SENATE STAFF ANALYSIS AND ECONOMIC IMPACT STATEMENT

(This document is based on the provisions contained in the legislation as of the latest date listed below.)

Prepared By: Criminal Justice Committee

BILL:	CS/SB 178
INTRODUCER:	Criminal Justice Committee and Senator Saunders
SUBJECT:	Controlled Substances
DATE:	February 15, 2006 REVISED:

	ANALYST	STAFF DIRECTOR	REFERENCE	ACTION
1.	Munroe	Wilson	HE	**Fav/2 amendments**
2.	Erickson	Cannon	CJ	**Fav/CS**
3.			HA	
4.			JA	
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; specify procedures for a pharmacist to verify the validity of prescriptions for controlled substances listed in Schedule II, Schedule III, or Schedule IV and the identity of the individual obtaining any controlled substance; authorize a pharmacist to record a prescription electronically if permitted by federal law for certain controlled substances; and impose additional requirements on prescriptions for controlled substances in Schedule II, Schedule III, or Schedule IV to prevent diversion.

The bill requires the Department of Health (department or DOH), by June 30, 2007, to design and establish an electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedule II, Schedule III, and Schedule IV by health care practitioners within Florida and the dispensing of such controlled substances to an individual at a specific address within Florida by a pharmacy permitted or registered by the Board of Pharmacy. Data regarding controlled substances subject to the requirements of the monitoring system must be reported to DOH as soon as possible, but not more than 35 days after the date the controlled substance is dispensed, each time that such controlled substance is dispensed. The bill provides exemptions from the data reporting requirements for controlled substances that are administered,

dispensed, or ordered in specified settings or for specified categories of patients. The department must determine by rule the data required to be reported under the prescription monitoring system. Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV commits a first-degree misdemeanor.

The bill requires 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 $2,196,352, from the Grants and Donations Trust Fund to DOH and authorizes three positions to implement the electronic monitoring system and the counterfeit-resistant prescription blanks. The Medical Quality Assurance Trust Fund may not be used to implement or fund the system.

The bill amends s. 893.04, F.S.

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

II. Present Situation:

Prescription Monitoring Systems

In an effort to control the diversion of controlled substances, over 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. 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.

The use of a serialized form, be it single, duplicate, or triplicate, may provide the following advantages:

- Eliminates almost all forgeries and counterfeit prescriptions.
- Prevents unlicensed persons or practitioners who have been disciplined from writing prescriptions for heavily abused drugs, without affecting prescriptions for non-abused drugs.
- Significantly reduces emergency room visits involving drugs requiring the form, as reported by the Drug Abuse Warning Network program of the United States Drug Enforcement Administration.
- Increases pharmacists' ability to determine whether the prescriptions are valid and written for the patient submitting the form.
- Provides strong evidence in diversion cases because each serialized form is assigned to a specific, individual practitioner.
- Provides an evidence trail beginning with the practitioner's signature on the form for the prescription blanks and, later in the process, additional information is added including the patient's name, the drug, the dispensing pharmacy and the dispensing pharmacist, thereby providing an audit trail for the prescribing and dispensing of controlled substances for state regulatory and law enforcement officials.
- Provides physicians with the convenience of a permanent record for their patient files of each prescription written.

Advantages of an electronic prescription data collection system include the following:

- Identifies "doctor shoppers" by tracking all their prescribing physicians and purchases from pharmacies.
- 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.

Controlled Substances

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act. The chapter classifies controlled substances into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for

abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Section 893.02, F.S., defines practitioner to mean a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number. The prescribing of controlled substances is a privilege that is separate from the regulation of the practice of the prescribing practitioner.

Section 893.05, F.S., allows a practitioner, in good faith and in the course of his or her professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may direct the administration of a controlled substance by a licensed nurse or an intern practitioner under his or her direction and supervision.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only, to dispense controlled substances upon a written or oral prescription under specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and the initials of the pharmacist filling the prescription and the date filled. Section 893.04(1)(d), F.S., requires the proprietor of the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The section requires the original container in which a controlled substance is dispensed to bear a label with specified information.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by regulation of 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]

[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.

Health Insurance Portability and Accountability Act of 1996
On December 20, 2000, President Clinton issued landmark rules to protect the privacy of peoples' medical records. The 1996 Health Insurance Portability and Accountability Act (HIPAA)[4] required the Administration to issue regulations protecting the privacy of health information. The United States Department of Health and Human Services issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which were originally scheduled to go into effect on February 26, 2001. The effective date for the regulations was delayed and the regulations 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.[5] Exceptions for state law are provided for public health (authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention) and state regulatory reporting (the ability of a state to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification).[6]

Senate Bill 176
Senate Bill 176 makes confidential and exempt personal identifying information of a patient, a practitioner as defined in s. 893.02, F.S., and a pharmacist as defined in s. 465.003, F.S., that is contained in any record held by 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[7], 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 DOH pursuant to s. 893.065, F.S.[8] A third degree felony is punishable by imprisonment up to 5 years, and a fine up to $5,000 may also be imposed.

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[4] 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.
[5] Sections 60.201, 160.203, 160.204, and 160.205, C.F.R.
[6] 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.
[7] Section 893.13, F.S.
[8] The Department of Health states that the department "and its regulatory boards have the authority to impose discipline on any licensed health care professional who is convicted or found guilty of a crime which relates to the practice of, or the ability to practice, a licensee's profession (s. 456.072(1)(c), F.S.). This section designates a new felony for which convicted licensees may be disciplined under this existing provision."

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

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

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. Such 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.[9] 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. The term "pharmacy" is defined. DOH is required, by June 30, 2007, to design and establish an electronic system to monitor the prescribing and dispensing of controlled substances listed in Schedules II, III, and IV by health care practitioners within Florida and the dispensing of such controlled substances to an individual at a specific address within Florida by a pharmacy permitted or registered by the Board of Pharmacy. The design of the electronic prescription monitoring system must be consistent with American Society for Automation in Pharmacy standards. Data regarding controlled substances subject to the requirements of the monitoring system must be reported to DOH as soon as possible but not

[9] The Department of Health states that currently "[p]hysicians may telephone in quantities greater than a 30 day supply for Schedule III -V controlled substances."

more than 35 days after the date the controlled substance is dispensed, each time such controlled substance is dispensed. A pharmacy or dispensing practitioner may meet the reporting requirements for the data required to be reported under the prescription monitoring system by providing to DOH in written or any electronic or magnetic format, including but not limited to, electronic submission via the Internet or magnetic disc or tape of each controlled substance listed in Schedules II, III or IV which it dispenses. The department must determine by rule the data required to be reported under the prescription monitoring system, and such data may include any data required under s. 893.04, F.S.

Exceptions to the reporting requirements under the electronic monitoring system are created for controlled substances that are: (1) administered by a health care practitioner directly to a patient; (2) dispensed by a health care practitioner authorized to prescribe controlled substances directly to a patient and limited to an amount adequate to treat the patient for a period of no more than 72 hours; (3) dispensed by a health care practitioner or pharmacist to an in-patient of a facility that holds an institutional pharmacy permit; (4) ordered from an institutional pharmacy permitted under s. 465.019, F.S., in accordance with the institutional policy for such controlled substances or drugs; (5) dispensed by a pharmacist or administered by a health care practitioner to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled which is licensed in Florida; or (6) prescribed by a health care practitioner for a patient less than 16 years of age.

A practitioner or pharmacist who dispenses a controlled substance must transmit the information required under the prescription monitoring system in an electronic or other format approved by DOH rule. The bill provides that the cost to the dispenser in submitting the required information may not be material or extraordinary as specified in the bill. The information submitted to DOH under the prescription monitoring system may be transmitted to any person or agency authorized to receive it pursuant to section 1 of SB 176, or similar legislation, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All required transmissions must comply with relevant federal and state privacy and security laws. However, any authorized agency receiving such information may maintain it for a period longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this section commits a first-degree misdemeanor, punishable by jail up to 1 year, and a fine up to $1,000 may be imposed.

The department and the regulatory boards for the health care practitioners must adopt rules to implement and administer this section. The department must cover all costs for the prescription monitoring system, and an amount necessary to cover such costs is to be appropriated annually, subject to the availability of funds, out of the Grants and Donations Trust Fund. The Medical Quality Assurance Trust Fund may not be used to implement or otherwise fund the electronic prescription-monitoring program.

Section 4. Creates s. 893.065, F.S., to require 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 prescription blanks may not be transferred.

Section 5. Appropriates $2,196,352 from the Grants and Donations Trust Fund to DOH, and three full-time equivalent positions are authorized for fiscal year 2006-07 to implement the electronic monitoring system and the counterfeit-resistant prescription blanks.

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 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, 2006, if SB 176, 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 Art. VII, s. 18 of the Florida Constitution.

B. Public Records/Open Meetings Issues:

An exemption to the Public Records Law for the identity of patients, practitioners, and pharmacists in the information and reports held by DOH is being addressed in separate legislation (SB 176).

C. Trust Funds Restrictions:

The provisions of this bill have no impact on the trust fund restrictions under the requirements of Article III, Subsection 19(f) of the Florida Constitution.

D. Other Constitutional Issues:

The bill requires DOH to determine by rule the data required to be reported under the prescription monitoring system, and such data may include any data required under s. 893.04, F.S., and must include the category of professional licensure of the prescribing practitioner. The bill imposes criminal penalties for any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this bill. Such persons are liable for a first-degree misdemeanor. To the extent the bill does not state what data must be reported and delegates that function to DOH, it, arguably, may raise an issue as to whether the legislative delegation to the department constitutes a proper delegation. The delegation also, arguably, may raise an issue as to whether such delegation allows an administrative

agency to define the elements of a crime. Article I, section 18 of the Florida Constitution provides that:

> No administrative agency, except the Department of Military Affairs in an appropriately convened court-martial action as provided by law, shall impose a sentence of imprisonment, nor shall it impose any other penalty except as provided by law.

In addressing the question as to "how much of a role may administrative agencies take in defining the elements of a crime," the Florida Supreme Court has declared that Article I, Section 18 of the Florida Constitution, though speaking only to quasi-adjudicatory powers of some administrative agencies, nevertheless embodies an overall constitutional policy that administrative agencies may not create a criminal statute or its equivalent and prescribe the penalty. See *B.H. v. State*, 645 So.2d 987, 46 A.L.R. 5th 877 (1994), certiorari denied 115 S.Ct. 2559, 515 U.S. 1132, 132 L.Ed.2d 812.

V. Economic Impact and Fiscal Note:

A. Tax/Fee Issues:

None.

B. Private Sector Impact:

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

Pharmacies and other dispensers may incur costs to comply with the reporting requirements under the prescription monitoring system. The Department of Health states that "[a]lthough the Department may not require reporting by material or extraordinary costs, any electronic reporting and monitoring may be more costly for a small business." The department also states that "[m]ore extensive record keeping will be easier for the large chain pharmacies than for the mom-and-pop size pharmacies."

C. Government Sector Impact:

The Department of Health states:

> Although the bill provides an appropriation from the Grants and Donations Trust Fund to implement the project, annual appropriations are contingent upon the availability of said funds, potentially impacting the Department's budget if funds for ongoing maintenance of the program are not available.

The Department of Health provides the analysis of the fiscal impact of the bill on the department:

	1st Year (06-07)	2nd Year (Annualized/ Recurr.)	3rd Year (Annualized/ Recurr.)
ESTIMATED EXPENDITURES GRANTS AND DONATIONS TRUST			
Expense			
Contract to develop the 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

Expense

	1st Year (06-07)	2nd Year (Annualized/ Recurr.)	3rd Year (Annualized/ Recurr.)
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 maximum travel- 2 FTE (Pharm)	$31,514	$31,514	$31,514
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
Subtotal (General Revenue)	**$2,205,995**	**$2,564,670**	**$2,994,213**
TOTAL ESTIMATED EXPENSES	**$4,402,347**	**$2,564,670**	**$2,994,213**
TOTAL REVENUES – Appropriation from Grants and Donations Trust Fund	**$2,196,352**		

The Department of Health provides the following fiscal comments:

> Section 5 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, it is as 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 were 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 (PG 422) 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 percent 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.

Explanation of other costs:

1. One FTE for the Board of Pharmacy would be required in year 1 and two FTEs for the Division of IT would be required in year 2. Salaries were computed at 10% above the minimum for the pay grade plus 28% for fringe.
2. One FTE for the Board of Pharmacy would be required in year 1. The pharmacist's salary was computed at mid-point range plus 28% for fringe due to the average starting salaries for pharmacists are $90,000.
3. Web based training: The cost would cover development and implementation of a web-based system available to reporting pharmacists and physicians, to teach them how to submit data to the system. The cost is based on an informal quote from the vendor.
4. Oracle License: Estimated cost of the license.
5. Server: Server costs will include a database server ($100,000), a web server ($50,000), a failover server (100,000) and workstation/printer ($3,000).
6. Data collection: There is an estimated cost for prescription data collection from pharmacies and electronic reporting to the state. This estimate is based on conversations with a vendor.
7. Database administrator: A half time database administrator would be required. The administrator will perform all database administrative functions.
8. Systems/Network Administrators/Help Desk: This function may be done by the Department of Health or contracted out. It includes but is not limited to: all communications equipment for application access, database and operating system software and licenses and maintenance, database, system and network administration services for a secure dedicated environment for our application. Because this information must always be available, this also covers the cost of high availability (24/7) access, support of dedicated server due to sensitive nature of data, as well as database size and help desk support. Servers will be supplied by the Department of Health.
9. Security Administration: This cost is for the licensing and administration of state of the art security, due to the extremely sensitive nature of this data. It includes the cost of a security administrator, and Digital User Certificates for Access Control and Authentication. These costs were based on an estimate of 10,000 users at $40 per user in the first year, with an increase of 10,000 users per year for 3 years and then a leveling off. New users would continue to be

added at an estimated cost of $40 each, while renewal of existing users was calculated at $20 each.

10. Secure Data Circuit: This provides an estimated cost for the data line from the Department of Health to the data contractor.
11. Network equipment: Additional network equipment would be needed such as racks for the servers, etc.
12. Hardware maintenance: Maintenance costs would be incurred to maintain the hardware.

Staff also notes that in previous years when similar legislation was filed to create an electronic prescription monitoring system and to develop counterfeit-resistant prescription blanks, funding was available from a $2.15 million agreement with OxyContin distributor Purdue Pharma L.P. to develop a state-of-the-art software program to prevent individuals from "doctor shopping" for improper narcotics prescriptions. The funding under this agreement is no longer available under the terms of that agreement. As previously noted, Section 5 of the bill provides an appropriation from the Grants and Donation Trust Fund and DOH reports that this appears to be inappropriate unless a specific grant or gift is provided to fund the requirements of the bill through this trust fund.[10]

VI. Technical Deficiencies:

None.

VII. Related Issues:

The Department of Health, in its analysis of the bill, has provided the following comments regarding particular provisions of the bill:

1. Section 3 of this bill, in conjunction with SB 176, 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.

[10] The Department of Health states: "[a]lthough the bill provides an appropriation from the Grants and Donation Trust Fund to implement the project, annual appropriations are contingent upon the availability of said funds, potentially impacting the Department's budget if funds for ongoing maintenance of the program are not available."

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 and 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 track them electronically now.
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.

VIII. Summary of Amendments:

None.