HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 397 w/CS Controlled Substances
SPONSOR(S): Harrell
TIED BILLS: HB 399 w/CS **IDEN./SIM. BILLS:** CS/SB 580, SB 578(c)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)	9 Y, 1 N	Garner	Collins
2) Health Care	20 Y, 3 N w/CS	Garner	Collins
3) Health Appropriations (Sub)	11 Y, 1 N	Massengale	Massengale
4) Appropriations			
5)			

SUMMARY ANALYSIS

Abuse of prescription drugs is rising rapidly in the United States. An estimated 9 million people aged 12 and older used prescription drugs for nonmedical reasons in 1999; more than a quarter of that number reported using prescription drugs nonmedically for the first time in the previous year.[1] The nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States and in Florida.

Florida's Comprehensive Drug Abuse Prevention and Control Act (Chapter 893, F.S.) establishes the schedules of controlled substances based upon a risk classification scheme, with Schedule I having the highest potential for illegal abuse and Schedule V having the lowest potential. Section 893.04, F.S., delineates those conditions under which pharmacists and practitioners may dispense controlled substances after either receiving a written or oral prescription for a controlled substance.

HB 397 w/CS expands the regulation of prescribing and dispensing controlled substances to minimize the diversion and abuse of prescription drugs. Provisions of the bill:

- Prohibit the sale, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for controlled substances, including penalties.
- Provide additional requirements for the dispensing of a controlled substance.
- Require the establishment of an electronic system to monitor the prescribing of controlled substances.
- Establish penalties.
- Provide for future legislative review and repeal on June 30, 2008, unless reenacted.
- Require the development and adoption of a counterfeit-proof prescription blank to be used voluntarily by physicians to prescribe Schedule II, Schedule III, or Schedule IV controlled substances.

The bill provides an effective date of July 1, 2005, except as otherwise provided.

The bill provides an appropriation of $2,196,352 from the Grants and Donations Trust Fund to the Department of Health in fiscal year 2004-05, and three full-time equivalent positions. According to the Department of Health, total expenditures needed to implement the act are $2,057,784 (FY 2004-05), $2,682,750 (FY 2005-06) and $3,584,168 (FY 2006-07).

[1] National Institute On Drug Abuse, *Prescription Drugs, Abuse, and Addiction.*

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

1. Reduce government?	Yes[]	No[X]	N/A[]
2. Lower taxes?	Yes[]	No[X]	N/A[]
3. Expand individual freedom?	Yes[]	No[X]	N/A[]
4. Increase personal responsibility?	Yes[X]	No[]	N/A[]
5. Empower families?	Yes[]	No[]	N/A[X]

For any principle that received a "no" above, please explain:

1. This bill expands the role of government by monitoring the prescribing patterns of physicians for certain controlled substances and monitoring a patient's medical profile.

2. This bill does not lower taxes, but may require an increase in the use of tax dollars in subsequent years for funding the monitoring system.

3. This bill does not expand an individual's freedom, but in some cases may limit an individual's freedom by having private medical information monitored by a state entity.

B. EFFECT OF PROPOSED CHANGES:

HB 397 w/CS creates a third degree felony offense for any person who, with the intent to injure or defraud any person or to facilitate any violation of specified prohibited acts under the Florida Comprehensive Drug Abuse Prevention and Control Act, sells, manufactures, alters, delivers, utters, or possesses any counterfeit-resistant prescription blanks for controlled substances adopted by rule of the Department of Health (DOH).

The bill imposes limitations, restrictions, and requirements upon the dispensing of a controlled substance by a pharmacist. A prescription for a Schedule II controlled substance may be dispensed only upon the written prescription of a practitioner except in an emergency as defined by departmental regulation, and the supply of the controlled substance dispensed is limited to no more than that required for a 72-hour period.

A pharmacist, prior to dispensing a controlled substance listed in Schedule II, Schedule III, or Schedule IV to an individual, is required to obtain suitable identification for the patient or the patient's agent and must only dispense a controlled substance once the prescription is considered valid by the pharmacist. A pharmacist filling prescriptions by mail is not required to comply with the patient identification requirements of this provision. Limitations are imposed restricting the dispensing of no more than a 30-day supply of a Schedule III controlled substance obtained via an oral prescription that must be reduced to writing.

The bill creates s. 893.055, F.S., providing for an electronic monitoring system for the prescription of controlled substances listed in Schedules II, III, and IV, and specifying that the department shall design the system consistent with the standards adopted by the American Society for Automation in Pharmacy (ASAP). The bill requires that a controlled substance listed in Schedule II, Schedule III, or Schedule IV that is dispensed in this state must be reported to the department as soon as possible, but not more than thirty-five days after the date the controlled substance is dispensed each time the controlled substance is dispensed. The reporting is limited and does not apply to controlled substances that are any one of the following:

- Directly administered by a health care practitioner to the patient.
- Dispensed directly to the patient by a health care practitioner for a period of no more than 72 hours.

- Dispensed (by a practitioner or pharmacist) to an inpatient of a facility with an institutional pharmacy.
- Ordered from an institutional pharmacy permitted under section 465.019, F.S.
- Dispensed to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled.
- Prescribed for a patient less than 16 years of age.

The bill allows DOH to specify the data required to be reported. In addition, the bill requires a dispenser to submit the information to the department in an electronic format. Also, the act specifies that the cost associated with the dispenser submitting the information shall not be material or extraordinary. Costs not considered material or extraordinary include, but are not limited to:

- Regular postage.
- Compact discs.
- Zip driver storage.
- Regular electronic mail.
- Magnetic tapes.
- Diskettes.
- Facsimile charges.

DOH must determine by rule the data required to be reported under the prescription monitoring system, and such data may include any data required under s. 893.04, F.S. Any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV is liable for a first degree misdemeanor punishable by jail up to 1 year and a fine of up to $1,000, and a third degree felony for the knowing and willful violation of this section. The bill also removes liability for providers authorized to use the information in the tracking system, but requires that they keep the confidentiality of any information obtained from the monitoring system pursuant to ss. 456.057 and 465.017. This bill also includes a "sunset" provision for the tracking system created in s. 893.055, F.S., of June 30, 2008, unless reviewed and saved from repeal through reenactment by the Legislature.

HB 397 w/CS also specifies that the Department of Health shall develop the counterfeit-resistant prescription blanks for controlled substances that may be used by practitioners to prescribe controlled substances listed in Schedules II, III, and IV. DOH may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances.

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

Present Situation

Abuse of prescription drugs is rising rapidly in the United States. An estimated 9 million people aged 12 and older used prescription drugs for nonmedical reasons in 1999; more than a quarter of that number reported using prescription drugs nonmedically for the first time in the previous year.[2] The National Institute on Drug Abuse would like to reverse this trend by increasing awareness and promoting additional research on this topic.

[2] National Institute On Drug Abuse, *Prescription Drugs, Abuse, and Addiction.*

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 (CNS) depressants, and stimulants—when abused can alter the brain's activity and lead to dependence and possible addiction.

A study prepared by The Lewin Group for the National Institute on Drug Abuse and the National Institute on Alcohol Abuse and Alcoholism estimated the total economic cost of alcohol and drug abuse to be $245.7 billion for 1992. Of this cost, $97.7 billion was due to drug abuse.[3] This estimate includes substance abuse treatment and prevention costs as well as other health care costs, costs associated with reduced job productivity or lost earnings, and other costs to society such as crime and social welfare. The study also determined that these costs are borne primarily by governments (46 percent), followed by those who abuse drugs and members of their households (44 percent).

The White House Office of National Drug Control Policy (ONDCP) also conducted a study to determine drug use costs to society. In 1992, the overall cost of drug abuse to society was approximately $102 billion, but by 2000, the projected overall cost reached $160.7 billion. ONDCP found that between 1992 and 2000, estimated costs to society of drug abuse increased health care costs by $61.3 billion; reduced worker productivity by $453.5 billion, and incurred other costs to society of over $141.1 billion.

Commonly Abused Prescription Drugs
While many prescription drugs can be abused or misused, these three classes are most commonly abused:

- *Opioid Substances*—Opioid substances are commonly prescribed because of their effective analgesic or pain relieving properties. Among the drugs that fall within this class (sometimes referred to as narcotics) are morphine, codeine, and related drugs. Morphine is often used before or after surgery to alleviate severe pain. Codeine is used for milder pain. Other examples of opioid substances that can be prescribed to alleviate pain include oxycodone (OxyContin-an oral, controlled release form of the drug); propoxyphene (Darvon); hydrocodone (Vicodin); hydromorphone (Dilaudid); and meperidine (Demerol), which is used less often because of its side effects. Chronic use of opioid substances can result in tolerance to the drugs so that higher doses must be taken to obtain the same initial effects. Long-term use also can lead to physical dependence: the body adapts to the presence of the drug and withdrawal symptoms occur if use is reduced abruptly.

- *CNS Depressants*—CNS depressants are used to treat anxiety and sleep disorders. CNS depressants slow down normal brain function, and in higher doses can become general anesthetics. CNS depressants can be divided into two groups, based on their chemistry and pharmacology:

  →Barbiturates, such as mephobarbital (Mebaral) and pentobarbital sodium (Nembutal), which are used to treat anxiety, tension, and sleep disorders.

  →Benzodiazepines, such as diazepam (Valium), chlordiazepoxide HCl (Librium), and alprazolam (Xanax), which can be prescribed to treat anxiety, acute stress reactions, and panic attacks. Benzodiazepines that have a more sedating effect, such as triazolam (Halcion) and estazolam (ProSom) can be prescribed for short-term treatment of sleep disorders.

  Discontinuing prolonged use of high doses of CNS depressants can lead to withdrawal. Because they work by slowing the brain's activity, a potential consequence of abuse is that when one stops taking a CNS depressant the brain's activity can rebound to the point that seizures can occur.

[3] This estimate includes illicit drugs and other drugs taken for non-medical purposes. It does not include nicotine.

- *Stimulants*—Stimulants are prescribed to treat narcolepsy and attention deficit/hyperactivity disorder. Stimulants are a class of drugs that enhance brain activity; they cause an increase in alertness, attention, and energy that are accompanied by increases in blood pressure, heart rate, and respiration.

  Historically, stimulants were used to treat asthma and other respiratory problems, obesity, neurological disorders, and a variety of other ailments. As their potential for abuse and addiction became apparent, the use of stimulants began to wane. Now, stimulants are prescribed for treating only a few health conditions, including narcolepsy, attention-deficit hyperactivity disorder (ADHD), and depression that has not responded to other treatments. Stimulants may also be used for short-term treatment of obesity, and for patients with asthma.

  The consequences of stimulant abuse can be extremely dangerous. Taking high doses of a stimulant can result in an irregular heartbeat, dangerously high body temperatures, and/or the potential for cardiovascular failure or lethal seizures. Taking high doses of some stimulants repeatedly over a short period can lead to hostility or feelings of paranoia in some individuals.

Role of Health Care Providers

About 70 percent of Americans—approximately 191 million people—visit a health care provider, such as a primary care physician, at least once every 2 years. Thus, health care providers are in a unique position not only to prescribe needed medications appropriately, but also to identify prescription drug abuse when it exists and help the patient recognize the problem, set goals for recovery, and seek appropriate treatment when necessary. Screening for any type of substance abuse is typically incorporated into a routine “patient history taking” with questions about what prescriptions and over-the-counter medicines the patient is taking and why. Screening also can be performed if a patient presents with specific symptoms associated with problem use of a substance.

Providers are encouraged by practice standards to note over time any rapid increases for medication needed, which may indicate the development of tolerance, or frequent requests for refills before the quantity prescribed should have been used. They should also be alert to the fact that those addicted to prescription medications may engage in "doctor shopping," moving from provider to provider in an effort to get multiple prescriptions for the drug they abuse.

Doctor Shoppers

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

A data search indicated that no studies in the United States have specifically addressed the profile of a doctor shopper. A search of international data produced a report and findings from a study in Australia, which indicated that most doctor shoppers switch only sporadically. However, the top 25 percent shop very actively, travel widely, and see many different practitioners, often on the same day. Doctor shoppers generally take the medicine themselves. Compared to the number of doctors consulted, in a recent survey most doctor shoppers have their prescriptions dispensed at few pharmacies. [4]

Frequent reasons used by doctor shoppers to obtain medicines are:

- Work hours interfere with sleep.
- Lost prescription.
- Relatives passed away.

[4] www.hic.gov.au

- Migraine, cramp, toothache, or diarrhea.
- Just arrived in area.
- Handbag stolen.

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

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

Illegal Use of Prescription Drugs
Another way in which people are illegally obtaining prescription drugs is by purchasing the drug from a legitimate patient in need of the medication. For example, one disturbing trend occurring in many schools is that students with ADD or ADHD are selling their prescription Ritalin drugs to make a profit from classmates. The prescription monitoring system will only identify this type of illegal use in the event the individuals selling the drugs are getting multiple prescriptions.

Many people view drug abuse and addiction as strictly a social problem. Parents, teens, older adults, and other members of the community tend to characterize people who take drugs as morally weak or as having criminal tendencies. They believe that drug abusers and addicts should be able to stop taking drugs if they are willing to change their behavior.

These myths have not only stereotyped those with drug-related problems, but also their families, their communities, and the health care professionals who work with them. Drug abuse and addiction comprise a public health problem that affects many people and has wide-ranging social consequences.

Addiction does begin with drug abuse when an individual makes a conscious choice to use drugs, but addiction is not just "a lot of drug use." Recent scientific research provides overwhelming evidence that not only do drugs interfere with normal brain functioning creating powerful feelings of pleasure, but they also have long-term effects on brain metabolism and activity. At some point, changes occur in the brain that can turn drug abuse into addiction—a chronic, relapsing illness. Those addicted to drugs suffer from a compulsive drug craving and usage and many cannot quit by themselves. Treatment is often necessary to end this compulsive behavior.

The Sun-Sentinel Series on Prescription Drug Abuse
Beginning in November 2003, the *Orlando Sun-Sentinel* newspaper ran a series of articles examining prescription drug abuse, in particular as it relates to Florida's Medicaid program. While HB 397 would affect all prescriptions of Schedules II thru IV drugs regardless of payer source, this series of articles provide relevant statistics.

The Sentinel found through an eight-month investigation that prescription drug abuse is widespread in the Medicaid program, sometimes resulting in the death of beneficiaries. Specifically, the reporters found the following:

- ✓ Over a three-year period of time, Medicaid paid $346.6 million in claims for controlled substances, most of which were for the maximum dosage allowed.
- ✓ Less than 3 percent of the state's medical professionals provided about two-thirds of these prescriptions.
- ✓ Sixteen doctors each ordered more than $1 million of controlled substances when only 574 of the state's 56,926 Medicaid physicians topped even $100,000 in pharmacy billing, and seven doctors prescribed more than $1 million worth of OxyContin alone over the past three years.

- ✓ The doctors that prescribed the most prescriptions were also linked to the largest number of multiple-drug related deaths in the state, with at least 40 doctors each having four or more patient deaths as a result of overdoses in the past two years. Sixteen had eight or more.

2002 Prescription Monitoring Model Act

In October 2002, the Alliance of States with Prescription Monitoring Programs (Alliance) and the National Association of State Controlled Substances Authorities (NASCSA) jointly adopted the Prescription Monitoring Program Model Act. The Model Act provides a statutory framework for establishing and operating a prescription monitoring program within states. Both organizations recommend that states use the Model Act to establish new and update existing monitoring programs.

The basis for the Model Act is a consensus document that reflects the best practices of states of the currently run monitoring programs, as well as the knowledge of many other states that have a longstanding interest in such programs. The prescription monitoring states cover half the U.S. individual and practitioner populations and have more than one-hundred years of combined experience in operating monitoring programs.

The Alliance is an organization of representatives of twenty-eight states that have adopted or are considering adoption of Prescription Monitoring Programs (PMPs); including all eighteen states that currently have such programs. NASCSA is an organization of forty-three states, of which Florida is a member, and comprises agencies responsible for prescription controlled substances in each of those states. PMPs provide a highly efficient means of collecting the prescribing and dispensing information that has been routinely collected as part of investigations into prescription drug diversion. States that operate PMPs have found that they are an effective tool for enforcement, education and prevention that does not interfere with legitimate prescribing and dispensing of pharmaceuticals.

The Model Act provides the following essential elements:

- Establishes, as a minimum standard, the collection of information for all prescriptions issued for Schedule II - IV controlled substances.

- Provides the option for states to collect information on Schedule V controlled substances and on drugs that have a potential for abuse but are not currently scheduled.

- Requires the submission of the minimum essential data elements to be collected for each prescription, and maintains an option for states to collect additional data elements, if needed. The entire list of data elements are considered essential for the optimal operation of a PMP.

- Mandates that pharmacies submit data electronically, since the use of computers is now the standard in pharmacy practice.

- Permits a waiver to be issued for paper submission of information if a particular pharmacy is unable to submit information electronically.

- Provides an option for states to also use state-issued, serialized prescription forms, if they so choose.

- Ensures the privacy and confidentiality of information collected by a PMP.

The Alliance of States with Prescription Monitoring Programs purports that, “To place this in context, the same prescription information has been available for decades to the parties that can access the PMPs’ information. The difference is that to examine the information without a PMP; each party must go through thousands of prescriptions to manually compile the information. The PMPs simply utilize new technology to make the information more readily accessible and analyzable. The information

users will need to adjust their approaches to deal with this greater accessibility, but that is an issue for the information users, not for the agency that operates the PMP and compiles the information. The sponsors of this Model Act recognize that each state will adapt it to specific local circumstances and concerns."

Other States

In an effort to control the diversion of controlled substances, more than fifteen states have established prescription monitoring systems. The fifteen states with tracking programs are California, Hawaii, Idaho, Illinois, Indiana, Kentucky, Massachusetts, Michigan, Nevada, New York, Oklahoma, Rhode Island, Texas, Utah, and Washington, according to the Drug Enforcement Administration and National Alliance for Model State Drug Laws. Another half-dozen states are considering prescription monitoring systems, and advocates are pushing for a *national system to link the state databases.*

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 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.

Kentucky spent $415,000 to start its program in 1999 and spends about $600,000 annually to operate it. Kentucky has received widespread praise for its program, and neighboring states are looking to it as a model. Supporters say it's successful because it has privacy protections and tracks all controlled substances, which are drugs that can be addictive or abused. To use the system, a doctor or police officer in Kentucky must submit a written request to the health agency for information. Police must have an open criminal case. Police can use the information to investigate a case but not to make an immediate arrest.

"We greatly support a statewide program, but our dream would be a nationwide program." Congress has provided $2 million this year for states to start prescription drug monitoring systems, but advocates say much more is needed. Rep. Hal Rogers, R-Ky., a senior member of the U.S. House Appropriations Committee, said he would support a national program and more federal money to help pay for it.

The Pharmaceutical Research and Manufacturers of America, the industry's trade group, supports monitoring of prescription drugs if proper safeguards are in place. "We do have a concern when the system is so heavy-handed that a physician is reluctant to write a prescription for a pain medication when it's truly needed," said Marjorie Powell, attorney for Pharmaceutical Research and Manufacturing.

Federal and State Privacy Concerns

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.

At the federal level, opponents point to the privacy regulations related to the Health Insurance Portability and Accountability Act of 1996 (HIPAA) as a possible barrier to the adoption of this system. Specifically, they point to the HIPAA Privacy Rule, which sets standards for how protected health information should be controlled by setting forth what uses and disclosures are authorized or required and what rights patients have with respect to their health information.

However, the privacy rule has explicit provisions that allow the disclosure of this type of protected health information without consent or authorization of the patient in several circumstances, including in situations where a state law is necessary for the purposes of serving a compelling public health, safety, or welfare need. Based on discussions with state and federal experts, the disclosure of protected health information as required in HB 397 is allowable under HIPAA..

This interpretation is consistent with earlier case law that allowed states to collect such information. Specifically, in 1977, the United States Supreme Court ruled that the New York statutes that required a copy of each written prescription of certain drugs be submitted to the Department of Health a reasonable exercise of the state's board police powers as long as the information is kept private; and that finding the state had not shown a necessity for the requirement was insufficient basis for holding the statutes unconstitutional, as set forth in *Whalen v. Roe,* 429 U.S. 589, 97S.CT.869 (1997).

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

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

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

Unlike the penumbra or "implicit" privacy right of the federal constitution, Florida's privacy provision is, in and of itself, a fundamental one that, once implicated, demands evaluation under a compelling state interest standard. The federal privacy provision, which contains a "penumbra" right of privacy created from the 1st, 3rd, 4th, 5th, and 9th amendments to the U.S. Constitution, extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and educating of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the federal constitution. See, In re T.W., 551 So.2d 1186 (Fla. 1989).

C. SECTION DIRECTORY:

Section 1. Creates s. 831.311, F.S., to prohibit the sell, manufacture, alteration, delivery, uttering, or possession of counterfeit-resistant prescription blanks for control substances; and providing penalties.

Section 2. Amends s. 893.04, F.S., to provide additional requirements for the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV, and providing rulemaking authority to the Board of Pharmacy.

Section 3. Creates s. 893.055, F.S., to require the Department of Health to establish an electronic system to monitor the prescribing of controlled substances listed in Schedules II, III, and IV, effective June 30, 2005; creates requirements for the reporting of dispensing controlled substances through the system; provides exceptions; provides reporting requirements; provides penalties; provides rulemaking authority to the department; require the department to cover all cost for the system; and includes a sunset provision for the tracking system of June 30, 2008.

Section 4. Creates s. 893.065, F.S., to require the department to develop and adopt by rule the form and content for a counterfeit-proof prescription blank for voluntary use by physicians to prescribe a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

Section 5. Appropriates $2,196,352 from the Grants and Donations Trust Fund to the Department of Health for fiscal year 2004-2005, and authorizes three full-time equivalent positions for implementing the provisions of ss. 893.055 and 893.065, Florida Statutes, as created by this act.

Section 6. Provides penalties upon the adoption by the Department of Health and each applicable professional regulatory board of the rules required pursuant to ss. 893.055(7) and 893.065, Florida Statutes, as created by this act.

Section 7. If a person dies of an apparent drug overdose, the bill requires that a law enforcement agency shall prepare a report, which shall be provided to the medical examiner, identifying each prescribed controlled substance which is found on or near the deceased or among the deceased's possession, and requires that the law enforcement agency identify the person who prescribed the drugs; requires that a medical examiner include in his or her report pursuant to s. 406.11, F.S., information identifying any Schedule II, Schedule III, or Schedule IV drug which is found in, on, or near the deceased or among the deceased's possessions.

Section 8. Provides an effective date of July 1, 2005, except as otherwise provided within the bill and if the linked bill (HB 399) is adopted.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None

2. Expenditures:

   According to the Department of Health (DOH), total expenditures needed to implement the act are $2,057,784 (FY 2004-05), $2,682,750 (FY 2005-06) and $3,584,168 (FY 2006-07). DOH will incur costs to design and establish an electronic prescription monitoring system and to develop counterfeit-resistant prescription blanks in Florida for controlled substances listed in Schedules II, III, and IV.

   Funding will come 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. Additional funds will be available through application for various grants.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   None

2. Expenditures:

None

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

HB 397 w/CS will directly affect all pharmacies in the state holding a community pharmacy permit through the associated costs of purchasing, installing, and maintaining any required software to transmit the reporting data. Pharmacy patients will most likely feel an indirect affect. Practitioners opting to use the proposed counterfeit-proof prescription blank will likely pay a higher price than for customary prescription blanks.

Third-party payers may see a reduction in the number of claims for controlled substance prescriptions as prescribers and dispensers have information available to indicate if a patient is currently receiving other controlled substance products that elicit the same therapeutic effect.

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.

D. FISCAL COMMENTS:

The department will be encumbered with initial and recurring expenses to develop, implement, and maintain the monitoring system. There will also be associated costs to promulgate policies and rules for the electronic monitoring system.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

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

2. Other:

The bill requires the Department of Health to determine by rule the data required to be reported under the prescription monitoring system, and such data may include any data required under section 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 punishable by jail up to 1 year and a fine of up to $1,000.

To the extent the bill does not state what data must be reported and delegates that function to the Department of Health, there is an issue as to whether the legislative delegation to the department constitutes a proper delegation. This also raises an issue on 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.

As previously mentioned, the act also raises questions relative to the privacy protections in Florida's Constitution. In Article I, Section 23, the Constitution provides as follows:

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

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

Unlike the penumbra or "implicit" privacy right of the federal constitution, Florida's privacy provision is, in and of itself, a fundamental one that, once implicated, demands evaluation under a compelling state interest standard. The federal privacy provision, which contains a "penumbra" right of privacy created from the 1st, 3rd, 4th, 5th, and 9th amendments to the U.S. Constitution, extends only to such fundamental interests as marriage, procreation, contraception, family relationships, and the rearing and educating of children. Since the people of this state have exercised their prerogative and enacted an amendment to the Florida Constitution that expressly and succinctly provides for a strong right of privacy not found in the United States Constitution, it is much broader in scope than that of the Federal Constitution. Subsequently, the court has consistently held that article I, section 23 was adopted in an effort to grant Floridians greater privacy protection than that available under the federal constitution. See, In re T.W., 551 So.2d 1186 (Fla. 1989).

B. RULE-MAKING AUTHORITY:

This bill requires the Department of Health and the Board of Pharmacy to promulgate rules.

C. DRAFTING ISSUES OR OTHER COMMENTS:

Subsection (9) of section 893.055 as created in the bill is meant to create a penalty for the knowing and willful disclosure and misuse of the data contained in the electronic monitoring system by anyone with access to the system. This language creates a conflict with subsection (6) in the same section, which creates a penalty for a provider not reporting into the system.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On February 4, 2004, the Subcommittee on Health Standards adopted three amendments to the bill, and then reported the bill favorably to the Committee on Health Care. The amendments include the following:

Amendment #1—Requires the Department of Health to establish an electronic monitoring system for controlled substances by January 1, 2005. The department has provided a fiscal analysis of the amendment's effect. By moving the date from June 20, 2005 to January 1, 2005, the department estimates that implementation and operational cost for the system would increase from $2,057,784 to $4,044,502 in FY 2004-05, $2,682,750 to $3,020,854 in FY 2005-06, and $3,584,168 to $3,758,059 FY 2006-07.

Amendment #2—Requires the electronic monitoring system to be operational by January 1, 2005.

Amendment #3—Establishes an effective date for s. 893.055, F.S., of January 1, 2005.

On March 11, 2004, the Committee on Health Care, by request of the sponsor, removed the amendments recommended by the subcommittee on a negative roll call vote. The Committee on Health Care adopted three amendments to the bill as originally filed, and then reported the bill favorably. The amendments include the following:

Amendment #4—Requires law enforcement to record any identified Schedule II, Schedule III, or Schedule IV drugs found on or near a person whose death is an apparent drug overdose, which shall be reported to the medical examiner; and requires a medical examiner preparing his or her report pursuant to section 406.11, F.S., to include in the report information identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV which is found in, on, or near the deceased, or among the deceased possessions.

Amendment #5—Requires the Secretary of the Department of Health to ensure only authorized department employees have access to the information in the electronic monitoring system created by this act.

Amendment #6—Provides penalties for violating the section; removes liability for accessing or failing to access the information for any practitioner or pharmacists authorized to obtain information from the electronic monitoring system; and requires that authorized persons who obtain information from the electronic information system authorized by this provision shall maintain the confidentiality of such information pursuant to ss. 456.057 and 465.017, F.S., or as otherwise required by law.

On April 14, 2004, the Subcommittee on Health Appropriations adopted one amendment to the bill, and then reported the bill favorably to the Committee on Appropriations. The amendment clarified that it is a third degree felony for anyone to willfully or knowingly disclose or use the information in electronic monitoring system for a purpose other than the intended purpose of the electronic monitoring system.