A bill to be entitled

An act relating to a prescription drug validation program; creating s. 893.055, F.S.; providing definitions; requiring the Department of Health to establish a comprehensive electronic system to monitor the prescribing and dispensing of certain controlled substances; requiring specified prescribing and dispensing information to be reported to the electronic system; requiring the department, in conjunction with specified organizations, to adopt rules concerning requirements for data to be submitted according to a reasonable person standard; providing a reporting period; providing for department review of the feasibility of reducing the reporting period after a specified date; providing for implementation of a shorter reporting period; providing exemptions from participation in the system; providing for suspension of reporting during declared emergencies; requiring all nonexempt pharmacists, pharmacies, dispensing physicians, or prescribing and dispensing health care practitioners to submit information in a prescribed format; providing that the cost to the dispenser in submitting the information required may not be material or extraordinary; providing that specified costs are not material or extraordinary; limiting access to the system; providing for use of data for specified purposes; requiring compliance with state and federal privacy and security laws; requiring the reporting of certain performance measures; providing criminal penalties for violations; requiring that all

costs incurred by the department for the program be paid through a federal grant or through available private funding sources; requiring the Office of Drug Control, in coordination with the department, to establish a direct-support organization; providing a definition; providing for a board of directors appointed by the director of the Office of Drug Control; providing contract requirements; authorizing certain activities and expenditures of the direct-support organization; providing requirements for the use of certain facilities and services; providing for audits; prohibiting the direct-support organization from exercising certain powers; establishing that a prescribing health care practitioner, dispensing physician, or pharmacist is not liable for use of the department-provided controlled substances prescription information of a patient; requiring a study of the feasibility of enhancing the prescription drug validation program for specified purposes; requiring certain persons to present specified identification to obtain prescriptions; providing for recordkeeping for certain transactions; requiring the Agency for Health Care Administration to continue implementation of electronic prescribing and an electronic prescribing clearinghouse; requiring rulemaking; establishing a Program Implementation and Oversight Workgroup; providing for membership; providing for reimbursement of certain member expenses; providing for meetings; providing purposes; requiring reports; providing for the creation, membership, and duties of

subcommittees; providing for a final report and termination of the workgroup; providing an effective date.

WHEREAS, as has been advocated by numerous pain management experts, addiction medicine experts, pharmacists, and law enforcement personnel, a prescription drug validation program that provides for reporting and advisory information is established pursuant to this act to serve as a means to promote the public health and welfare and to detect and prevent controlled substance abuse and diversion, and

WHEREAS, while the importance and necessity of the proper prescribing, dispensing, and monitoring of controlled substances, particularly pain medication, have been established, controlled prescription drugs are too often diverted in this state, often through fraudulent means, including outright theft, phony pharmacy fronts, loose Internet medical evaluations, and inappropriate importation; in addition, there is a criminal element that facilitates the prescription drug abuse epidemic through illegal profitmaking from the diversion of certain controlled substances that are prescribed or dispensed by physicians, health care practitioners, and pharmacists, and

WHEREAS, in 2007, 8,620 drug-related deaths occurred in this state, 3,159 of which were caused by the abuse of prescription drugs, an average of nearly 9 Floridians dying each day from prescription drug abuse; Schedule IV benzodiazepines, such as Xanax and Valium, were found to be present in more drug-related deaths than cocaine; and opiate pain medications contribute to increasing numbers of drug-related deaths, and

WHEREAS, pharmaceutical drug diversion hurts this state significantly in terms of lost lives, increased crime, human misery from addiction, and ballooning health care costs connected to treatment, medical expenses, and Medicaid fraud that all Floridians ultimately bear, and

WHEREAS, the intent of this act is not to interfere with the legitimate medical use of controlled substances; however, the people of this state are in need of and will benefit from a secure and privacy-protected statewide electronic system of specified prescription drug medication information created primarily to encourage safer controlled substance prescription decisions that reduce the number of prescription drug overdoses and the number of drug overdose deaths; to educate and inform health care practitioners and provide an added tool in patient care, including appropriate treatment for patients who have become addicted; to guide public health initiatives to educate the population on the dangers of misusing prescription drugs; to prevent the abuse or diversion of prescribed controlled substances; and to ensure that those who need prescribed controlled substances receive them in a manner that protects patient confidentiality, and

WHEREAS, while certain medicines are very helpful if properly prescribed to a patient in need and then used as prescribed, they may be dangerous or even deadly if improperly dispensed, misused, or diverted, and

WHEREAS, it is the intent of the Legislature to encourage patient safety, responsible pain management, and proper access to useful prescription drugs that are prescribed by a

knowledgeable, properly licensed health care practitioner who dispenses prescription drugs and that are dispensed by a pharmacist who is made aware of the patient's prescription drug medication history, thus preventing, in some cases, an abuse or addiction problem from developing or worsening, making such a problem possible or easier to identify, and facilitating the order of appropriate medical treatment or referral, and

WHEREAS, a Program Implementation and Oversight Workgroup will provide information to the Governor and Legislature regarding the implementation of the program, and

WHEREAS, such an electronic system will also aid administrative and law enforcement agencies in ongoing controlled drug-related investigations, maintaining such information for any such investigation with a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future, NOW, THEREFORE,

Be It Enacted by the Legislature of the State of Florida:

Section 1. Section 893.055, Florida Statutes, is created to read:

893.055 Prescription drug validation program.--

(1) As used in this section, the term:

(a) "Advisory report" means information provided by the department in writing to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber,

dispenser, pharmacy, or patient. The advisory reports issued by the department 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 the matters that are the subject of the report, and no person who participates in preparing an advisory report is permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with preparing such a report.

(b) "Controlled substance" means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c) "Department" means the Department of Health.

(d) "Dispenser" means a dispensing pharmacist or dispensing health care practitioner.

(e) "Health care practitioner" or "practitioner" means any practitioner subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, or chapter 466.

(f) "Pharmacy" means any pharmacy subject to licensure or regulation by the department under chapter 465 that dispenses or delivers a controlled substance to a patient in this state.

(g) "Prescriber" means a prescribing physician or other prescribing health care practitioner.

(2)(a) By December 1, 2010, the department shall design and establish a comprehensive electronic system that has controlled substance prescriptions provided to it and that provides prescription information and, as determined by the

department, may provide advisory reports to authorized pharmacists, pharmacies, prescribing practitioners, and dispensing health care practitioners. The system shall be designed to provide information regarding the prescription of controlled substances in order to prevent the inadvertent, improper, or illegal use of controlled substances and shall 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. The system shall 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 shall also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI) and electronic protected health information (EPHI). The validating of prescribed controlled substances shall include a dispensing transaction with a dispenser not located in this state but is otherwise subject to the jurisdiction of this state as to that dispensing transaction.

(b) The department shall 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, and such rules shall be developed with a reasonable person standard for prescription drug dispensers and prescribers. The department shall work with the professional health care licensure boards

and other appropriate organizations, such as health care associations, including those relating to pain management, the Florida Prosecuting Attorneys Association, the Florida Association of Criminal Defense Lawyers, the Attorney General, the 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.

(c) All dispensers and prescribers subject to such reporting requirements shall be notified by the department of the implementation date for such reporting requirements.

(3) The pharmacist-in-charge of each pharmacy, regarding each controlled substance dispensed by a pharmacist under the supervision of the pharmacist-in-charge, and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department, the following minimum information for inclusion in the database:

(a) The name of the prescribing practitioner and the practitioner's federal Drug Enforcement Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b) The date the prescription was filled and the method of payment therefor, including cash. This paragraph does not authorize the department to include individual credit card or other account numbers in the database.

(c) The name, address, and date of birth of the person for whom the prescription was written.

(d) The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e) The name and address of the pharmacy or other location from which the controlled substance was dispensed.

(f) The name of the pharmacist or practitioner dispensing the controlled substance, the practitioner's National Provider Identification (NPI), and other appropriate identifying information as determined by department rule.

(4) Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 15 days after the date the controlled substance is dispensed. One year after the date dispensers begin providing information to the electronic system, the department shall assess the feasibility of reducing the period in which the controlled substance information must be submitted after it is dispensed. If a shorter reporting period is appropriate, the department shall implement such reporting period after notification to dispensers. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved methodology and format. Such approved formats may include, but are not limited to, electronic submission via the Internet or on disc.

(5) The following are exempt from this section when administering controlled substances:

(a) A health care practitioner administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(b) A pharmacist or health care practitioner administering a controlled substance to a patient or resident receiving care as an admitted patient at a hospital, nursing home, hospice, or intermediate care facility for the developmentally disabled that is licensed in this state.

(c) A person administering a controlled substance in the health care system of the Department of Corrections.

(d) A person administering a controlled substance in the emergency room of a licensed hospital.

(e) A pharmacist or health care practitioner administering a controlled substance to a person under the age of 16.

(6) The department may suspend requirements for reporting dispensing information to the electronic system of controlled prescription drugs during a state-declared or nationally declared disaster.

(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other format approved by rule of the department. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b) A pharmacy, prescriber, or dispenser may access information in the prescription drug validation program's electronic system that relates to a patient of that pharmacy, prescriber, or dispenser for the purpose of reviewing the patient's controlled drug prescription history to ensure a proper standard of care. 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 management and for management of the database. Confidential and exempt information in the database shall only be released as provided in s. 893.0551.

(c) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations.

(8) To assist in fulfilling the program responsibilities, performance measures shall be reported annually by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

(a) Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b) Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

(c) Increased coordination among prescription drug validation program partners.

(d) Involvement of stakeholders in achieving improved patient health care and reduction of prescription drug abuse and prescription drug diversion.

(9) Any person who knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10) All costs incurred by the department in administering the prescription drug validation program shall be reimbursed through federal or private grant funding applied for or received by the state. The department and state government shall cooperate in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial cost for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant.

(11) The Office of Drug Control, in coordination with the department, shall establish a direct-support organization to provide assistance, funding, and promotional support for the

activities authorized for the prescription drug validation program.

(a) As used in this subsection, the term "direct-support organization" means an organization that is:

1. A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2. Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures to or for the direct or indirect benefit of the department in the furtherance of the prescription drug validation program.

(b) The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c) The director of the Office of Drug Control shall appoint a board of directors for the direct-support organization. The director may designate employees of the Office of Drug Control and any state agency, other than the Department of Health, to serve on such board. Members of the board shall serve at the pleasure of the director of the Office of Drug Control.

(d) The direct-support organization may operate under written contract with the Office of Drug Control. The contract must provide for:

1. Approval of the articles of incorporation and bylaws of the direct-support organization by the Office of Drug Control.

2. Submission of an annual budget for the approval of the Office of Drug Control.

3. Certification by the Office of Drug Control in consultation with the department 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.

4. The 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.

5. The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

6. 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.

(e) The direct-support organization is specifically authorized to collect and expend funds to be used for the functions of the direct-support organization's board of

directors, as necessary; establishing and administering the prescription drug validation program's electronic database, including hardware, software, and personnel; conducting studies on the efficiency and effectiveness of the program; providing funds for future enhancements of the program within the intent of this section; providing health care practitioner education, including distribution of materials to promote public awareness and education and conducting workshops or other meetings; travel expenses; administrative costs, including personnel, audits, facilities, and equipment; and all other requirements necessary to establish the program as outlined in this section.

(f) 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 department, and in the best interests of the state. 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.

(g) The Office of Drug Control, in consultation with the department, 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, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with opportunities for the public to use such facilities for established purposes. Any moneys received

from rentals of facilities and properties managed by the Office of Drug Control and the department may be held by the Office of Drug Control or in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the Office of Drug Control. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the Office of Drug Control if the direct-support organization is no longer approved by the Office of Drug Control to operate in the best interests of the state.

(h) The Office of Drug Control, in consultation with the department, may adopt requirements with which a direct-support organization must comply in order to use department and Office of Drug Control administrative services, property, or facilities.

(i) The Office of Drug Control may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, sex, age, or national origin.

(j) The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the Office of Drug Control and the Office of Policy and Budget in the Executive Office of the Governor.

(k) The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

(12) A prescriber or dispenser is authorized access to the information under this section 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. This subsection 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 this subsection for accessing or failing to access such information.

(13) To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department, in collaboration with the Office of Drug Control, shall study the feasibility of enhancing the prescription drug validation program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving prescription drug prescribing practices, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. In addition, the direct-support organization shall provide funding for the department, 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.

(14) A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, prior to releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance 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 dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent, or by a method determined by the department, before dispensing the controlled substance. The person purchasing, receiving, or otherwise acquiring the controlled substance does not have to be the specific patient to whom the prescription is prescribed. A record shall be maintained for 2 years of the person acquiring the controlled substance, which record shall include the person's name and signature using the proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means a government-issued identification containing the person's picture, printed name, and signature.

(15) The Agency for Health Care Administration shall continue the implementation of electronic prescribing by health care practitioners, health care facilities, and pharmacies under

s. 408.061 and the electronic prescribing clearinghouse collaboration with the private sector under s. 408.0611.

(16) By October 1, 2010, the department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this section, including rules governing access to the database.

Section 2. (1) The Program Implementation and Oversight Workgroup is created within the Executive Office of the Governor. The director of the Office of Drug Control shall be a nonvoting, ex officio member of the workgroup and shall act as chair. The Office of Drug Control and the Department of Health shall provide staff support for the workgroup.

(a) The following state officials shall serve on the workgroup:

1. The Attorney General or his or her designee.

2. The Secretary of Children and Family Services or his or her designee.

3. The Secretary of Health Care Administration or his or her designee.

4. The State Surgeon General or his or her designee.

(b) In addition, the Governor shall appoint nine members of the public to serve on the workgroup. Of these nine appointed members, one member must have professional or occupational expertise in computer security; one member must be a licensed, board-certified oncologist; one member must be a licensed, board-certified, fellowship-trained physician who has experience in pain management; one member must have professional or occupational expertise in e-Prescribing or prescription drug

validation programs; one member must be a licensed, board-certified pharmacist with professional or occupational expertise in pharmacy operations; one member must have professional or occupational expertise in law enforcement with experience in prescription drug investigations; one member must have professional or occupational expertise as an epidemiologist with a background in tracking and analyzing drug trends; and two members must have professional or occupational expertise as providers of substance abuse treatment, with priority given to a member who is a former substance abuser.

(c) Members appointed by the Governor shall be appointed to a term of 3 years each. Any vacancy on the workgroup shall be filled in the same manner as the original appointment, and any member appointed to fill a vacancy shall serve only for the unexpired term of the member's predecessor.

(d) Members of the workgroup and members of subcommittees appointed under subsection (4) shall serve without compensation but are entitled to reimbursement for per diem and travel expenses as provided in s. 112.061, Florida Statutes.

(e) The workgroup shall meet at least quarterly or upon the call of the chair.

(2) The purpose of the workgroup is to monitor the implementation and safeguarding of the electronic system established for the prescription drug validation program under s. 893.055, Florida Statutes, and to ensure privacy, protection of individual medication history, and the electronic system's appropriate use by physicians, dispensers, pharmacies, law

enforcement, and those authorized to request information from the electronic system.

(3) The Office of Drug Control shall 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 that contains a summary of the work of the workgroup during that year and the recommendations developed in accordance with the workgroup's purpose as provided in subsection (2). Interim reports may be submitted at the discretion of the chair.

(4) The chair of the workgroup shall appoint subcommittees that include members of state agencies that are not represented on the workgroup for the purpose of soliciting input and recommendations from those state agencies as needed by the workgroup to accomplish its purposes. In addition, the chair may appoint subcommittees as necessary from among the members of the workgroup in order to efficiently address specific issues. If a state agency is to be represented on any subcommittee, the representative shall be the head of the agency or his or her designee. The chair may designate lead and contributing agencies within a subcommittee.

(5) The workgroup shall provide a final report in accordance with the workgroup's purpose as provided in subsection (2) on July 1, 2012, to the Governor, the President of the Senate, and the Speaker of the House of Representatives. Such report may only be prepared using data that does not identify a patient or dispenser. The workgroup shall expire and this section is repealed on that date.

Section 3. This act shall take effect July 1, 2009.