**The Florida Senate**

# BILL ANALYSIS AND FISCAL IMPACT STATEMENT

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

Prepared By: The Professional Staff of the Governmental Oversight and Accountability Committee

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| BILL: | CS/CS/CS/SB 462 |
| INTRODUCER: | Governmental Oversight and Accountability Committee, Judiciary Committee, Health Regulation Committee, and Senator Fasano |
| SUBJECT: | Controlled Substances/Prescription Monitoring |
| DATE: | April 2, 2009 REVISED: |

| | ANALYST | STAFF DIRECTOR | REFERENCE | ACTION |
|---|---|---|---|---|
| 1. | Munroe | Wilson | HR | **Fav/CS** |
| 2. | Sumner | Maclure | JU | **Fav/CS** |
| 3. | Naf | Wilson | GO | **Fav/CS** |
| 4. | | | HA | |
| 5. | | | | |
| 6. | | | | |

## Please see Section VIII. for Additional Information:

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| A. COMMITTEE SUBSTITUTE..... | X | Statement of Substantial Changes |
| B. AMENDMENTS..... | | Technical amendments were recommended |
| | | Amendments were recommended |
| | | Significant amendments were recommended |

## I. Summary:

The bill requires the Department of Health (DOH), by December 1, 2010, to design and establish a comprehensive electronic system to monitor the prescribing and dispensing of certain controlled substances. The bill requires prescribers and dispensers of certain controlled substances to report specified information to the DOH for inclusion in the system.

The bill provides exemptions from the data reporting requirements for controlled substances that are administered, dispensed, or ordered in specified settings or for specified categories of patients. Data regarding the dispensing of each controlled substance must be submitted to the DOH, by a procedure and in a format established by the DOH, and must include minimum information specified in the bill. Any person who knowingly fails to report the dispensing of a controlled substance commits a first-degree misdemeanor.

The Office of Drug Control, in coordination with the DOH, is authorized to establish a direct-support organization to provide assistance, funding, and promotional support for activities authorized for the prescription drug validation program. The bill creates a 10-member Program Implementation and Oversight Task Force within the Executive Office of the Governor to

monitor the implementation and safeguarding of the electronic system established for the prescription drug validation program.

The bill provides immunity from liability for prescribers and dispensers who in good faith receive and use information from the prescription drug validation program. A person may not recover damages against a prescriber or dispenser authorized to access information under the drug validation program for accessing or failing to access such information.

The bill requires each physician who practices in a privately owned pain-management facility that primarily engages in the treatment of pain by prescribing narcotic medications to register the facility with the DOH, unless it is a Florida-licensed hospital, ambulatory surgical center, or mobile surgical facility.

This bill creates section 893.055, Florida Statutes, and one undesignated section of law. The bill amends sections 458.309 and 459.005, Florida Statutes.

## II. Present Situation:

### Prescription-Drug-Monitoring Programs

In an effort to control the diversion of controlled substances, 38 states have enacted legislation establishing prescription-drug-monitoring programs (32 of the programs are currently operational)[1]. 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-drug-monitoring programs 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-drug-monitoring programs 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-drug-monitoring programs 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, New York, and Texas are the only states to require the use of a single-copy, serialized prescription form.

### Efforts of the Agency for Health Care to Promote Electronic Prescribing

Under the authority provided in ss. 408.061 and 408.0611, F.S., the Agency for Health Care Administration (AHCA) has collected information on the benefits of electronic prescribing and manages a clearinghouse of information on electronic prescribing. Electronic prescribing allows providers to exchange health information that integrates data on prescription medicine from pharmacy benefits managers, payers, and pharmacies. Electronic prescribing may provide a

[1] United States Department of Justice, Drug Enforcement Administration, Office of Diversion Control. See "A closer Look at State Prescription Monitoring Programs," at http://www.deadiversion.usdoj.gov/faq/rx_monitor.htm (Last visited on March 22, 2009).

means for prescribing practitioners to improve the coordination of patient drug therapy and quality of care. During 2008 the AHCA, in collaboration with other stakeholders, developed a proposal to conduct a pilot project that would demonstrate the patient safety benefits of the electronic prescribing of controlled substances. The ACHA will see funding to support this study in 2009.[2]

**Controlled Substances**

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

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

"Prescription" is defined under s. 893.02(20), F.S., to mean and include an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04, F.S. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription.

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice only, to dispense controlled substances upon a written or oral prescription under

[2] Agency for Health Care Administration, *Senate Bill 462 Bill Analysis* (2009) (on file with the Senate Committee on Judiciary).

specified conditions. An oral prescription for controlled substances must be promptly reduced to writing by the pharmacist. The written prescription must be dated and signed by the prescribing practitioner on the day when issued. There must appear on the face of the prescription or written record for the controlled substance: the full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed; the full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number must be printed thereon; if the prescription is for an animal, the species of animal for which the controlled substance is prescribed; the name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof; the number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled; 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 a controlled substance is filled to retain the prescription on file for a period of two years. The section requires the original container in which a controlled substance is dispensed to bear a label with specified information.

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

**Office of Drug Control**

Section 397.332, F.S., specifies the duties of the Office of Drug Control. The Office of Drug Control is created within the Executive Office of the Governor. The Governor must appoint a director of the Office of Drug Control, who is subject to confirmation by the Florida Senate. The purpose of the Office of Drug Control is to work in collaboration with the Office of Planning and Budgeting to:

- Coordinate drug control efforts and enlist the assistance of the public and private sectors in those efforts, including, but not limited to, federal, state, and local agencies.
- Provide information to the public about the problem of substance abuse and the substance abuse programs and services that are available.
- Act as the Governor's liaison with state agencies, other state governments, the federal Office of National Drug Control Policy, federal agencies, and with the public and private sectors on matters that relate to substance abuse.
- Work to secure funding and other support for the state's drug control efforts, including, but not limited to, establishing cooperative relationships among state and private agencies.
- Develop a strategic program and funding initiative that links the separate jurisdictional activities of state agencies with respect to drug control. The office may designate lead and contributing agencies to develop such initiatives.
- Advise the Governor and the Legislature on substance abuse trends in this state, the status of current substance abuse programs and services, the funding of those programs and services, and the status of the Office of Drug Control in developing and implementing the state drug control strategy.
- Make recommendations to the Governor on measures that the director considers advisable for the effective implementation of the state drug control strategy.

**Health Insurance Portability and Accountability Act of 1996**

The 1996 Health Insurance Portability and Accountability Act (HIPAA)[3] required the Administration 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 only apply to health plans, health care clearinghouses and certain health care providers. The regulations permit states to afford greater privacy protections to health information.[4] Exceptions for state law are provided for public health and state regulatory reporting.[5]

**American Society for Automation in Pharmacy**

The American Society for Automation in Pharmacy assists its members with the application of computer technology in pharmacy.[6] The society promotes the application of computer technology in the pharmacist's role as caregiver and the efficient operation and management of a pharmacy.[7] The society's membership includes independent and hospital pharmacies, state boards of pharmacy, and government agencies. The society has adopted standards for prescription monitoring programs.

## III. Effect of Proposed Changes:

**Whereas Clauses**

The bill includes a number of "whereas clauses" that provide justification for the establishment of the prescription drug validation program and the other provisions of the bill.

**Prescription Drug Validation Program**

The bill requires the Department of Health (DOH), by December 1, 2010, to design and establish a comprehensive electronic system for controlled substance prescriptions. The system must be designed to provide information regarding dispensed prescriptions of controlled substances in order to prevent the inadvertent, improper, or illegal use of controlled substances and may not infringe upon the legitimate prescribing of a controlled substance by a prescribing practitioner, dispensing pharmacist, or dispensing practitioner acting in good faith and in the course of professional practice.

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[3] Section 262 of the Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, enacted on August 21, 1996, directed the United States Department of Health and Human Services to develop standards to protect the security, including the confidentiality and integrity, of health information.

[4] Sections 160.201, 160.203, 160.204, and 160.205, C.F.R.

[5] The federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) generally preempts state health information privacy laws, unless they provide a higher level of protection than the act. (Pub. L. No.104-191, s. 262, 110 Stat. 1936, 2029.) However, these state privacy provisions may not be preempted if the Secretary of Health and Human Services determines that the state law has as its principal purpose the regulation of the manufacture, registration, distribution, dispensing, or other control of any controlled substances (as defined in 21 U.S.C. s. 802), or that is deemed a controlled substance by state law. (45 C.F.R. s. 160.203 (a)(2)). See also, 42 U.S.C.A s. 1320d-7.

[6] See the website of the American Society for Automation in Pharmacy at http://www.asapnet.org/index.html (Last visited on March 22, 2009).

[7] *Id.*

The system must be consistent with standards of the American Society for Automation in Pharmacy for the validation of prescribing and dispensing controlled substances to an individual. The electronic system must also comply with the Health Insurance Portability and Accountability Act (HIPAA) and all other relevant state and federal privacy and security laws and regulations. The validating of prescribed controlled substances must include a dispensing transaction with a dispenser who is not located in Florida but who is otherwise subject to the jurisdiction of Florida regarding that dispensing transaction.

The system will provide prescription information to a patient's health care practitioner and, as determined by the DOH rule, advisory reports to authorized pharmacies, prescribing practitioners, and dispensing health care practitioners. Advisory reports are written information concerning the dispensing of controlled substances provided by the DOH to a prescriber, dispenser, pharmacy, or patient. The advisory reports are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report. A person who participates in the preparation of an advisory report is not permitted or may not be required to testify in any civil action regarding any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing the report.

The DOH must adopt rules concerning the reporting, accessing, evaluation, management, development, implementation, and storage of information within the system, including rules for when information is provided to pharmacies, prescribers, health care practitioners, health care regulatory boards, and law enforcement agencies. The rules must be developed with a reasonable-person standard for prescription drug dispensers, prescribers, and patients. The DOH must work with professional licensure boards and other appropriate organizations, including the Attorney General, the Florida Department of Law Enforcement, and the Agency for Health Care Administration, to develop the reasonable-person standard for rules appropriate for the prescription drug validation program.

The DOH must notify all dispensers and prescribers subject to the reporting requirements of the implementation date for the reporting requirements. The DOH must adopt rules to implement the prescription drug validation program by October 1, 2010.

The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance must submit to the electronic system, by a procedure and in a format established by the DOH, the following minimum information for inclusion in the database:

- The name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification or other appropriate identifier, and the date of the prescription.
- The date the prescription was filled and the method of payment.
- The name, address, and date of birth of the person for whom the prescription was written.
- The name, national drug code, quantity, and strength of the controlled substance dispensed.
- The name and address of the pharmacy or other location from which the controlled substance was dispensed.

- The name of the pharmacy or practitioner other than a pharmacist dispensing the controlled substance and the practitioner's National Provider Identification.
- Other appropriate identifying information as determined by the DOH rule.

A dispensing practitioner or pharmacy must report to the DOH data regarding controlled substances subject to the requirements of the validation system as soon as possible, but not more than 15 days after the date the controlled substance is dispensed, each time that such controlled substance is dispensed. The bill provides that a pharmacy or dispensing practitioner must meet the reporting requirements by providing the information to the DOH concerning each controlled substance in a DOH-approved, secure methodology and format. The formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail. The bill provides that the cost to the dispenser in submitting the required information may not be material or extraordinary as specified in the bill.

The bill creates exceptions to the reporting requirements for controlled substances that are:

- Administered by a health care practitioner directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular session;
- Dispensed by a pharmacist or administered by a health care practitioner to a patient or resident receiving care as an admitted patient or resident at a hospital, nursing home, hospice, or intermediate care facility for the developmentally disabled which is licensed in Florida;
- Administered to a person in the health care system of the Department of Corrections;
- Administered in the emergency room of a licensed hospital;
- Administered by a health care practitioner to a person under the age of 16; or
- Dispensed by a pharmacist or a dispensing practitioner as a one-time, 72-hour emergency resupply of a controlled substance to a patient.

The DOH may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.

A pharmacy, prescriber, or dispenser may access information in the prescription drug validation program's electronic system which relates to a patient of that pharmacy, prescriber, or dispenser for the purpose of reviewing the patient's controlled drug prescription history. Other access to the program's electronic system shall be limited to the program's manager and designated program staff, who may act only in the absence of the program manager. Access by the program manager or such designated staff is only for prescription drug program management and for management of the database. The information submitted to the DOH under the prescription drug validation program may be transmitted to any person or agency authorized to receive it, and that person or agency may maintain the information received for up to 24 months before purging the information from its records. All required transmissions must comply with relevant federal and state privacy and security laws. However, any authorized agency receiving such information may maintain the information for a period longer than 24 months if the information is pertinent to an ongoing investigation or prosecution.

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

The DOH must report performance measures as specified in the bill by each December 1, beginning in 2011. The DOH staff may request data without identifying information so that the DOH may undertake public health care and safety initiatives that take advantage of observed trends. The Program Implementation and Oversight Task Force may request data without identifying information for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives.

All costs incurred by the DOH for the prescription drug validation program, shall be reimbursed through federal, private, or grant funding applied for by the State of Florida. The establishment and implementation of the prescription drug validation program are contingent upon receipt of the nonstate funding, and specific legislative appropriation may not be used to fund the program. The DOH and state government must cooperate in seeking grant funds and other funding for the DOH so long as the costs of doing so are not considered material. The DOH must comply with the competitive-solicitation requirements for the procurement of any goods or services required to implement the prescription drug validation program.

**Direct-Support Organization**

The Office of Drug Control, in coordination with the DOH, may establish a direct-support organization to provide assistance, funding, and promotional support for activities authorized for the prescription drug validation program. The director of the Office of Drug Control must appoint a board of directors for the direct-support organization. Members of the board serve at the pleasure of the director. The direct-support organization may operate under written contract with the Office of Drug Control. The bill specifies the requirements of the contract executed between the Office of Drug Control and the direct-support organization, which include:

- Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.
- Submission of an annual budget for the approval of the Office of Drug Control.
- Annual certification by the Office of Drug Control in consultation with the DOH that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug validation program and in the best interest of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.
- Reversion, without penalty, to the Office of Drug Control, or to the state if the Office of Drug Control ceases to exist, of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug validation program if the direct-support organization ceases to exist or if the contract is terminated.
- The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.
- The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an

explanation to such donors of the distinction between the Office of Drug Control and the direct-support organization.

The direct-support organization is specifically authorized to collect and expend funds to be used for the functions of the organization's board of directors; establishing and administering the prescription drug validation program's electronic database; conducting studies on the efficiency and effectiveness of the program; providing funds for future enhancements of the program; providing health care practitioner education; providing funds for travel expenses and administrative costs; and fulfilling all other requirements needed to establish the program.

The activities of the direct-support organization must be consistent with the goals and mission of the Office of Drug Control, as determined by the office in consultation with the DOH, and in the best interests of Florida. The direct-support organization must obtain a written approval from the director of the Office of Drug Control for any activities in support of the prescription drug validation program before undertaking those activities. The Office of Drug Control, in consultation with the DOH, may permit, without charge, appropriate use of administrative services, property, and facilities of the Office of Drug Control and the department by the direct-support organization, as specified in the bill.

The direct-support organization must have an independent annual audit that must be provided to the Office of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.

**Prescriber or Dispenser Immunity from Liability**

A prescriber or dispenser is authorized access to the information under the prescription drug validation program for his or her patient for his or her review of the patient's controlled drug prescription history to ensure a proper standard of care. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug validation program. The bill does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under the drug validation program for accessing or failing to access such information.

**Feasibility Study and Training**

To the extent that funding is provided, the Office of Drug Control may study the feasibility of enhancing the prescription drug validation program for the purposes of public health initiatives and statistical reporting The direct-support organization must provide funding for the DOH, in collaboration with the Office of Drug Control, to conduct training for health care practitioners and other appropriate persons in using the program to support the program enhancements.

**Identification of Persons Acquiring Controlled Substances**

The bill requires a pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person who is not known to the dispenser, to require the person to present valid photographic identification or other verification of his or

her identity to the dispenser. If the person does not have proper identification, the bill allows the dispenser to verify the identity and the validity of the prescription for controlled substances through alternate means. The bill requires pharmacies and dispensers to maintain a record for two years of the person acquiring the controlled substance, which includes the person's name and signature using proper identification. "Proper identification" means a government-issued identification containing the person's picture, printed name, and signature. Institutional settings, long-term care facilities, and hospitals are exempt from the requirement to obtain proper identification.

**Electronic Prescribing**

The bill requires the Agency for Health Care Administration (AHCA) to continue implementing electronic prescribing by health care practitioners, health care facilities, and pharmacies, and the electronic prescribing clearinghouse.

**Program Implementation and Oversight Task Force**

The bill creates a 10-member Program Implementation and Oversight Task Force within the Executive Office of the Governor to monitor the implementation and safeguarding of the electronic system established for the prescription drug validation program. The task force must also ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law enforcement agencies, and those authorized to request information from the electronic system. The Office of Drug Control must submit a report to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1 of each year which contains a summary of the work and recommendations of the task force during that year. On July 1, 2012, a final report must be provided to the Governor, the President of the Senate, and the Speaker of the House of Representatives. The workgroup expires on July 1, 2012.

**Registration of Pain-Management Facilities**

The bill requires each privately owned pain-management facility that employs a physician licensed under ch. 458 who is primarily engaged in the treatment of pain by prescribing controlled substance medications to register the facility with the DOH unless it is a Florida-licensed hospital, ambulatory surgical center, or mobile surgical facility. A physician is primarily engaged in the treatment of pain by prescribing narcotic medications when the majority of the patients seen on any day the facility is open are issued narcotic prescriptions for the treatment of nonmalignant pain.

The bill requires the DOH to inspect each pain-management facility annually to ensure that it complies with Board of Medicine rules adopted pursuant to s. 458.309(4) and (5), F.S., as proposed in the bill, unless the facility is accredited by a nationally recognized accrediting agency approved by the Board of Medicine.

The bill requires the Board of Medicine to adopt rules setting forth standards of practice for physicians practicing in privately owned pain-management facilities that primarily engage in the treatment of pain by prescribing controlled substance medications. The bill specifies criteria that

the Board of Medicine rules must address: facility operations; physical operations; infection control requirements; health and safety requirements; quality assurance requirements; patient records; training requirements for all facility health care practitioners; and inspections.

The actual costs for registration and inspection or accreditation of a pain-management facility shall be paid by the physician seeking to register the facility.

**Effective Date**

The bill provides an effective date of July 1, 2009.

## IV. Constitutional Issues:

### A. Municipality/County Mandates Restrictions:

The provisions of this bill have no impact on municipalities and the counties under the requirements of Article VII, Section 18 of the Florida Constitution.

### B. Public Records/Open Meetings Issues:

An exemption to the Public Records Law for identifying information of patients, practitioners, and pharmacists in the information and reports held by the DOH is being addressed in separate legislation (CS/SB 440).

### C. Trust Funds Restrictions:

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

### D. Other Constitutional Issues:

**Access to Courts**

The bill grants immunity from any civil, criminal, or administrative liability to a prescriber or dispenser acting in good faith for liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug validation program. To the extent that this immunity imposes a possible barrier to a litigant's right to seek redress it raises questions about possible infringements on the right of access to the courts. Section 21, Art. I of the State Constitution provides that the courts shall be open to all for redress for an injury. To impose a barrier or limitation on litigants right to file certain actions it would have to meet the test announced by the Florida Supreme Court in *Kluger v. White*.[8] Under the constitutional test established by the Florida Supreme Court in *Kluger v. White*, the Legislature would have to: (1) provide a reasonable alternative remedy or commensurate benefit, or (2) make a legislative showing of overpowering public necessity for the abolishment of the right and no alternative method of meeting such public necessity.

[8] See *Kluger v. White*, 28 So.2d 1 (Fla. 1973).

**Delegation of Rulemaking**

On lines 225-245, the bill specifies that the DOH must adopt rules concerning the reporting, evaluation, management, and storage of information within the system, including rules for when information is provided to pharmacies, prescribers, health care practitioners, health care regulatory boards, and law enforcement agencies, and such rules must be developed with a "reasonable-person standard" for prescription drug dispensers, prescribers, and patients. The bill requires the DOH to work with various entities to develop the "reasonable-person standard" for rules appropriate for the prescription drug validation program. It is unclear what "reasonable-person standard" means in the context of delegated legislative rulemaking authority.

Under its rulemaking authority delegated by the Legislature, the DOH is authorized to define terms for which it is implementing duties conferred upon it. To the extent that the bill does not provide sufficient guidelines to the DOH, it raises the question of whether the bill provides adequate limitations and safeguards so that the Legislature's delegation to the DOH is not a violation of Section 3, Article II of the Florida Constitution.

Under the nondelegation doctrine, the Florida Supreme Court struck down a former section of law respecting the power of the Board of Psychological Examiners to grant certificates with the title "psychologist" and to determine the qualifications of applicants as unconstitutional, in that it failed sufficiently to fix the standards to be applied and in effect delegated the application of the statute without sufficient limitations on the board's discretion.[9]

Section 3, Article II of the Florida Constitution provides that the powers of the state government shall be divided into legislative, executive, and judicial branches. No person belonging to one branch shall exercise any powers appertaining to either of the other branches unless expressly provided herein. The Florida Supreme Court recently reiterated the requirements of the nondelegation doctrine:

> [U]nder article II, section 3 of the constitution the Legislature 'may not delegate the power to enact a law or the right to exercise unrestricted discretion in applying the law.'[10] This prohibition, known as the nondelegation doctrine, requires that 'fundamental and primary policy decisions . . . be made by members of the [L]egislature who are elected to perform those tasks, and [that the] administration of legislative programs must be pursuant to some minimal standards and guidelines ascertainable by reference to the enactment establishing the program."[11]

[9] See *Husband v. Cassel*, 130 So.2d 69 (1961).
[10] See *Bush v. Schiavo*, 885 So.2d 321, 331 (Fla. 2004) (citing *Sims v. State*, 754 So.2d 657, 668 (Fla.2000)).
[11] See *Bush v. Schiavo*, 885 So.2d 321, 332 (Fla. 2004) (citing *Askew v. Cross Key Waterways*, 372 So.2d 913, 925 (Fla.1978)).

The Florida Supreme Court has acknowledged that "[w]here the Legislature makes the fundamental policy decision and delegates to some other body the task of implementing that policy under adequate safeguards, there is no violation of the [Delegation of Powers] doctrine."[12] "In other words, statutes granting power to the executive branch 'must clearly announce adequate standards to guide . . . in the execution of the powers delegated. The statute must so clearly define the power delegated that the [executive branch] is precluded from acting from whim, showing favoritism, or exercising unbridled discretion."[13]

## V. Fiscal Impact Statement:

### A. Tax/Fee Issues:

The bill requires the physician who registers a pain-management facility to pay for the actual costs for registration and inspection of the facility. The bill does not establish the amount of the fee or authorize the DOH to set the fee within a specified range.

### B. Private Sector Impact:

Pharmacies and other dispensers will incur costs to comply with the reporting requirements under the prescription drug validation program. The bill provides that such costs may not be material or extraordinary. Costs not considered to be material or extraordinary under the bill include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

### C. Government Sector Impact:

The DOH will incur costs to implement the bill; however, the bill requires all costs incurred by the DOH for the prescription drug validation program to be reimbursed through federal grants or private funding applied for or received by the State of Florida.

Section 287.057(5)(f)6., F.S., provides an exemption for contractual services and commodities that are otherwise subject to the competitive-bid requirements of that section of law if the services or commodities are health services involving examination, diagnosis, treatment, prevention, medical consultation, or administration. The bill provides that, notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(5)(f), F.S., the DOH must comply with the competitive solicitation requirements for the procurement of any goods or services required under the bill.

During federal fiscal year 2008, the Florida Department of Children and Families received a $50,000 funding grant from the U.S. Department of Justice under its Developing and Enhancing Prescription Drug Monitoring Programs.

[12] See *Askew v. Cross Key Waterways*, 372 So.2d 913 at 921. (Fla.1978).
[13] See *Bush v. Schiavo*, 885 So.2d 321, 332 citing *Lewis v. Bank of Pasco County*, 346 So.2d 53, 55-56 (Fla.1976).

## VI. Technical Deficiencies:

None.

## VII. Related Issues:

Lines 162-194 provide definitions for use in the bill. The bill amends ch. 893, F.S., the Florida Comprehensive Drug Abuse Prevention and Control Act, which already provides definitions for the chapter for various terms, including, "dispense," "practitioner," and "prescription." These terms as used in the chapter are comparable to those in the bill and appear to be redundant and confusing. For instance, the term "health care practitioner" as defined in the bill includes medical physicians, osteopathic physicians, naturopathic physicians, podiatric physicians, and dentists but excludes veterinarians who also prescribe and may also dispense controlled substances under ch. 893, F.S.

## VIII. Additional Information:

A. Committee Substitute – Statement of Substantial Changes:
(Summarizing differences between the Committee Substitute and the prior version of the bill.)

**CS/CS/CS by Governmental Oversight and Accountability on March 31, 2009:**
Editorial and clarifying changes are made to the bill. The entities to and the circumstances in which confidential and exempt information shall be released are revised. The exemptions from the reporting requirements are revised. The access of a pharmacy, prescriber, or dispenser to information in the database to review a patient's controlled substance prescription history is no longer restricted to the sole purpose of ensuring a proper standard of care. The documents constituting "proper identification" necessary for receiving controlled substances are revised. The amendments to ss. 458.309 and 459.005, F.S., are revised for clarification. The subjects that the Board of Medicine must promulgate rules to address under ss. 458.309 and 459.005, F.S., are revised.

**CS/CS by Judiciary on March 25, 2009:**
The definition of "department" is deleted from the definitions section of the bill. The rulemaking language for the department is amended to include rules for accessing, developing, and implementing information within the electronic system. The responsibility to submit information to the electronic system is now that of the "pharmacy" rather than the "pharmacist" dispensing controlled substances. The bill adds language to provide that the establishment and implementation of the prescription drug validation program is contingent upon receipt of the nonstate funding, and that specific legislative appropriation may not be used to fund the program. The bill amends the name of the Governor's 10 member group to monitor the implementation and safeguarding of the electronic system from "workgroup" to "task force."

**CS by Health Regulation on March 4, 2009:**
The DOH, rather than the AHCA, is required to implement a prescription drug validation program. The prescription drug monitoring program is renamed to the prescription drug validation program. The design and establishment of the program is revised to include the assistance of a workgroup and direct support organization. The bill grants immunity from

any civil, criminal, or administrative liability to a prescriber or dispenser acting in good faith for liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug validation program. The bill requires physicians to register pain-management facilities with the DOH.

B. Amendments:

None.