HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: CS/HB 893 Controlled Substances
SPONSOR(S): Health Care Council; Harrell and others
TIED BILLS: **IDEN./SIM. BILLS:** CS/CS/SB 518

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Committee on Health Quality	9 Y, 0 N	Lowell	Lowell
2) Healthcare Council	15 Y, 0 N, As CS	Lowell	Gormley
3) Policy & Budget Council			
4)			
5)			

SUMMARY ANALYSIS

This bill requires the Agency for Health Care Administration ("AHCA") to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies. The bill also requires AHCA to develop a website that provides information on the process and advantages of electronic prescribing; the availability of electronic prescribing software, including no-cost and low-cost software; and state and federal electronic prescribing incentive programs. Additionally, AHCA must convene quarterly meetings of stakeholders to assess and accelerate the implementation of electronic prescribing.

The bill also requires the development and adoption of a counterfeit-resistant prescription blank by the Department of Health to be used voluntarily by physicians to prescribe Schedule II, Schedule III, or Schedule IV controlled substances. The bill prohibits the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks. The bill provides additional requirements for the dispensing of a controlled substance.

Further, the bill provides that if a person dies of an apparent overdose, a law enforcement agency must prepare a report identifying each prescribed controlled substance listed in Schedule II, III, or IV that is found on or near the deceased or among the deceased's possessions.

Last, the bill requires AHCA to annually report to the Governor and Legislature on the implementation of electronic prescribing by healthcare practitioners, facilities, and pharmacies. The report must include information on federal and private-sector electronic prescribing initiatives and readily available data from electronic prescribing networks on the number of healthcare practitioners using electronic prescribing and the number of prescriptions electronically transmitted.

The bill appropriates $100,000 in nonrecurring general revenue funds to fund the provisions of the bill for Fiscal Year 2007-2008.

The effective date of the bill is July 1, 2007.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. HOUSE PRINCIPLES ANALYSIS:

Provide Limited Government – The bill creates additional regulation regarding the dispensing of schedule II-IV prescription drugs; creates reporting requirements for law enforcement and medical examiners when a person dies of an apparent drug overdose; and creates a penalty for violations involving certain prescription blanks for controlled substances in schedules II-IV.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

Electronic Prescribing
Electronic prescribing, in its simplest form, is the electronic generation and transmission of a patient's prescription by a healthcare practitioner at the point of care. Electronic prescribing offers numerous benefits, including reduced errors and improved patient safety.

Numerous software companies offer stand-alone electronic prescribing products. While the cost of the product varies, some products are available at no cost to the healthcare practitioner.[1]

On a technical level, electronic prescribing involves a secure, electronic connection between the physician and the pharmacy. In addition, electronic prescribing software generally allows a healthcare practitioner to not only securely access the patient's health plan formulary, but also the patient's medication history, all at the point of care. Medication history is generally available in an 11 to 24 month rolling window, and it generally includes both written and electronically transmitted prescriptions.

Under current law, there is no state agency tasked with monitoring the adoption of electronic prescribing by healthcare practitioners, healthcare facilities, or pharmacies. Consequently, little statistical information regarding the use of electronic prescribing software is available.

Pharmaceutical Drug Dispensing
Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. Controlled substances are classified 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 893.05, 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. 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.

[1] *See e.g.,* http://www.nationalerx.com/ (viewed April 17, 2007) and http://www.iscribe.com/ (offering free web-based electronic prescribing software).

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice to dispense controlled substances upon a written or oral prescription under specified conditions:

- An oral prescription must be promptly reduced to writing by the pharmacist;
- The written prescription must be dated and signed by the prescribing practitioner on the date issued; and
- The face of the prescription or written record for the controlled substance must include:
    - 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;
    - 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 original container in which a controlled substance is dispensed must bear a label with the following information:

- The name and address of the pharmacy from which the controlled substance was dispensed;
- The date on which the prescription for the controlled substance was filled;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled;
- The name of the prescribing practitioner;
- The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed;
- The directions for the use of the controlled substance prescribed in the prescription; and
- A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

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 rule of the department, 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]

Prescription Drug Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003.[5] The National Institute on

[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] Overview of Findings from the 2003 National Survey on Drug Use and Health (viewed March 16, 2007) http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm

Drug Abuse seeks to reverse this trend by increasing awareness and promoting additional research on the topic.

Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction.

Doctor Shopping
Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for non-medical use. People obtain these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it.

A data search indicated that no studies in the United States have specifically addressed the profile of a doctor shopper. A search of international data produced a report and findings from a study in Australia, which indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different practitioners, often on the same day. Doctor shoppers generally take the medicine themselves. Compared to the number of doctors consulted, in a recent survey most doctor shoppers have their prescriptions dispensed at few pharmacies. [6]

Effect of Proposed Changes

Electronic Prescribing Clearinghouse
This bill requires the Agency for Health Care Administration ("AHCA") to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies.

In addition, AHCA must develop a website that provides information on:
- The process and advantages of electronic prescribing;
- The availability of electronic prescribing software, including no-cost and low-cost software; and
- State and federal electronic prescribing incentive programs.

The bill also requires AHCA to convene quarterly meetings of stakeholders to assess and accelerate the implementation of electronic prescribing. "Stakeholders" include organizations representing healthcare practitioners, facilities, and pharmacies; electronic prescribing networks; and regional health information organizations.

Last, AHCA is required to annually report to the Governor and Legislature on the implementation of electronic prescribing by healthcare practitioners, facilities and pharmacies. The report must include information on federal and private-sector electronic prescribing initiatives and readily available data from electronic prescribing networks on the number of healthcare practitioners using electronic prescribing and the number of prescriptions electronically transmitted.

Prescribing Practices for Schedule II, II, and IV Drugs
The bill amends section 893.04, F.S., by:
- Authorizing a pharmacist to record an oral prescription for controlled substances electronically;
- Providing that 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 it to writing or records the prescription electronically. Such prescriptions must contain the date of the oral authorization;

[6] www.hic.gov.au

- Limiting a pharmacist from dispensing more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription;
- Limiting the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply;
- Prohibiting a pharmacist 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 may dispense a 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;
- Providing that 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; and
- Prohibiting a pharmacist from knowingly filling a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

Counterfeit-Resistant Blanks
HB 895 also specifies that the department will develop counterfeit-resistant blanks for controlled substances that may be used by practitioners to prescribe controlled substances listed in Schedule II, Schedule III, or Schedule IV. DOH 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 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 adopted by rule by the Department of Health.

Law Enforcement – Drug Overdose Requirements
If a person dies of an apparent drug overdose, the bill requires that a law enforcement agency shall prepare a report, which will be provided to the medical examiner, identifying each prescribed controlled substance that is found on or near the deceased or among the deceased's possession, and requires the law enforcement agency to identify the person who prescribed the drugs. The bill also requires that a medical examiner include in his or her report pursuant to s. 406.11, F.S., information identifying any Schedule II, Schedule III, or Schedule IV drug which is found in, on, or near the deceased or the deceased possessions.

C. SECTION DIRECTORY:

Section 1. Creates s. 831.311, F.S., to provide violations involving certain prescription blanks.

Section 2. Amends s. 893.04, F.S., relating to pharmacist prescribing practices.

Section 3. Creates s. 408.0611, F.S., relating to an electronic prescribing clearinghouse.

Section 4. Creates s. 893.065, F.S., relating to counterfeit-resistant prescription blanks.

Section 5. Provides that the penalties created in s. 831.311, F.S., are effective only upon adoption of certain rules.

Section 6. Creates an unnumbered section of law relating to drug overdose.

Section 7. Provides an effective date of July 1, 2007.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

The bill appropriates $100,000 in non-recurring general revenue to fund the provisions of the bill for Fiscal Year 2007-08.

The Criminal Justice Impact Conference has not considered the prison bed impact of this bill on the Department of Corrections. The bill creates a third degree felony that is not ranked in the offense severity ranking chart. Traditionally, the conference has found that an unranked third degree felony will have an insignificant prison bed impact on the department.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

The agency has sufficient rulemaking authority to implement the provisions of this bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

D. STATEMENT OF THE SPONSOR

"The strike-all amendment removes the creation of a controlled substance database within the Department of Health in favor of requiring the Agency for Health Care Administration to create a website for health care practitioners and pharmacies to access, with the patient's permission, private-sector patient medication history for all legend drugs—not just controlled substances—further bolstering our efforts in promoting e-prescribing and electronic medical records."

IV. AMENDMENTS/COUNCIL SUBSTITUTE CHANGES

On April 17, 2007, the Healthcare Council adopted two amendments to the bill. The first amendment strikes the substance of the amendment previously adopted in the Health Quality Committee in favor of requiring AHCA to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies. In addition, the amendment requires AHCA to:

- Develop a website that provides information on the process and advantages of electronic prescribing; the availability of electronic prescribing software, including no-cost and low-cost software; and state and federal electronic prescribing incentive programs.

- Convene quarterly meetings of stakeholders to assess and accelerate the implementation of electronic prescribing. "Stakeholders" include: organizations representing healthcare practitioners, facilities, and pharmacies; electronic prescribing networks; and regional health information organizations.

- Annually report to the Governor and Legislature on the implementation of electronic prescribing by healthcare practitioners, facilities and pharmacies. The report must include information on federal and private-sector electronic prescribing initiatives and readily available data from electronic prescribing networks on the number of healthcare practitioners using electronic prescribing and the number of prescriptions electronically transmitted.

The second amendment appropriates $100,000 in nonrecurring general revenue funds to fund the provisions of the first amendment.

The bill was reported favorably with a Council Substitute.

On March 20, 2007, the Health Quality Committee adopted one amendment to the bill. The amendment removes provisions relating to the electronic prescription monitoring database. The amendment requires the Agency for Health Care Administration to contract for the creation of a secure, privacy-protected website that will provide private-sector medication history to prescribing practitioners, pharmacists, and pharmacies. The amendment provides immunity for accessing or failing to access the system. The amendment makes the contractor expressly liable for the improper release of patient information.

The bill was reported favorably with a Recommended Council Substitute. The analysis is drafted to the Council Substitute.