HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 989 w/CS Controlled Substances
SPONSOR(S): Harrell
TIED BILLS: HB 997 **IDEN./SIM. BILLS:** SB 2390(s), SB 1784(c)

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1) Health Standards (Sub)	5 Y, 2 N	Rawlins	Collins
2) Health Care	19 Y, 1 N w/CS	Rawlins	Collins
3) Public Safety & Crime Prevention	17 Y, 0 N	Kramer	De La Paz
4) Health Appropriations (Sub)			
5) Appropriations			

SUMMARY ANALYSIS

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 893.002, F.S., delineates those practitioners who may prescribe or dispense controlled substances. Practitioners authorized to prescribe controlled substances, providing such licensees hold a valid federal controlled substance registry number, include: medical physicians, osteopathic physicians, podiatric physicians, naturopaths, dentists, and veterinarians. These practitioners may also dispense controlled substances. Pharmacists licensed under Chapter 465, F.S., may dispense, but may not prescribe controlled substances.

This bill expands the regulation of prescribing and dispensing controlled substances to minimize the diversion and abuse of prescription drugs. Provisions include:

- additional requirements for the dispensing of a controlled substance;
- the establishment of an electronic system to monitor the prescribing of controlled substances; and
- requiring 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 for an unspecified appropriation from general revenue to the Department of Health for 2003-2004 to cover the cost incurred by the department in implementing the counterfeit-resistant prescription blanks.

The bill provides a continuing appropriation for implementing the prescription monitoring system from General Revenue and specifies that the Medical Quality Assurance Trust Fund may not be used to fund the system.

According to the Department of Health, the total fiscal impact is $2,196,352 for FY 03-04 and $2,545,390 for FY 04-05.

The bill provides an effective date of July 1, 2004, except as otherwise provided.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. DOES THE BILL:

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

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

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.

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:

Controlled Substances

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 893.002, F.S., delineates those practitioners who may prescribe or dispense controlled substances. Practitioners authorized to prescribe controlled substances, providing such licensees hold a valid federal controlled substance registry number, include: medical physicians (chapter 458, F.S.), osteopathic physicians (chapter 459, F.S.), podiatric physicians (chapter 461, F.S.), naturopaths (chapter 462, F.S.), dentists (chapter 466, F.S), and veterinarians (chapter 474, F.S.). These practitioners may also dispense controlled substances. Pharmacists licensed under Chapter 465, F.S., may dispense, but may not prescribe controlled substances.

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Dispensing controlled substances: The bill imposes limitations, restrictions, and requirements upon the dispensing of a controlled substance by a pharmacist. Currently, 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. The bill specifies that an emergency supply of a Schedule II controlled substance dispensed is limited to no more than that required for a 72-hour period. Current law provides that oral prescriptions must be promptly reduced to writing by the pharmacist.[1] The bill provides that a controlled substance listed in Schedule III or IV may be dispensed upon an oral prescription if, before filing the prescription, the pharmacist reduces it to writing and indicates the date of the oral authorization. The bill further provides that a pharmacist may not dispense more than a 30-day supply of a Schedule III controlled substance based on an oral prescription.

[1] s. 893.04(1)(a), F.S.

The bill specifies that all written prescriptions for a Schedule II, III or IV controlled substance must include both a written and a numerical notation of the quantity on the face of the prescription and a notation of the date with the abbreviated month written on the face of the prescription.

The bill provides that a pharmacist, prior to dispensing a controlled substance listed in Schedule II, Schedule III, or Schedule IV to an individual, must obtain suitable identification for the patient or the patient's agent and must only dispense a controlled substance if the prescription is considered valid by the pharmacist. If the patient or the patient's agent does not have appropriate identification, the pharmacist may dispense the controlled substance only if the pharmacist determines that the order is valid and includes such information in the patient's record. The requirement for patient identification is not required by pharmacist filling prescriptions by mail.

Electronic Monitoring System: 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 specifies that the Department of Health shall design the system. 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 through the system as soon as possible but not more than 30-days after the date the controlled substance is dispensed. The reporting is limited and excludes a practitioner that:

- directly administers the drug;
- dispenses directly to the patient for a period of no more than 72 hours;
- dispenses (by a practitioner or pharmacist) to an inpatient of a facility with an institutional pharmacy;
- orders from an institutional pharmacy;
- dispenses to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled; or
- prescribes for a patient less than 16 years of age.

The bill allows the Department of Health to specify the data required to be reported under this section and requires a dispenser submit the information to the department in an electronic format. As well, the bill 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 disks;
- zip driver storage;
- regular electronic mail;
- magnetic tapes;
- diskettes; and
- facsimile charges.

The bill provides that the information submitted to the department as provided for in section 2 of HB 997 (tied bill)[2] or similar legislation may be transmitted and allows the department to maintain the

[2] HB 997 currently provides that all information and records reported under s. 893.055 which would identify a patient or practitioner are confidential and exempt from the provisions of s. 119.07(1), F.S. and s. 24(a), Article I of the state constitution. The bill authorizes the Department of Health to disclose a patient's or practitioner's identity to:

1. A practitioner who requests information and certifies that it is necessary to provide medical treatment to a current patient, subject to the patient's written consent. The practitioner is permitted to designate one person in his or her office to access the information and provide it to the practitioner.
2. A pharmacist who requests information and certifies that it is to be used to dispense controlled substances.
3. A criminal justice agency which is engaged in a specific investigation involving a violation of law.
4. An employee or agent of the Department of Health who is involved in a specific investigation.
5. An employee of the Agency for Health Care Administration who is involved in an investigation relating to Medicaid.

information for up to 24 months, unless there is an ongoing investigation, before purging it from its records and specifies that all transmittals comply with relevant federal and state privacy and security laws. The bill specifies that any person who knowingly fails to report the required information commits a misdemeanor of the first degree, punishable by incarceration for up to one year..

Counterfeit-resistant prescription blanks: The bill specifies that the department shall develop counterfeit-resistant prescription blanks that may be used by practitioners to prescribe controlled substances. The bill also provides that it is a third degree felony for any person with intent to injure or defraud any person or to facilitate any violation of s. 893.13, relating to sale of controlled substances, to sell, manufacture, alter, deliver or possess any counterfeit-resistant prescription blanks for controlled substances. The maximum sentence for a third degree felony is five years in prison.

The bill further provides that the penalty provisions of the bill do not apply until the Department of Health and each applicable professional regulatory board adopts rules required by the bill.

Appropriations: The bill provides a continuing appropriation for implementing the prescription monitoring system from General Revenue and specifies that the Medical Quality Assurance Trust Fund may not be used to fund the system.

The bill provides for an unspecified appropriation from general revenue to the Department of Health for 2003-2004 to cover the cost incurred by the department in implementing the counterfeit-resistant prescription blanks.

Background Information provided by staff of Committee on Health Care :
Abuse of prescription drugs is rising rapidly in the United States. An estimated 9 million people[3] 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. The National Institute on Drug Abuse would like to reverse this trend by increasing awareness and promoting additional research on this 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 - opioids, 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. This estimate includes substance abuse treatment and prevention costs as well as other healthcare 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).

As well, the White House Office of National Drug Control Policy (ONDCP) conducted a study to determine how much money is spent on illegal drugs that otherwise would support legitimate spending or savings by the user in the overall economy. ONDCP found that, between 1988 and 1995, Americans spent $57.3 billion on drugs, broken down as follows: $38 billion on cocaine, $9.6 billion on heroin, $7 billion on marijuana, and *$2.7 billion on other illegal drugs and on the misuse of legal (prescription) drugs.*

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6. The patient, for purposes of verifying the information for accuracy.

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

COMMONLY ABUSED PRESCRIPTION DRUGS

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

- *Opioids.* Opioids 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 opioids 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 opioids 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* - used to treat anxiety and sleep disorders. CNS depressants slow down normal brain function. In higher doses, some CNS depressants 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.

- 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 is 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. As well, 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, over time, note 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 U.S. have specifically addressed the profile of a Doctor Shopper. However, a search of international data produced a report and findings from a study in Australia which indicated that most Doctor Shoppers shop 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[4]most Doctor Shoppers have their prescriptions dispensed at few pharmacies.

Frequent reasons used by Doctor Shoppers to obtain medicines are:

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

Doctor Shoppers’ age and gender: data showed that:

- 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 aged over 65 years; and
- 58% are female.

[4] www.hic.gov.au

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.

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 over 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 is comprised of 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; and

- 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

The 15 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 others are considering them, and advocates are pushing for a *national system to link the state databases.*

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 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.

THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

HIPAA is the acronym for the Health Insurance Portability and Accountability Act of 1996. The Centers for Medicare & Medicaid Services (CMS) is responsible for implementing various unrelated provisions of HIPAA, therefore HIPAA may mean different things to different people.

- HIPAA Health Insurance Reform, Title I of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) protects health insurance coverage for workers and their families when they change or lose their jobs.

- The Administrative Simplification provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA, Title II) require the Department of Health and Human Services to establish national standards for electronic health care transactions and national identifiers for providers, health plans, and employers. It also addresses the security and privacy of health data. It is anticipated that adopted standards will improve the efficiency and effectiveness of the nation's health care system by encouraging the widespread use of electronic data interchange in health care. The Final Rule adopting HIPAA standards for the security of electronic health information was published in the Federal Register on February 20, 2003. This final rule specifies a series of administrative, technical, and physical security procedures for covered entities to use to assure the confidentiality of electronic protected health information. The standards are delineated into either required or addressable implementation specifications

Health care providers and health care clearinghouses must assure their customers (for example, patients, insured individuals, providers, and health plans) that the integrity, confidentiality, and availability of electronic protected health information they collect, maintain, use, or transmit is protected.

The confidentiality of health information is threatened not only by the risk of improper access to stored information, but also by the risk of interception during electronic transmission of the information. According to the Centers for Medicare and Medicaid (CMS) currently, no standard measures exist in the health care industry that address all aspects of the security of electronic health information while it is being stored or during the exchange of that information between entities. The final rule adopted standards as required under Title II, subtitle F, sections 261 through 264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Pub. L. 104–191. These standards require measures to be taken to secure this information while in the custody of entities covered by HIPAA (covered entities) as well as in transit between covered entities and from covered entities to others.

Congress included provisions to address the need for safeguarding electronic health information and other administrative simplification issues in HIPAA. Section 1173(d) of the Act requires the Secretary of the Department of Health and Human Services (HHS) to adopt security standards that take into account:

- the technical capabilities of record systems used to maintain health information;
- the costs of security measures;
- the need to train persons who have access to health information;
- the value of audit trails in computerized record systems; and
- the needs and capabilities of small health care providers and rural health care providers.

Section 1173(d) of the Act also requires that the standards ensure that a health care clearinghouse, if part of a larger organization, has policies and security procedures that isolate the activities of the clearinghouse with respect to processing information as to prevent unauthorized access to health

information by the larger organization. Covered entities that maintain or transmit health information are required to:

- maintain reasonable and appropriate administrative, physical, and technical safeguards to ensure the integrity and confidentiality of the information and to protect against any reasonably anticipated threats or hazards to the security or integrity of the information; and
- unauthorized use or disclosure of the information.

The rule requires that each covered entity (as now described in § 160.102) engaged in the electronic maintenance or transmission of health information pertaining to individuals assess potential risks and vulnerabilities to such information in its possession in electronic form, and develop, implement, and maintain appropriate security measures to protect that information. Importantly, these measures would be required to be documented and kept current.

The HIPPA security standards were based on three basic concepts that were derived from the Administrative Simplification provisions of HIPAA:

- First, the standard should be comprehensive and coordinated to address all aspects of security.
- Second, it should be scalable, so that it can be effectively implemented by covered entities of all types and sizes.
- Third, it should not be linked to specific technologies, allowing covered entities to make use of future technology advancements.

Security and privacy are inextricably linked. The protection of the privacy of information depends in large part on the existence of security measures to protect that information. It is noteworthy that there are several distinct differences between the HIPPA Privacy Rule and the Security Rule:

- The security standards define administrative, physical, and technical safeguards to protect the confidentiality, integrity, and availability of electronic protected health information. The standards require covered entities to implement basic safeguards to protect electronic protected health information from unauthorized access, alteration, deletion, and transmission.
- The Privacy Rule, by contrast, 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.

The security rule narrows the scope of the information to which the safeguards must be applied from that of the privacy rule, electronic health information pertaining to individuals, to protected health information in electronic form. Thus, the scope of information covered in this rule is consistent with the Privacy Rule, which addresses privacy protections for ‘‘protected health information.’’ However, the scope of the Security Rule is more limited than that of the Privacy Rule. The Privacy Rule applies to protected health information in any form, whereas this rule applies only to protected health information in electronic form.[5]

Office for Civil Rights

The privacy provisions of the federal law, the Health Insurance Portability and Accountability Act of 1996 (HIPAA), apply to health information created or maintained by health care providers who engage in certain electronic transactions, health plans, and health care clearinghouses. The Department of Health and Human Services (HHS) has issued the regulation, "Standards for Privacy of Individually Identifiable Health Information," applicable to entities covered by HIPAA. The Office for Civil Rights (OCR) is the Departmental component responsible for implementing and enforcing the privacy regulation.

[5] http://www.cms.hhs.gov/hipaa

C. SECTION DIRECTORY:

Section 1. Creates s. 831.311, F.S., prohibiting the sale, 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., providing 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., requiring the department to establish an electronic system to monitor the prescribing of controlled substances listed in Schedules II, III, and IV; requiring the dispensing of such controlled substances to be reported through the system; providing exceptions; providing reporting requirements; providing penalties; providing rulemaking authority to the department; requiring the department to cover all cost for the system; and providing a continuing appropriation

Section 4. Creates s. 893.065, F.S., requiring 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 from the General Revenue Fund to the Department of Health for fiscal year 2003-2004 an amount sufficient to cover the costs incurred by the department in implementing the provisions of ss. 893.055 and 893.065, Florida Statutes, as created by this act.

Section 6. The penalties created in ss. 831.311(2) and 893.055(6), Florida Statutes, by this act shall be effective only 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. Provides an effective date of July 1, 2004, except as otherwise provided within the bill.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

   None.

2. Expenditures:

   According to the Department of Health:

   Total Fiscal Impact: FY 03-04 - $2,196,352
   FY 04-05 - $2,545,390

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

   This bill does not appear to have a fiscal impact on local governments

2. Expenditures:

   This bill does not appear to have a fiscal impact on local governments.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

This bill 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.

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:

In Whalen v. Roe, 429 U.S. 589, 97 S.Ct.869 (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 were a reasonable exercise of the state's broad police powers and did not violate a patient's constitutionally protected "zone of privacy".

Article I, section 23 of the Florida Constitution contains an explicit right of privacy as follows:

> Right of privacy.--Every natural person has the right to be let alone and free from governmental intrusion into his 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.

The Florida Supreme Court has determined that this "amendment embraces more privacy interests, and extends more protection to the individual in those interests, than does the federal Constitution." In re T.W., 551 So.2d 1186 (Fla. 1989). It is possible that the provisions of this bill could be challenged on privacy grounds – particularly if a court finds that the system developed by the department contains inadequate security provisions to protect the prescription records. Currently, section 893.07 allows law enforcement officers to inspect and copy pharmacy records. The legislature adopted this provision in 1973 and there has been no report court decision challenging the statute on privacy grounds.

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 s. 893.04, F.S., and must include the category of professional licensure of the prescribing practitioner. The bill imposes criminal penalties for any person who knowingly fails to report the dispensing of a controlled substance listed in Schedule II, Schedule III, or Schedule IV as required by this bill. Such persons are liable for a first degree misdemeanor 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, it raises an issue as to whether the legislative delegation to the department to by rule determine what data must be reported constitutes a proper

delegation. The delegation 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.

In addressing the question "how much of a role may administrative agencies take in defining the elements of a crime," the Florida Supreme Court has declared that Article I, Section 18 of the Florida Constitution which states that no administrative agency shall impose sentence of imprisonment nor shall it impose any other penalty except as provided by law, though speaking only to quasi-adjudicatory powers of some administrative agencies, nevertheless embodies an overall constitutional policy that administrative agencies may not create criminal statute or its equivalent and prescribe the penalty. See B.H. v. State, 645 So.2d 987, 46 A.L.R. 5th 877 (1994), certiorari denied 115 S.Ct. 2559, 515 U.S. 1132, 132 L.Ed.2d 812.

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:

None.

IV. AMENDMENTS/COMMITTEE SUBSTITUTE CHANGES

On March 27, 2003, the Subcommittee on Health Standards reported the bill favorably to the Committee on Health Care with a "strike everything amendment and 2 amendments to the amendment.

Amendment 1 is a strike-all amendment and represents a preliminary compromise of all the stakeholders, creating s. 831.311, F.S., specifying that it is unlawful to sell, manufacture, alter, deliver, utter or possess counterfeit-resistant prescription blanks for controlled substances, and provides a felony penalty of the third degree which provides: pursuant to s. 775.082, F.S., a fine of up to $5000; pursuant to s. 775.083, F.S., imprisonment up to 5 years; and pursuant to s. 775.084, F.S., extension of either fines or imprisonment for habitual felony offenders.

The amendment amends s. 893.04, F.S., specifying that no prescription for a controlled substance listed in Schedule III, Schedule IV, or Schedule V may be filled or refilled more than 5 times within a period of six months after the date on which the prescription was written unless the prescription is renewed by a practitioner.

Also, the amendment specifies that a pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any individual without first obtaining suitable identification and documenting in writing or electronic format the identity of the individual, specifying the data elements for identification purposes. Creates an exception of when the lack of identification is appropriate. The amendment gives the Board of Pharmacy the authority to adopt rules procedures for a pharmacist to verify the validity of a prescription for a controlled substance. In addition, the amendment speaks to the situation when dispensing a controlled substance by mail.

The amendment requires that a pharmacist must reduce to writing an oral prescription for a Schedule III or Schedule IV controlled substance and specifies that all written prescriptions

issued for a Schedule II, Schedule III, or Scheduled IV prescription must include both a written and numerical notation of the quantity on the face of the prescription and a notation of the date and month written out on the face of the prescription. The provisions of the amendment limit the pharmacist to dispensing no more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription, limits the pharmacist liability that may unknowingly fill a prescription that has been forged for a controlled substance.

The amendment creates s. 893.055, F.S., providing for the electronic monitoring system for the prescription of controlled substances listed in Schedules II, III, and IV, and specifying that the Department of Health shall design the system. The amendment 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 30-days after the date the controlled substance is dispensed. The reporting is limited and excludes a practitioner that:

- directly administers the drug;
- dispenses directly to the patient for a period of no more than 72 hours;
- dispenses (by a practitioner or pharmacist) to an inpatient of a facility with an institutional pharmacy;
- orders from an institutional pharmacy;
- dispenses to a patient or resident receiving care from a hospital, nursing home, assisted living facility, home health agency, hospice, or intermediate care facility for the developmentally disabled; or
- prescribes for a patient less than 16 years of age.

The amendment allows the Department of Health to specify the data required to be reported under this section and requires a dispenser submit the information to the department in an electronic format. As well, the amendment 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 disks;
- zip driver storage;
- regular electronic mail;
- magnetic tapes;
- diskettes; and
- facsimile charges.

Authorizes that the information submitted to the department as provided for in section 2 of HB 997 (tied bill) or similar legislation may be transmitted and allows the department to maintain the information up to 12 months, unless there is an ongoing investigation, before purging it from its records and specifies that all transmittals comply with relevant federal and state privacy and security laws. The amendment specifies that any person who knowingly fails to report the required information commits a misdemeanor of the first degree.

The amendment specifies that the department shall develop the counterfeit-resistant prescription blanks for controlled substances that may be used by practitioners to prescribe controlled substances.

The amendment specifies an undetermined general revenue appropriation for 2003-2004 to cover the cost incurred by the department in implementing the provisions of ss. 893.055 and 893.065, F.S., the monitoring system and counterfeit-resistant prescription blanks.

The amendment limits the penalty provisions of the bill until the Department of Health adopts rules.

Amendments 2 and 3 to the "strike everything" amendment provide that oral prescriptions may be reduced to a written format or recorded electronically if permitted by federal law.

On April 9, 2003, the Committee on Health Care adopted a substitute amendment and reported the bill favorably with a committee substitute.