HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 913 CS Controlled Substances
SPONSOR(S): Harrell and others
TIED BILLS: HB 943 **IDEN./SIM. BILLS:** SB 178

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Care Regulation Committee	6 Y, 2 N, w/CS	Bell	Mitchell
2) Criminal Justice Committee			
3) Health Care Appropriations Committee			
4) Health & Families Council			
5)			

SUMMARY ANALYSIS

HB 913 CS increases the regulation of prescription of Schedule II, III, and IV drugs.

The bill requires the Department of Health to contract for the design, establishment, and maintenance of an electronic prescription monitoring database by June 30, 2007. The database will include the prescription of 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, 2009. HB 943 is linked to HB 913 CS to provide a public records exemption for the information in the monitoring database. HB 943 CS 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 total cost to implement HB 913 CS will be $4,402,347 in the first year, $2,564,670 in the second year, and $2,994,213 in the third year.

The effective date of the bill is July 1, 2005.

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. The Department of Health estimates the total expense for the system will be $402,402,347 in the first year, $2,564,670 in the second year and $2,994,213 in the third year.

Safeguard Individual Liberty – The bill may limit an individual's freedom by having private medical information monitored.

B. EFFECT OF PROPOSED CHANGES:

Florida Comprehensive Drug Abuse Prevention and Control Act

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.

Electronic Monitoring of Schedule II, III, and IV Prescriptions

HB 913 CS creates s. 893.055, F.S., providing for 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 (DOH) 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 DOH as soon as possible, but not more than thirty-five days after each time the controlled substance is dispensed. The reporting is limited and does not apply to controlled substances that are any one of the following:

- 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.

- Prescribed for a patient less than 16 years of age.

The bill allows DOH to develop the data required to be reported via the rule-making process. In addition, the bill requires a dispenser to submit the information to the department in an electronic format. The act also specifies that the cost to the dispenser associated with submitting the information is limited to actual reporting costs. The bill provides reporting costs to include, but are not limited to:

- Regular postage;
- Compact discs;
- Zip-drive storage;
- Regular electronic mail;
- Magnetic tapes;
- Diskettes; and
- Facsimile charges.

DOH 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, 2009, 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., as follows:

- The bill authorizes a pharmacist to record an oral prescription for controlled substances electronically.

- The bill provides 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. Currently, oral prescriptions must be promptly reduced to writing by the pharmacist.

- Under the provisions of the bill, a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based upon an oral prescription. Currently, there is no specific limitation on the length of supply of a Schedule III drug based on an oral prescription.

- The bill limits the dispensing of Schedule II drugs in an emergency situation based upon an oral prescription to a 72-hour supply. Currently, a Schedule II drug can only be dispensed upon a written prescription except in the case of an emergency in which a Schedule II drug can be dispensed based on an oral prescription.

- Under the bill, 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 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.

- The bill provides 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. A pharmacist is permitted, upon verification by the prescriber, to document any information required on the prescription.

- The bill provides that 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.

Counterfeit-Resistant Blanks

HB 913 CS also specifies that the Department of Health (DOH) 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.

CURRENT 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.

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 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 DOH, 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]

It is a first degree misdemeanor to distribute or dispense a controlled substance in violation of chapter 893, F.S., or to refuse or fail to make, keep, or furnish any record required under the chapter.[4]

Drug Overdose

Section 406.14, F.S., currently provides that any evidence material to the determination of the cause of death in possession of the law enforcement officers assigned to the investigation of the death must be made available to the medical examiner. The section provides that it is the duty of the law enforcement officer assigned to and investigating the death to immediately establish and maintain liaison with the medical examiner during the investigation of the cause of death. Section 406.11, F.S., provides that a district medical examiner must determine the cause of death of a human being in certain circumstances. The section does not require any particular information to be included in any report that the medical examiner creates.

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. 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

[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] S. 893.03(7)(b), F.S.

prescription drugs – opioid substances, central nervous system (CNS) depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction.

BACKGROUND

Prescription Monitoring Systems

In an effort to control the diversion of controlled substances, over fifteen states have established prescription monitoring systems. 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.
- 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 privacy provision, which contains a "penumbra" right of privacy, is more limited

than the state provision. The federal privacy provision is directly created in the 1st, 3rd, 4th, 5th, and 9th amendments to the U.S. Constitution and extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and 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.[5]

Doctor Shoppers

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for non-medical use. People are obtaining 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]

Frequent reasons used by doctor shoppers to obtain medicines are:

- Work hours interfere with sleep.
- Lost prescription.
- Relatives passed away.
- Migraine, cramp, toothache, or diarrhea.
- Just arrived in area.
- Handbag stolen.

Data shows that the age and gender of most doctor shoppers are as follows:

- 20% are aged between 15 and 29 years.
- 57% are aged between 30 and 49 years.
- 15% are aged between 50 and 64 years.
- 8% are 65 years and older.
- 58% are female.

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.

[5] See, In re T.W., 551 So.2d 1186 (Fla. 1989).
[6] www.hic.gov.au

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:

Department of Health -Estimated Expenditures	1st Year (06-07)	2nd Year (07-08) (Annualized /Recurr.)	3rd Year (08-09) (Annualized/ Recurr.)
Grants and Donation Trust			
Expense			
Contract to develop the electronic system (non-recurring)	$1,927,378		
Training Consultant (recurring)	$40,000		
Project Manager (non-recurring)	$200,000		
Education/Training (recurring)	$28,974		
Subtotal (Grants and Donations)	$2,196,352		
General Revenue			
Salaries			
2 Senior Data Base Analyst PG 025 (Div of IT)		$90,086	$120,115
1 Regulatory Program Administrator PG 422(Board of Pharmacy)	$37,755	$50,340	$50,340
1 Senior RPh PG 093 (Board of Pharmacy)	$53,818	$71,758	$71,758
Other Personal Services			
Training Consultant (recurring)		$40,000	$40,000
Estimated Expenditures			
Expense package professional level- 4 FTEs (non-recurring)	$6,686	$6,686	
Web based training (non-recurring)	$35,000		
Printing and mailing of supplemental training manual and materials (non-recurring)	$15,000		
Oracle License (recurring)	$319,151	$71,300	$71,300
Recurring expense package with limited travel- 2 FTEs (Div of IT)		$20,780	$20,780
Recurring expense package with	$31,514	$31,514	$31,514

maximum travel- 2 FTE (Pharm)			
Data collection by contractor (recurring)	$303,000	$505,000	$510,250
Systems/Network Administrators/Help Desk (recurring)	$103,125	$137,500	$151,250
Systems/Network Administrators/Help Desk (recurring)	$596,000	$860,000	$926,000
Security Administration, software, and Licensing (recurring)	$315,000	$525,000	$850,000
Marketing and Public Education/ Training (recurring)		$28,974	$28,974
Secure Data Circuit (recurring)	$60,000	$60,000	$60,000
Postage/Printing/Advertising (recurring)	$5,000	$5,000	$5,000
Network Equipment (recurring)	$25,000	$25,000	$25,000
Hardware Maintenance (recurring)	$30,360	$30,360	$30,360
Operating Capital Outlay			
Computer/server/printer/fax (non-recurring)	$265,000		
OCO standard package for 2FTEs 1FTE in year 1 and 2 FTE in year 2	$3,800	$3,800	
Human Resources Services	$786	$1,572	$1,572
TOTAL ESTIMATED EXPENSES	**$4,402,347**	**$2,564,670**	**$2,994,213**

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

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

Practitioners opting to use the proposed counterfeit-proof prescription blank will likely pay a higher price than for customary prescription blanks.

D. FISCAL COMMENTS:

Department of Health Fiscal Comments

Section 3 of the bill provides appropriations from the Grants and Donation Trust Fund. This appears inappropriate unless a specific grant or gift were provided to fund this project through this trust fund. Absent such an infusion of funds, the department assumed funding would come from General Revenue or other sources since Section 3 prohibits the use of the Medical Quality Assurance Trust Fund (MQATF). Funding in year 1 would be used primarily for the development stage, while general revenue funding would be needed for the implementation stage.

The department proposes to contract with a private vendor to develop the electronic monitoring system. The development costs will not be known until such time as vendors respond to an Invitation to Bid (ITB).

The department also proposes to start marketing and public relations as well as training of users and customers of the system immediately upon passage of the bill. The estimated costs are based on hiring a training consultant and providing on-site marketing and training in eleven regions throughout the state. The training consultant will also work with the vendor in developing the web-based training module(s).

A Regulatory Program Administrator for the Board of Pharmacy will oversee the operation of the electronic monitoring system and act as liaison with all health professional customers, law enforcement agencies, IT staff, Medicaid and AHCA. A 25% lapse was computed for year 1.

Although Section 5 of the bill provides three additional full-time equivalent positions, this program will require a pharmacist to oversee the day to day operations to operate efficiently. As in the Kentucky model a pharmacist is necessary to review duplicate reports for accuracy prior to sending to the requestor.

Counterfeit-Prescription Blanks

HB 913 CS makes it a third degree felony to sell, manufacture, alter, deliver or possess a counterfeit resistant prescription blank for controlled substances under certain circumstances. The offense is not ranked in the offense severity ranking chart of the Criminal Punishment Code. The criminal Justice Impact Conference has not met to consider the prison bed impact of this bill on the Department of Corrections. However, the conference generally determines that a bill which creates an unranked third degree felony will have an insignificant prison bed impact.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

   This bill does not require counties or municipalities to spend funds or take action requiring the expenditure of funds. This bill does not reduce the percentage of state tax shared with counties or municipalities. This bill does not reduce the authority that municipalities have to raise revenue.

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 of Health has sufficient rule-making authority to implement the provisions in the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Department of Health Comments

1. According to the Department of Health section 3 of this bill, in conjunction with the tied public records bill HB 943 CS, contains many of the recommended features of a Model Act for Prescription Monitoring Programs as developed by the National Association of State Controlled Substance Authorities and the Alliance of States with Prescription Monitoring Programs in 2002. For example, the Model Act recommends that states collect information about each prescription indicating whether the prescription was a new or refill prescription and the type of payment for the prescription (i.e. whether paid for by cash, Medicare, Medicaid, or other third party payer). These recommendations are based on the experiences of states that have been operating prescription-monitoring programs for several years. This type of information is valuable to investigator and regulatory boards that evaluate prescription records in making preliminary determinations whether or not the prescription drugs are being misused or abused.
2. This bill contains a number of exemptions to reporting of prescriptions for controlled substances. Most states exempt drugs that are administered directly (applied on or into the patient's body) as well as drugs dispensed to patients in residential facilities. Even when diversion occurs in these settings, it is not usually detected by a prescription-monitoring program. However, diversion to patients who receive care from a hospital (e.g. emergency room), assisted living facility, or hospice may be detectable with a prescription monitoring program. Consideration should be given to eliminating these exemptions.
3. The system will not capture any prescription information from prescriptions dispensed over the Internet as they are not under the state's jurisdiction.
4. The system will not capture any prescription information from prescriptions dispensed from veterans' facilities, federal health programs, other countries or other states as they are not under the state's jurisdiction.
5. The greatest challenge in developing the system will be patient identifiers so the data can be used effectively when names are misspelled, incomplete information is submitted, date of birth is incorrect, etc. Unlike Medicaid where each patient has a unique identifier, the general population does not.
6. Cash transactions will be difficult to capture as not all pharmacies currently track them electronically.
7. While this bill provides that knowingly failing to report the required data is a criminal misdemeanor, there is a need for the practice acts to be amended to include it as a disciplinary violation.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE & COMBINED BILL CHANGES

On April 5, 2006 the Health Care Regulation Committee adopted one amendment and reported the bill favorably.

The amendment:

- Creates an electronic monitoring systems (database) for prescription of controlled substances listed in Schedule II, III and IV;
- Requires the Department of Health to contract for the design, establishment, and maintenance of the electronic database consistent with the standards of the American Society for Automation in Pharmacy by June 30, 2007;
- Requires that a pharmacist who prescribes a controlled substance listed in Schedule II, III, and IV report to the electronic database as soon as possible, but not to exceed 35 days;

- Provides a list of facilities and situations that are exempt from Schedule II, III, and IV prescription drug reporting;
- Requires the Department of Health to develop the data to be reported to the electronic database by rule;
- Provides that the cost of reporting to the electronic database is limited to actual reporting cost;
- Provides that the data in the database may be transmitted to certain persons and agencies; and
- Provides that the electronic database enabling legislation stands repealed October 2, 2009, unless reviewed and saved from repeal through reenactment by the Legislature.

The analysis is drafted to the committee substitute.