. A health care practitioner, pharmacy, or pharmacist who violates requirements pertaining to the website constitutes grounds for disciplinary action. Any contractor entering into a contract 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, as a defense in tort, in any other application regarding the maintenance of confidentiality of information, or for any breach of contract.

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., and 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 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

[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).

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]

[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.

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 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 may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or his professional judgment, that the order is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent. Any pharmacist, who dispenses by mail a controlled substance listed in Schedule II,

[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.
[8] Section 893.13, F.S.

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 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., by June 30, 2008, to provide that the Agency for Health Care Administration (AHCA) must contract with a vendor for the design and operation of a secure, privacy-protected website that provides a health care practitioner,[9] pharmacy,[10] or pharmacist access to comprehensive patient medication history. In order to provide comprehensive patient medication history, the AHCA must require the contracted vendor to subcontract with private-sector organizations that currently operate electronic prescribing networks that provide such medication history.

The contracted vendor must comply with all applicable state and federal privacy laws[11] and maintain the website within the United States, and create a system to verify with the DOH 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 only the website 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 only the website 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

[9] The bill defines "health care practitioner" as, "with the exception of a pharmacist, a practitioner licensed under ch. 456, F.S., and authorized by law to prescribe drugs."
[10] The bill defines "pharmacy" as a pharmacy subject to licensure or regulation by the DOH under ch. 465, F.S., which dispenses or delivers a controlled substance listed in Schedule II, Schedule III, or Schedule IV to a patient in this state.
[11] The bill defines "federal privacy laws" as the provisions relating to the disclosure of patient privacy information under federal law, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. No. 104-91, and its implementing regulations, the Federal Privacy Act, 5 U.S.C. s. 552(a), 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.

pharmacist may not have access to pharmacy-identifying information within a patient's medication history.

Recovery is not allowed in any court in this state against a health care practitioner, pharmacy, or pharmacist authorized to obtain information under this section for accessing or failing to access such information. A violation of this section by a health care practitioner, pharmacy, or pharmacist constitutes grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(k), F.S. 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 section, as a defense in tort, in any other application regarding the maintenance of confidentiality of information, or for any breach of contract.

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 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.

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:

None.

VII. Related Issues:

None.

VIII. Summary of Amendments:

None.