HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 893 Controlled Substances
SPONSOR(S): Harrell and others
TIED BILLS: HB 895 **IDEN./SIM. BILLS:**

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

SUMMARY ANALYSIS

House Bill 893 requires the Department of Health to contract for the design, establishment, and maintenance of an electronic prescription monitoring database by June 30, 2008. The database will include Schedule II, III, and IV drugs prescribed by health care practitioners in Florida. The bill provides for exemptions from reporting. Unless reenacted by the Legislature, this portion of the bill will sunset October 2, 2010. HB 893 is linked to HB 895 to provide a public records exemption for the information in the monitoring database. HB 895 provides a list of entities that have access to the information in the database.

The bill also requires the development and adoption of a counterfeit-resistant prescription blank 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.

The Department of Health estimates the cost to implement the bill will be $4,818,803 in the first year, $3,251,597 in the second year, and $3,726,645 in the third year.

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. The bill requires the Department of Health to develop an electronic prescription monitoring system.

Safeguard Individual Liberty – The bill may limit an individual's freedom by requiring the monitoring of private medical information.

B. EFFECT OF PROPOSED CHANGES:

Present Situation

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.

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.[1] 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.[2] 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.[3]

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.[4] The National Institute on 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.

[1] Section 893.04(1)(f), F.S.
[2] Section 893.04(1)(g), F.S.
[3] 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.
[4] 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

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. [5]

Prescription Monitoring Systems
In an effort to control the diversion of controlled substances, twenty-four states have established prescription monitoring systems.[6] 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.

Potential Advantages of an Electronic Prescription Data Collection System
Potential advantages of an electronic prescription data collection system include the following:

- Identifies "doctor shoppers" by tracking all their prescribing physicians and purchases from pharmacies. Doctor shopping is when a person continually switches physicians so that they can obtain enough of a drug to feed their addiction;
- Provides complete and reliable information on prescribing and dispensing activities so that investigators can identify, rank, and set priorities for cases;
- Maximizes investigators' effectiveness by providing prescription data in a convenient, comprehensive, and timely method;
- Reduces intrusion into professional practices because investigators no longer need to make office visits to gather information on practitioner prescribing patterns; and
- Reduces the need for investigators to make pharmacy visits in order to gather data on pharmacy or pharmacists' dispensing patterns.

Potential Disadvantages of an Electronic Prescription Data Collection System
Some opponents of prescription monitoring systems dislike the concept of mandatory disclosure of protected health information and point to federal and state privacy laws as barriers to these monitoring systems. There is a possibility that the tracking system could violate the Florida Constitution's Right to Privacy. In 1980, the citizens of Florida approved an amendment to Florida's Constitution, which grants Florida citizens an explicit right of privacy. Contained in Article I, Section 23, the Constitution provides as follows:

> *Right of privacy--Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.*

This right to privacy protects Florida's citizens from the government's uninvited observation of or interference in those areas that fall within the range of the zone of privacy afforded under this provision.

Unlike the implicit privacy right of the Federal Constitution, Florida's privacy provision is, in and of itself, a fundamental one that, once implicated, demands evaluation under a compelling state interest standard. The federal right of privacy, is more limited than the state provision, and extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and

[5] www.hic.gov.au
[6] Status of State Prescription Drug Monitoring Programs (viewed March 16, 2007) http://www.natlalliance.org/pdfs/Status%20of%20States%20-%20Web%20Version9.pdf

educating of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that Article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the Federal Constitution.[7]

Effect of Proposed Changes

Electronic Monitoring of Schedule II, III, and IV Prescriptions
HB 893 creates s. 893.055, F.S., creating an electronic monitoring system for the prescription of controlled substances listed in Schedules II, III, and IV, pursuant to chapter 893, F.S. The bill specifies that the Department of Health ("department") shall contract for the design, establishment and maintenance of the electronic monitoring system. The system must be consistent with the standards of the American Society for Automation in Pharmacy (ASAP).

The bill requires that a controlled substance listed in Schedule II, Schedule III, or Schedule IV that is dispensed in this state must be reported to the department no more than thirty-five days after each time the controlled substance is dispensed. The reporting does not apply if the controlled substance is:

- Directly administered by a health care practitioner to the patient;
- Dispensed directly to the patient by a health care practitioner for a treatment supply of no more than 72 hours;
- Dispensed by a practitioner or pharmacist to an inpatient of a facility with an institutional pharmacy;
- Ordered from an institutional pharmacy permitted under section 465.019, F.S.;
- Dispensed 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; or
- Prescribed for a patient less than 16 years of age.

The bill allows the department to develop the data required to be reported by rule. In addition, the bill requires a dispenser to submit the information to the department in an electronic or other format determined by the department. The act also specifies that the cost to the dispenser associated with submitting the information is limited to actual reporting costs.

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. Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV is liable for a first degree misdemeanor punishable by jail up to 1 year and a fine of up to $1,000. It is a third degree felony for the knowing and willful violation of this section.

The bill requires the contract vendor maintaining and administering the database to maintain confidentiality of the data. The bill authorizes release of information to certain persons. Authorized persons may maintain the prescription information for up to a maximum of 2 years. If the information is pertinent to an ongoing investigation or prosecution it may be kept longer than 2 years. If there is an unauthorized release of information the contractor is liable.

This bill also includes a "sunset" provision for the tracking system created in s. 893.055, F.S., of October 2, 2010, unless reviewed and saved from repeal through reenactment by the Legislature.

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;

[7] *See In re T.W.*, 551 So.2d 1186 (Fla. 1989).

- 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;
- 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. 893.055, F.S., relating to an electronic monitoring system for prescription of controlled substances listed in Schedules II-IV.

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, 2006.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   The Department of Health will incur costs to design and establish an electronic prescription-monitoring system; and to develop counterfeit-resistant prescription banks for controlled substances listed in Schedules II, III, and IV.

	1st Year (07-08)	2nd Year (08-09) (Annualized /Recurr.)	3rd Year (09-10) (Annualized/ Recurr.)
Salaries			
1 Operations & Mgmt Consultant II PG 423	$ 54,858	$ 54,858	$ 54,858
Expense			
Expense package professional level- 1 FTEs (non-recurring)	$ 3,426		
Recurring expense package with limited travel- 1 FTE	$ 12,057	$ 12,057	$ 12,057
Marketing and Public Education (recurring)	$ 25,000	$ 25,000	$ 25,000
Printing (recurring)	$ 5,000	$ 5,000	$ 5,000
Contracted Services - Development			
Contract to develop the electronic system (non-recurring)	$ 2,090,400		
Contractor infrastructure costs	$ 250,000		
Contracted Services - Administration			
Data Contractor	$ 325,000	$ 505,000	$ 510,250
Database Administrator	$ 125,000	$ 137,500	$ 151,250
System/Network Administrator 24/7 support	$ 600,000	$ 660,000	$ 726,000
Security Administration Contractor	$ 250,000	$ 275,000	$ 302,500
Security Admin., Software, Licensing	$ 600,000	$ 900,000	$ 1,200,000
Oracle License (non-recurring)	$ 319,968		
Oracle Maintenance (recurring)	$ 70,393	$ 70,393	$ 80,952
Network Equipment (recurring)	$ 25,000	$ 25,000	$ 25,000
Secure Data Circuit (recurring)	$ 60,000	$ 60,000	$ 60,000
Software Maintenance & Defect Remediation		$ 459,888	$ 505,877

Back up Tapes		$ 60,000	$ 66,000
Computer Hardware	$ 1,000	$ 1,500	$ 1,500
Operating Capital Outlay			
OCO standard package 1 FTE (non-recurring)	$ 1,300		
Human Resources Services			
Human Resource Package 1 FTE	$ 401	$ 401	$ 401
TOTAL ESTIMATED EXPENSES	$ 4,818,803	$ 3,251,597	$ 3,726,645

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Health care practitioners and pharmacies will incur a cost to submit the controlled substances prescription data required under the bill. Notwithstanding the prohibition of "material or extraordinary" costs in submitting data, the long-term cost in terms of workflow modifications, diversion of staff time, and acquisition of equipment to report may be substantial over the course of a calendar year.

D. FISCAL COMMENTS:

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.

The President's budget request for the grant program in fiscal year 2007 is $9.9 million. The grant application deadline for States was January 11, 2007 (for federal fiscal year 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.

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:

Right to Privacy
There is a possibility that the tracking system could violate the Florida Constitution's Right to Privacy. In 1980, the citizens of Florida approved an amendment to Florida's Constitution, which grants Florida citizens an explicit right of privacy. Contained in Article I, Section 23, the Constitution provides as follows:

> *Right of privacy--Every natural person has the right to be let alone and free from governmental intrusion into the person's private life except as otherwise provided herein. This section shall not be construed to limit the public's right of access to public records and meetings as provided by law.*

This right to privacy protects Florida's citizens from the government's uninvited observation of or interference in those areas that fall within the range of the zone of privacy afforded under this provision.

B. RULE-MAKING AUTHORITY:

The department is provided 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 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.