HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 897 Controlled Substances
SPONSOR(S): Llorente
TIED BILLS: HB 937 **IDEN./SIM. BILLS:**

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	Health Care Regulation Policy Committee	7 Y, 0 N	Calamas	Calamas
2)	Public Safety & Domestic Security Policy Committee		Kramer	Kramer
3)	Health & Family Services Policy Council			
4)	Full Appropriations Council on General Government & Health Care			
5)				

SUMMARY ANALYSIS

The bill requires the Agency for Health Care Administration (AHCA) to design and implement a prescription drug monitoring database to monitor dispensing of Schedule II, III and IV controlled substances.

The bill requires pharmacies and dispensing practitioners to report certain information about the dispensing of those substances within 15 days of dispensing in a manner consistent with state and federal privacy and security laws. The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, and requires AHCA to promulgate rules defining the manner of reporting. The bill provides several exemptions from the reporting requirements for controlled substances:

- Administered by a health care practitioner directly to a patient
- Dispensed by a health care practitioner and limited to a 72-hour supply
- Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility with an institutional pharmacy
- Ordered from an institutional pharmacy
- Used for patients receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled

The bill makes it a first degree misdemeanor for any person to knowingly fail to make a report required by the bill.

The bill provides that all “costs incurred by the agency” in implementing the bill “shall be through federal, private, or grant funding applied for by the state”.

The bill creates a significant negative impact to the Grants and Donations Trust Fund within AHCA. The impact is estimated to be $4,036,348 in the first year and a recurring impact of $2,930,348 for the implementation of the controlled substance data system. (See Fiscal Analysis.)

The effective date of the bill is July 1, 2009.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substances 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 Diversion and 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.

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for nonmedical use. People obtain these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed the same drug and may be abusing it. A study in Australia indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different

[1] s. 893.04(1)(f), F.S.
[2] s. 893.04(1)(g), F.S.
[3] *See* 21 C.F.R. 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, *see* http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm (last viewed March 16, 2007).

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]

Use of prescription pain relievers without a doctor's prescription or only for the experience or feeling they caused ("nonmedical" use) is, after marijuana use, the second most common form of illicit drug use in the United States.[6] According to the Drug Abuse Warning Network (DAWN), approximately 324,000 emergency department visits in 2006 involved the nonmedical use of pain relievers (including both prescription and over-the-counter pain medications).[7]

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey[8] indicates there are 7.0 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these, 5.2 million used pain relievers, an increase from 4.7 million in 2005.

Of those 7 million people who used pain relievers nonmedically in the past 12 months, 55.7 percent reported they received the drug from a friend or relative for free. Another 9.3 percent bought the drugs from a friend or family member. Another 19.1 percent reported they obtained the drug through just one doctor. Only 3.9 percent got the pain relievers from a drug dealer or other stranger, and only 0.1 percent reported buying the drug on the Internet. Among those who reported getting the pain reliever from a friend or relative for free, 80.7 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor, while only 1.6 percent reported that the friend or relative had bought the drug from a drug dealer or other stranger.[9]

According to recent U.S. DEA statistics, the top 25 pain management clinics for dispensing of time release opiods and other pain relievers are all located in Florida.[10]

National data indicate that the percent of the population using prescription pain relievers for nonmedical purposes in the past year ranged from a low of 2.48 percent in area of the District of Columbia to a high of 7.92 percent in northwest Florida. In Florida, for example: Palm Beach County measured 4.53 percent; Broward County measured 3.82 percent; Miami-Dade and Monroe Counties measured 3.59 percent; and Escambia, Okaloosa, Santa Rosa and Walton Counties combined measured 7.92 percent.[11]

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[5] *See*, www.hic.gov.au (last viewed March 24, 2009).

[6] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Results from the 2007 National Survey on Drug Use and Health: National findings (DHHS Publication No. SMA 08-4343, NSDUH Series H-34) (2008), *see* http://oas.samhsa.gov/p0000016.htm (last viewed March 21, 2009); *cited in*, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, *see* http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm (last viewed March 21, 2009).

[7] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits, (August 2008), *see* http://dawninfo.samhsa.gov/files/ED2006/DAWN2K6ED.pdf (last viewed March 24, 2009), *cited in*, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, *see* http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm (last viewed March 21, 2009).

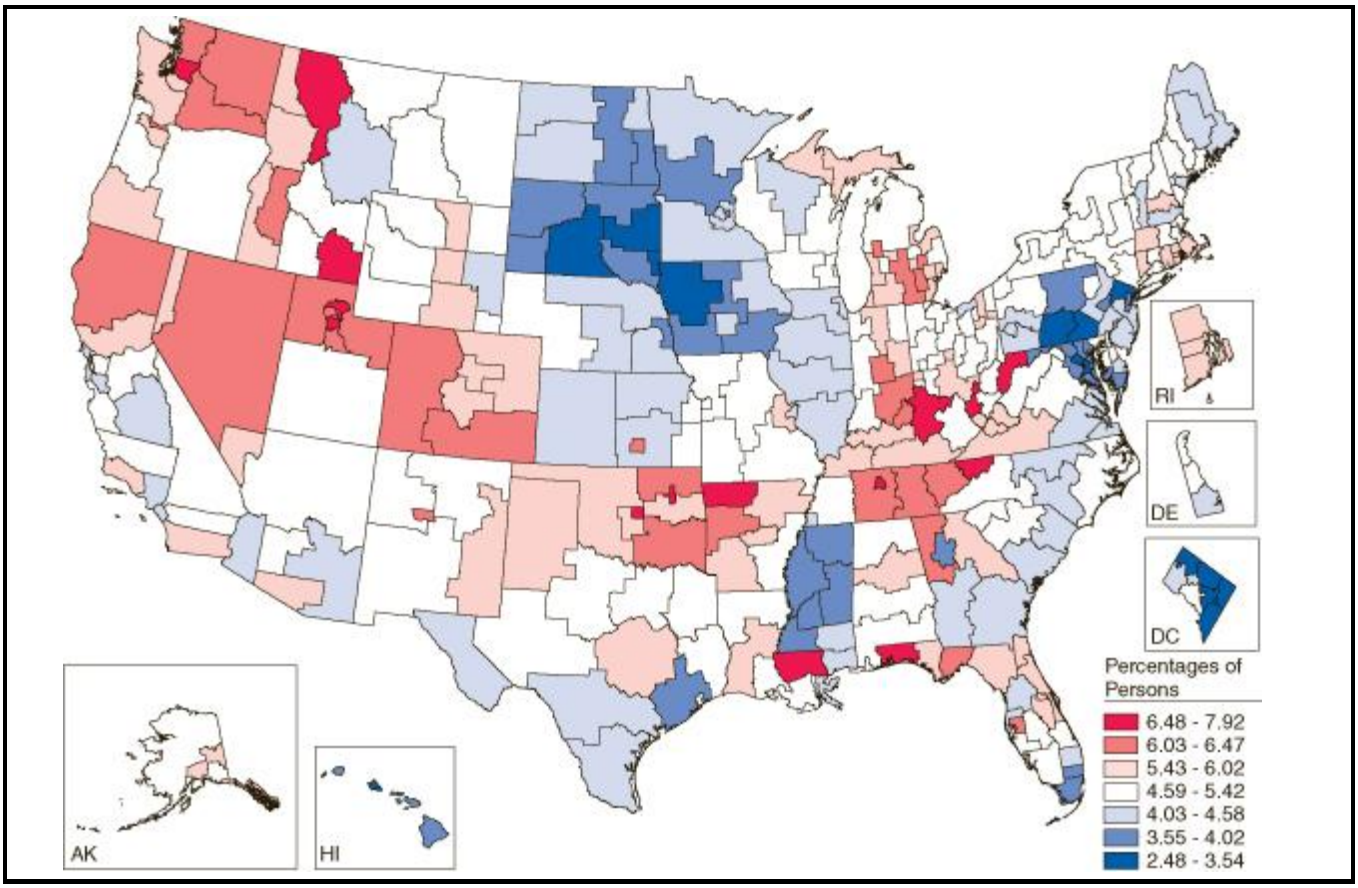
[8] 2006 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, *see* http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#High (last viewed March 21, 2009).

[9] *Id.*

[10] Data drawn from the Automation of Reports and Consolidated Orders System, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, *see* http://www.deadiversion.usdoj.gov/arcos/index.html (last viewed March 24, 2009).

[11] Substance Abuse and Mental Health Services Administration, Office of Applied Studies, The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006, June 19, 2008, *see* http://www.oas.samhsa.gov/2k8/pain/substate.cfm (last viewed March 21, 2009).

Figure 1. Nonmedical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older, by Substate Region*: Percentages, Annual Averages Based on 2004, 2005, and 2006 NSDUHs



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (June 19, 2008). The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006.

The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by abuse of prescriptions drugs[12]. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.[13] According to the Commission's data, 1581 deaths in Florida from January 2008 through June 2008 were caused by prescription drugs.[14] That averages to 8.6 deaths per day.

Prescription Drug Monitoring Programs

Currenty, 38 states have enacted legislation establishing prescription-drug-monitoring programs, and 32 states have operational programs.[15] Prescription-drug-monitoring programs 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-drug-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

[12] Florida Department of Law Enforcement, Medical Examiners Commission, Drugs Identified in Deceased Persons Interim Report, November 2008, *see* http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/Publications.aspx (last viewed March 21, 2009). The prescription drugs tracked by the Commission are prescription benzodiazepines, Barisoprodol/Meprobamate, and all opioids, excluding heroin.
[13] *Id.*
[14] Florida Department of Law Enforcement, *supra* note 11 at Table 1, Summary of Drug-Related Deaths January – June 2008.
[15] National Alliance for Model State Drug Laws, Status of State Prescription Drug Monitoring Programs, *see* http://www.namsdl.org/presdrug.htm (last viewed March 21, 2009).

listed in Schedules II through V.[16] Prescription-drug-monitoring programs may also 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.

Advocates claim the 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.

Privacy and Security

The 1996 Health Insurance Portability and Accountability Act (HIPAA) required the federal government to issue regulations protecting the privacy of health information. The U.S. Department of Health and Human Services (HHS) issued Standards for Privacy of Individually Identifiable Health Information on December 28, 2000, which took effect on April 14, 2003. The regulations establish a set of national standards for the protection of health information, and apply to health plans, health care clearinghouses and certain health care providers. The regulations permit states to afford greater privacy protections to health information. Exceptions for state law are provided for public health and state regulatory reporting.[17]

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:

> 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 express privacy provision is of itself a fundamental right 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 education 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.[18]

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[16] Some states, like Ohio, include non-controlled pain medications with high risk of abuse.
[17] U.S. Department of Health & Human Services, Health Information Privacy, *see* http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary/index.html (last viewed March 21, 2009).
[18] In re T.W., 551 So.2d 1186 (Fla. 1989).

Funding

Beginning in 2002, Congress appropriated funding to the U.S. Department of Justice to support a Prescription Drug Monitoring Program.[19] The Program awards funds in the form of Harold Rogers grants to state regulatory and law enforcement agencies for the purposes of:

- Building a data collection and analysis system at the state level.
- Enhancing existing programs' ability to analyze and use collected data.
- Facilitating the exchange of collected prescription data among states.
- Assessing the efficiency and effectiveness of the programs funded by the grant program.[20]

In 2008, 17 grant awards were made to various state agencies and an educational institution, between $50,000 and $670,000, including an award to the Florida Department of Children and Family Services of $50,000.[21] Grants were awarded for planning, implementation and enhancement of prescription drug monitoring programs, and for training and technical assistance. Funding for Fiscal Year 2009 has not yet been determined.

American Society for Automation in Pharmacy

The American Society for Automation in Pharmacy (ASAP) is an organization whose mission is to "assist its member in advancing the application of computer technology in the pharmacist's role as caregiver and in the efficient operation and management of a pharmacy."[22] Its members include independent pharmacies and hospital pharmacies as well as individuals from colleges of pharmacy, state boards of pharmacy, state and national associations, and government agencies. The ASAP publishes standards for the implementation of prescribed drug monitoring programs.[23]

Electronic Prescribing

Electronic prescribing is the electronic generation and transmission of a patient's prescription by a health care practitioner at the point of care. Electronic prescribing involves a secure, electronic connection between the physician and the pharmacy. In addition, electronic prescribing software generally allows a healthcare practitioner to not only securely access the patient's health plan formulary, but also the patient's medication history, all at the point of care. Medication history is generally available in an 11 to 24 month rolling window, and it generally includes both written and electronically transmitted prescriptions. Numerous software companies offer stand-alone electronic prescribing products. While the cost of the product varies, some products are available at no cost to the healthcare practitioner.[24]

In 2007, the Legislature passed and the Governor signed into law SB 1155. That bill required AHCA to work with private-sector initiatives and relevant stakeholders to create a "clearinghouse" of information on electronic prescribing for healthcare practitioners, facilities, and pharmacies. As required by the bill, AHCA developed a website that provides information on the process and advantages of electronic prescribing, the availability of electronic prescribing software, including no-cost and low-cost software, and state and federal electronic prescribing incentive programs.[25] AHCA also reports annually to the Governor and Legislature on the implementation of electronic prescribing by health care practitioners, facilities and pharmacies.

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[19] U.S. Department of Justice Appropriations Act (Public Law 107-77).
[20] U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers Prescription Drug Monitoring Program, *see* http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html (last viewed March 21, 2009).
[21] U.S. Department of Justice, Bureau of Justice Assistance, Harold Rogers Prescription Drug Monitoring Program FY 2008 Grantees, *see* http://www.ojp.usdoj.gov/BJA/grant/prescripdrugs.html (last viewed March 21, 2009).
[22] *See* http://www.asapnet.org/index.html.
[23] The Standards are available for purchase at http://www.asapnet.org/bookstore.html (last viewed March 24, 2009).
[24] *See e.g.,* http://www.nationalerx.com/ and http://www.iscribe.com/ (offering free web-based electronic prescribing software) (last viewed March 21, 2009); Florida ePrescribe Clearinghouse, Products and Services, *see* http://www.fhin.net/eprescribe/Technology/products.shtml (last viewed March 21, 2009).
[25] Florida E-Prescribe Clearinghouse, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed March 24, 2009); Agency for Health Care Administration, *see* http://ahca.myflorida.com/dhit/ElectronicPrescribing/ePrescribeIndex.shtml (last viewed March 24, 2009).

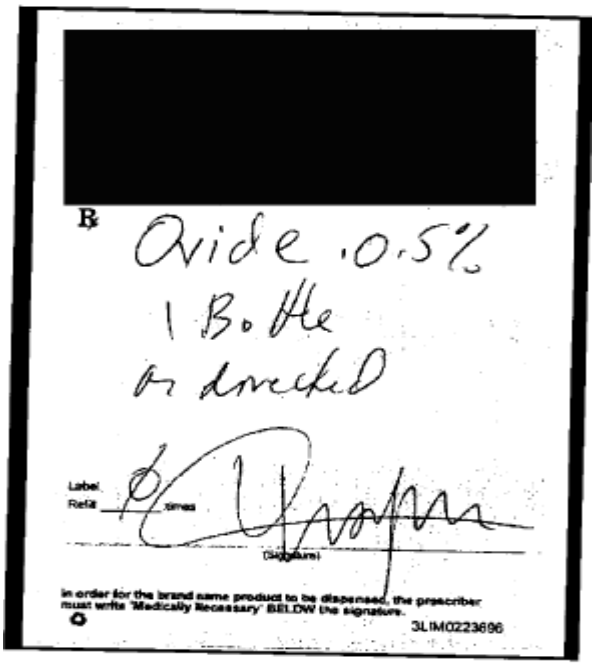
According to AHCA and the Institute of Medicine, electronic prescribing offers numerous benefits, including:[26]

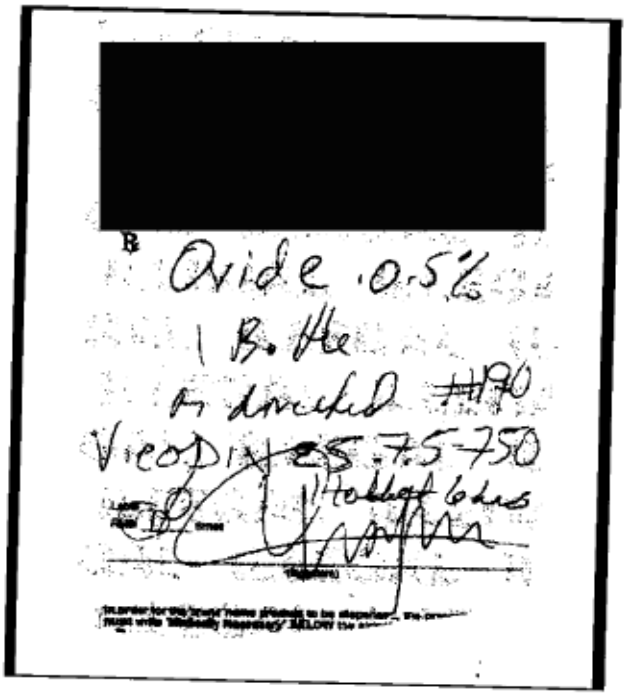
- Reduced health care and legal costs by preventing medication prescription errors caused by events such as illegible hand writing, look-alike or sound-alike drugs, drug-to-drug interactions, incorrect dosing, drug allergy reactions, duplication of drugs, etc.;
- Real-time communications between doctors, pharmacies and patients;
- Provision of drug pricing, payer coverage and preferred drug information;
- Improved clinical outcomes by creating complete patient medication history and providing critical drug alerts and patient specific information at the health care professionals' fingertips; and
- Reduction of fraud and crime by increasing the security of prescriptions.

According to AHCA's most recent report, E-prescribing improved prescription security by providing a complete audit trail of each transaction, from the prescribing physician's office to the dispensing pharmacy, to the patient picking up the prescription. E-prescribing requires a secure log-in process for prescribing practitioners and pharmacies, which must be credentialed and approved before they can participate.[27,28] E-prescribing provides an additional back-up for prescription records, which makes it useful in situations of natural disaster when paper records may be destroyed.[29]

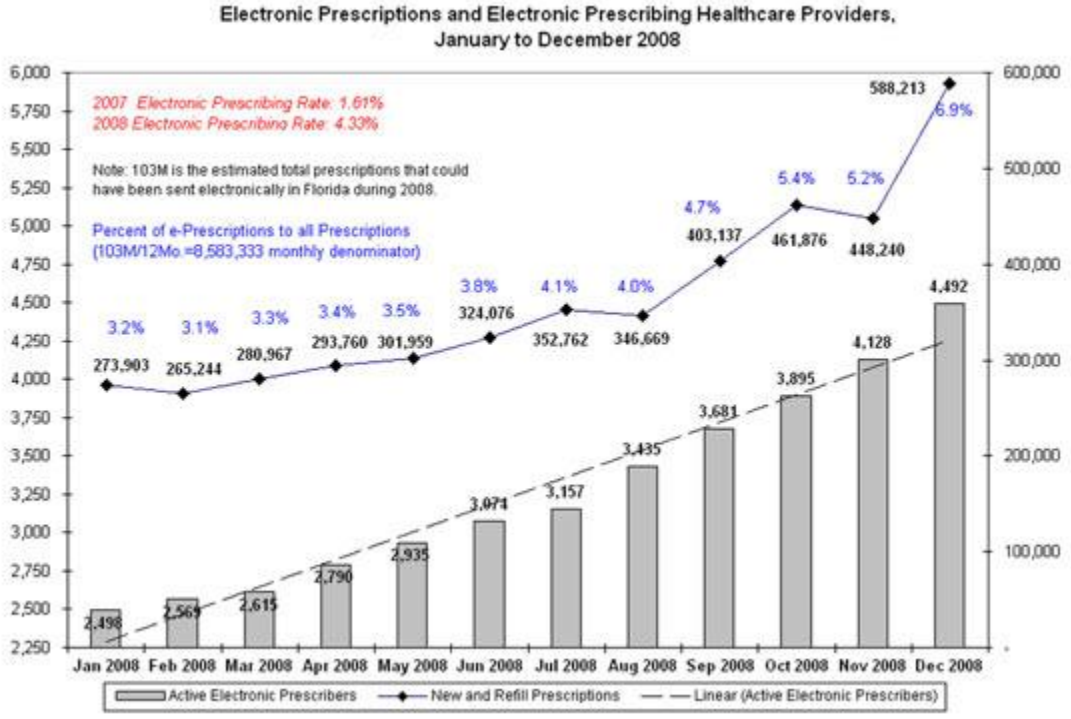
According to AHCA, eliminating paper and handwritten prescriptions can reduce fraud and abuse related to alterations of the paper prescription. For example, this paper prescription for head lice written to a Medicaid recipient was altered to include 190 tablets of Vicodin, a controlled substance. According to AHCA, this alteration was discovered when the pharmacist returned the prescription to the prescribing doctor with a note about his illegible handwriting.[30]

[26] Agency for Health Care Administration, Advantages of ePrescribing, *see* http://www.fhin.net/eprescribe/Benefits/Benefits.shtml (last viewed March 24, 2009), *citing* Institute of Medicine, Committee on Identifying and Preventing Medication Errors, "Preventing Medication Errors: Quality Chasm Series" (2006).
[27] Agency for Health Care Administration, Florida Center for Health Information and Policy Analysis, Second Annual Florida Electronic Prescribing Report, January 2009, *see* http://www.fhin.net/eprescribe/Index.shtml (last viewed March 21, 2009). "Secure access is possible using a virtual private network (VPN) connection over the Internet, which creates a protected electronic channel for the safe transmission of encrypted medication information. Infrastructure technology partners, vendors and others are bound through strong contracts to ensure the authentication of users, the integrity of prescriptions, and the privacy and security of personal health information that passes through the secure networks. Unwarranted prescription activity can be identified much more readily in the electronic system through the use of embedded auditing features."
[28] *Id.* at 7.
[29] *Id.*
[30] *Id.* at 6.





The use of e-prescribing is rising. Of the 6,157 licensed pharmacies in Florida, 71.33 percent were activated to receive electronic prescriptions in 2008, an increase from 63 percent in 2007.[31] Similarly, in 2007 the highest monthly total of e-prescribing healthcare professionals was 2,331. The highest monthly total of e-prescribing physicians in 2008 was 4,492, an increase of 92.75 percent.[32] Among e-prescribers, the number of e-prescriptions issued per month rose 72 percent between 2007 and 2008.[33]



Source: SureScripts-RxHub, *cited in*, Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics.

[31] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Dashboard 2008 Metrics, *see* http://www.fhin.net/eprescribe/Dashboard/FLmetrics.shtml (last viewed March 21, 2009).
[32] *Id*.
[33] *Id*.

Some opponents of e-prescribing believe it imposes a significant financial burden on prescribing practitioners, and is a precursor to interoperable electronic medical records, the value of which is currently debated by medical community.[34]

Funding

Medicare has a new program to encourage physicians to adopt e-prescribing systems.[35] Beginning in 2009, and during the next four years, Medicare will provide incentive payments to eligible health care practitioners who use electronic prescribing. Practitioners will receive a 2 percent incentive payment in 2009 and 2010; a 1 percent incentive payment in 2011 and 2012; and a one half percent incentive payment in 2013. Beginning in 2012, Medicare health care practitioners not using electronic prescribing will receive reduced payments for Medicare-covered services.[36] Exemptions may be awarded on a case-by-case basis if it is determined that compliance would result in significant hardship for the practitioner.[37]

The recently enacted American Recovery and Investment Act (ARRA)[38] authorized approximately $19 billion for Medicare and Medicaid incentives to assist providers in adopting health information technology as well as state loan programs. The incentives will be available for five years, starting in 2011.

Effect of Proposed Changes

The bill requires AHCA to design and implement a prescription drug monitoring database to monitor dispensing of Schedule II, III and IV controlled substances, consistent with the standards of the American Society for Automation in Pharmacy.

The bill requires pharmacies and dispensing practitioners to report certain information about the dispensing of those substances within 15 days of dispensing in a manner consistent with state and federal privacy and security laws. The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, which may include, but is not limited to, any data required under s. 893.04, F.S., and requires AHCA to promulgate rules defining the manner of reporting. The bill provides that the costs of such reporting may not be "material or extraordinary", and provides guidance for interpreting that term. The bill makes it a first degree misdemeanor for any person to knowingly fail to make a report required by the bill, punishable as provided in s. 775.082 F. S. or S. 775.083 F. S. [39]

The bill provides several exemptions from the reporting requirements for controlled substances:

- Administered by a health care practitioner directly to a patient
- Dispensed by a health care practitioner and limited to a 72-hour supply
- Dispensed by a health care practitioner or a pharmacist to an inpatient of a facility with an institutional pharmacy
- Ordered from an institutional pharmacy
- Used for patients receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled

The bill allows information in the database to be "transmitted" by "any person or agency authorized to receive it pursuant to chapter 119".[40] Recipients of such information must purge the information from their records after 24 months, unless the information relates to an ongoing investigation or prosection.

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[34] *See, e.g.,* Stephen R. West, "Congress Shouldn't Practice Medicine", *Tallahassee Democrat*, February 8, 2009, available at http://tallahassee.com/article/20090208/OPINION05/902080311/1006/opinion (last viewed March 21, 2009); "Obama's $80 Billion Exaggeration", *Wall Street Journal*, *see* http://online.wsj.com/article/SB123681586452302125.html (last viewed March 21, 2009).
[35] Pursuant to the Medicare Improvements for Patients and Providers Act of 2008.
[36] *Id.* Reimbursement will be reduced by 1 percent in 2012, 1.5 percent in 2013 and 2 percent in 2014.
[37] Agency for Health Care Administration, ePrescribing Clearinghouse, ePrescribing Initiatives and Incentive Programs, *see* http://www.fhin.net/eprescribe/ePrescribingInitiatives/NationalIncentivePrograms.shtml (last viewed March 21, 2009).
[38] Public Law 111-05 (2009).
[39] These sections provide for a sentence of up to one year of imprisonment and up to $1,000 in fines.
[40] Chapter 119, F.S., governs public records.

The bill provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state".

The effective date of the bill is July 1, 2009.

B. SECTION DIRECTORY:

Section 1: Creates section 893.055, F.S., relating to an electronic monitory system for prescription of certain controlled substances.

Section 2: Provides an effective date of July 1, 2009.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   Uncertain. The bill provides that all "costs incurred by the agency" in implementing the bill "shall be through federal, private, or grant funding applied for by the state". If AHCA successfully obtains federal, private or grant funding, those funds would be revenue increases.

2. Expenditures:

   AHCA estimates a significant fiscal impact, including two FTEs and contracted services. In the first year, AHCA estimates a cost of $4,036,348 for the contract to design and maintain the system. AHCA's estimated recurring impact is $2,930,348 for the implementation of the controlled substance data system.

   See Fiscal Comments.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None.

2. Expenditures:

   None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

The bill requires dispensing practitioners and pharmacists to report certain information within 15 days of dispensing certain controlled substances. The bill requires AHCA to develop rules as to how the reporting shall be accomplished, but provides that costs to the private sector "may not be material or extraordinary", and includes examples of charges that meet that requirement. The costs associated with reporting will vary according to the technological and personnel capabilities of each pharmacy and dispensing practitioner.

Prevention and prosecution of prescription drug abuse, and greater awareness by practitioners of patient doctor shopping, may lead to lower health care costs overall.

D. FISCAL COMMENTS:

The bill requires AHCA to design and establish a prescription drug monitoring system. Estimates for such systems vary.

Department of Health Fiscal Estimates

Department of Health estimates for in-house design and implementation of such a system are significant:[41]

	1st Year (09-10)	2nd Year (10-11) (Annualized /Recurr.)	3rd Year (11-12) (Annualized/ Recurr.)
Salary			
1 Operations & Management Consultant II (OMC II), PG 423	$54,858	$54,858	$54,858
3 Regulatory Specialist II (RS II), PG017	$118,881	$118,881	$118,881
1 Government Analyst II (GA II), PG 026	$51,748	$51,748	$51,748
1 Operations & Management Consultant Manager (OMC Mgr), PG425	$61,737	$61,737	$61,737
Expense			
Non-Recurring Expense Package (OMC II), limited travel	$3,412		
Non-Recurring Expense Package (3-RSII), no travel	$10,236		
Non-Recurring Expense Package (GA I), limited travel	$3,412		
Non-Recurring Expense Package (OMC Mgr), maximum travel	$3,412		
Non-Recurring Expense Package (11 Contracted positions)	$37,532		
Recurring Expense Package (OMC II), limited travel	$12,268	$12,268	$12,268
Recurring Expense Package (3-RSII), no travel	$20,100	$20,100	$20,100
Recurring Expense Package (GA I), limited travel	$12,268	$12,268	$12,268
Recurring Expense Package (OMC Mgr), maximum travel	$20,212	$20,212	$20,212
Non-Recurring Expense Package (Contracted positions), no travel	$73,700	$20,100	$6,700
Promotion (printing & postage)	$10,000	$10,000	$10,000
Rulemaking Conference Room Rentals	$10,000		
Rulemaking Travel	$16,800		
System Development (non-recurring)			
Windows Standard Server 2003	$3,248		
RDBMS	$0		
Dynamic PDF Generator	$1,497		
Dynamic PDF Merger	$799		
Fax Software	$250		
Backup Software License	$8,000		
System Administration (recurring)			
RDBMS Maintenance	$70,393	$70,393	$80,952
Software Maintenance and Defect Remediation	$0	$437,008	$480,709
Indirect Operating Expenses	$1,500	$1,500	$1,500
Computer Hardware	$1,000	$1,500	$1,500
Network Equipment	$25,000	$25,000	$25,000
Hardware Maintenance	$0	$0	$0

[41] Department of Health Bill Analysis, Economic Statement and Fiscal Note, House Bill 1015 (2009).

Backup Tapes		$60,000	$66,000
Private secure data circuit		$60,000	$60,000
Contracted Services			
Promotion (mail processing)	$1,500	$1,500	$1,500
FAW Publications	$500		
System Development (non-recurring)			
Project Managers - 2 @ 2080 hrs	$447,200		
.Net Developers - 4 @ 2080 hrs	$748,800		
Business Analyst - 1 @ 2080 hrs	$187,200		
Testing Expert - 2 @ 2080 hrs	$374,400		
Database Administrator (DBA) - 1 @ 2080 hrs	$208,000		
Data-Integration consultant - .5 @ 1040 hrs	$104,000		
Infrastructure Support consultant - .5 @ 1040 hrs	$104,000		
System Administration (recurring)			
Data Contractor	$325,000	$505,000	$510,250
Database Administrator (DBA) - 1 @ 2080 hrs	$0	$137,500	$151,250
Project Manager - 2 @ 2080 hrs	$0	$447,200	
System/Network Administrator	$100,000	$110,000	$121,000
Operating Capital Outlay			
OCO standard package (6 FTE)	$6,000		
OCO standard package (11 Contracted positions)	$11,000		
System Development (non-recurring)			
RDBMS Enterprise License	$319,968		
Windows Enterprise Server 2003	$4,521		
Crystal Enterprise (per proc)	$30,000		
DF IntelliServer	$300,000		
Initial Tape sets for backup services	$60,000		
Web Server	$15,178		
App Server	$42,640		
DB server	$85,280		
Staging Server	$21,320		
Crystal Server	$42,640		
DF IntelliServer	$21,320		
Security Server	$63,960		
Fax Desktop with card	$1,009		
Human Resources			
HR standard package (6 FTE)	$2,406	$2,406	$2,406
TOTAL ESTIMATED EXPENSES	**$4,260,105**	**$2,241,179**	**$1,870,839**

Office of Drug Control Fiscal Estimates

The Office of Drug Control notes that costs may range between $100,000 and $4,000,000, and provided estimates based on two models:[42]

1. Tasks partially retained by the state with use of FTE and non-FTE (i.e. contracted) personnel and contracted goods and services:
    - First year: $1,222,500
    - Second year: $1,865,000
    - Follow-on years: $1,850,000

2. Most of the tasks contracted with no FTE:
    - First year: $550,000
    - Second year: $695,000
    - Follow-on years: $680,000

Specifically:

Program Management and IT staff costs:
Project manager, administrative assistant, systems analyst, programmer, database administrator and epidemiologist. Cost is estimated to be $470,000

Implementation: The Operating requirements previously discussed in option one, servers, server operating software, licenses, the development, printing and mailing of notification of the implementation date, limited training classes (formal and informal) and training manual, requisite installation for travel: $320,000.

Annual Operation: The operating costs and the administrative, data collection and IT staff functions already discussed including clinical and technical support personnel, communications, requests by patient for prescription history review, supplies, and travel: $550,000.

DOH Rule Development: Travel costs for two meetings of ten members for Rule Development: $30,000. There would be no or limited costs for those within the Tallahassee area or those within day time travel distance.

DOH Rule workshop statewide: Costs for seven workshops for two people and materials: $25,000.

The Office of Drug Control also suggests that training be provided (although this is not currently required by the bill):

- An orientation course during the implementation phase of the prescription drug validation program.
- A course for persons who are authorized to access the prescription drug validation program information, but who did not participate in the orientation course.
- A DOH educational program to inform the public about the prescription drug validation program.

The Office estimates the cost of training (including a training consultant, travel and material/website development) is: First year: $55,000, second year: $55,000 and then thereafter for the follow-on years: $40,000.

Agency for Health Care Administration Fiscal Estimates

The Agency for Health Care Administration also finds a significant fiscal impact, including two FTEs and contracted services.

Summary:

[42] EOG / Office of Drug Control 2009 Bill Analysis & Economic Impact Statement for House Bill 897 (2009).

The first year, the fiscal impact is expected to be $4,036,348 for the contract to design and maintain the system. The estimated recurring impact is $2,930,348 for the implementation of the controlled substance data system.

The FTEs would be responsible for contract management, database maintenance as well as responding to requests from patients, providers, pharmacies and law enforcement agencies. Pharmacies will incur the cost of reporting all prescribed controlled substances to the Agency every 15 days.

Detail:
The first year impact would be $4,036,348 and the estimated recurring impact is $2,930,348 for the implementation of the controlled substance data system. The State of Tennessee has a program similar to the controlled substance prescription monitoring program in the bill. Tennessee has approximately 1,300 reporting pharmacies. Tennessee's estimated start up costs to contract for the development of their PMP database was $750,000 and $200,000 annually to maintain. Florida has approximately 4,500 pharmacies, so the estimated start up costs to contract for the development of a PMP database is $1,100,000 and approximately $400,000 annually to maintain. The bill allows providers and pharmacists to make submissions to the Agency in written or any electronic or magnetic format, including, but not limited to, electronic submission via the Internet or magnetic disc or tape, each controlled substance listed in Schedule II, Schedule III, or Schedule IV which it dispenses. It is estimated that 20%, or about 1,000 reporting providers and/or pharmacies will use a nonstandard form of reporting which will need to be put into a format that the controlled substance PMP database can read. Each provider and/or pharmacy is required to submit reports every 15 days, or twice a month. The Agency will contract with a vendor to format the nonstandard submissions for $2,400,000 annually based on an estimated average $100 per report which may vary, depending on whether the information is submitted on paper, tape, or disc.

In the first year, one FTE government analyst II (10% above minimum) would be required, spending approximately 75% of work time developing the request for proposals, contract development and contract monitoring and 25% of work time on other activities including notifying to providers and pharmacies of the new reporting requirement and directing the administrative assistant who would be primarily responsible for handling requests for public access or answering routine questions from pharmacies and physicians related to the program.

It is estimated that the number of requests for access to records from patients would be 2,000 based on the number of requests from patients received by Florida Medicaid for access to records increased by a factor of ten. It is estimated that the average time to process requests is 1.00 hours. This time includes review of the written request and search for the patient's records that would be provided under contract. The work hours required to process requests each year would be 2000 work hours (2,000 applications x 1 hour).

In the first year, one FTE administrative assistant II (10% above minimum) would be required, spending 50% of work time assisting with and documenting the request for proposal, contract development and contract monitoring process and 50% assisting with requests from physicians, pharmacists, law enforcement agencies and the general public. In the second year, 80% of time would be spent on processing requests for access from law enforcement and the general public, and answering routine questions from physicians and pharmacists.

FISCAL IMPACT ON AHCA/F	**Amount Year 1 FY 09-10**	**Amount Year 2 FY 10-11**
1. Non-Recurring Impact:		
Revenues:		
Licenses	$0	$0
Fees	$0	$0
Grants	$0	$0

				$0	$0
Transfers In / Another Agen				$0	$0
Total Non-Recurring Revenu				**$0**	**$0**
Expenditures:					
Salaries				$0	$0
OPS					
Other Personal Services	1.00	@	$0	$0	$0
	0.00	@	$0	$0	$0
Total Non-Recurring OPS				$0	$0
Expense (Agency Standard Expense & Operating Capital Outlay Package)					
Professional Staff	2.00	@	$3,000	$6,000	$0
Support Staff	0.00	@	$2,400	$0	$0
Additional Travel Expense	0.00	@	$0	$0	$0
	0.00			$0	$0
Total Non-Recurring Expe				**$6,000**	**$0**
Operating Capital Outlay (Agency Standard Expense & Operating Capital Outlay Package)					
Laptop Computers	0.00	@	$0	$0	$0
Total Operating Capital Ou				**$0**	**$0**
Special Categories					
Contracted Services				$1,100,000	$0
				$0	$0
Total Non-Recurring Specia					
Categories				$1,100,000	$0
Total Non-Recurring Expend				**$1,106,000**	**$0**

2. Recurring Impact:

	Class		**Pay**			
	Code	**FTEs**	**Grade**	**Rate**		
Revenues:						
Licenses					$0	$0
Fees					$0	$0
Grants					$0	$0
Transfers In/Another Agenc					$0	$0
Total Recurring Revenues					**$0**	**$0**
Expenditures:						
Salaries						
Government Analyst II	2225	1.00	**26**	51,215	$65,479	$65,479
Administrative Assistant II	0712	1.00	**18**	32,403	$41,427	$41,427
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
		0.00	**0**	0	$0	$0
Total Salary and Benefits		2.00	**FTEs**	83,618	$106,906	$106,906
OPS						
Other Personal Services		0.00	@	$0	$0	$0
		0.00	@	$0	$0	$0

Total OPS				$0	$0
Expenses					
Professional Staff	2.00	@	$11,320	$22,640	$22,640
Support Staff	0.00	@	$5,620	$0	$0
Additional Travel Expenses	0.00	@	$0	$0	$0
				$0	$0
Total Expenses				$22,640	$22,640
Contracted Services	2.00		$0	$0	$0
Human Resources Service					
FTE Positions	2.00	@	$401	$802	$802
OPS Positions	0.00	@	$132	$0	$0
Total Human Resources Se				$802	$802
Special Categories					
Contracted Services				$2,800,000	$2,800,000
				$0	$0
				$0	$0
Total Special Categories				$2,800,000	$2,800,000
Total Recurring Expenditure	**2.00**	**FTEs**	**83,618**	**$2,930,102**	**$2,930,102**

3. Long Run Effects Other Than Normal Growth:

4. Total Revenues and Expenditures:

Sub-Total Non-Recurring Rev				$0	$0
Sub-Total Recurring Revenue				$0	$0
Total Revenues				**$0**	**$0**
Sub-Total Non-Recurring Expenditures				$1,106,000	$0
Sub-Total Recurring Expendit				$2,930,348	$2,930,348
Total Expenditures	**2.00**	**FTEs**		**$4,036,348**	**$2,930,348**

Difference (Total Revenues minus Total Expenditures) **($4,036,348)** **($2,930,348)**

5. Funding of Expenditures:

	$0	$0
Total	**$0**	**$0**

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 an action requiring the expenditure of funds. The bill does not reduce the percentage of a state tax shared with counties or municipalities. The bill does not reduce the authority that municipalities have to raise revenue.

2. Other:

State collection of patient-specific information on the use of controlled substances by law-abiding individuals may implicate the express right of privacy contained in Article I, Section 23, of the Florida Constitution.

B. RULE-MAKING AUTHORITY:

The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, which may include, but is not limited to, any data required under s. 893.04, F.S., and requires AHCA to promulgate rules defining the manner of reporting. The bill appears to provide sufficient rulemaking authority for these functions. However, the bill does not provide AHCA rulemaking authority to design and implement the prescription drug database. It is unclear whether rules are necessary to comply with that directive.

C. DRAFTING ISSUES OR OTHER COMMENTS:

The bill requires the Department of Health and regulatory boards to promulgate rules defining what information must be reported, which may include, but is not limited to, any data required under s. 893.04, F.S., and requires AHCA to promulgate rules defining the manner of reporting. This bifurcation of rulemaking duties may create inefficiencies. In addition, it is unclear whether the rules promulgated by the Department of Health and its regulatory boards are intended to create obligations on practitioners enforceable by Department of Health through disciplinary action upon a license.

The bill allows for access to the prescription drug monitoring database by “any person or agency authorized to receive it pursuant to chapter 119”. Chapter 119 does not provide specific authorization to access the prescription drug monitoring database; rather, it presumptively allows public access to the database. House Bill 937 creates an express public records exemption for the prescription drug monitoring database, but does not place that exemption in chapter 119. This provision appears to conflict with the public records exemption in House Bill 937.

The bill provides that all “costs incurred by the agency” in implementing the bill “shall be through federal, private, or grant funding applied for by the state”. The bill may not provide sufficient authority for AHCA to receive private donations to implement the prescription drug monitoring database.

There is no provision in this bill to require the Agency for Health Care Administration to notify persons if there is an accidental or deliberate data breach, which is necessary to protect the public and persons prescribed controlled substances.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES