By the Committee on Health Regulation; and Senators Fasano and Gaetz

588-02727A-10 20101722c1

A bill to be entitled

An act relating to the prescription drug monitoring program; amending s. 893.055, F.S.; requiring that the comprehensive electronic database system containing information concerning prescriptions of controlled substances comply with the minimum requirements for authentication and certification of the National All Schedules Prescription Electronic Reporting Act; requiring the Department of Health to provide reports from the prescription drug monitoring program to the Department of Law Enforcement; requiring the Department of Health, after consultation with the Department of Law Enforcement and other associations, to adopt rules; requiring the Department of Health to establish a method to allow corrections to the program database; revising the information to be submitted to the program database by a pharmacy or prescriber; revising the acts of dispensing or administering controlled substances which are exempt from reporting; requiring a pharmacy, prescriber, practitioner, or dispenser to register with the Department of Health in order to obtain certain information from the prescription drug monitoring program; requiring the program manager and certain other individuals who have access to the prescription drug monitoring program database to submit fingerprints to the Department of Health; requiring the Department of Health to follow the proper procedures established by the Department of Law Enforcement to request state and national criminal

history record checks; prohibiting the Agency for Health Care Administration from having direct access to information in the prescription drug monitoring program database for purposes of Medicaid fraud cases or investigations; requiring a patient, legal guardian, or designated health care surrogate to provide the patient's phone number and a copy of a government-issued photo identification in order to verify information in the prescription drug monitoring program database; authorizing the State Surgeon General to enter into agreements with other states to exchange prescription drug monitoring information after specified conditions are met; providing factors for considering such agreements; limiting the purposes for which information may be shared under such agreements; amending s. 893.0551, F.S.; authorizing the disclosure of information in the prescription drug monitoring program under certain conditions; providing an effective date.

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

Section 1. Subsections (2), (3), (5), and (7) of section 893.055, Florida Statutes, are amended, and subsection (8) is added to that section, to read:

893.055 Prescription drug monitoring program.—

(2)(a) By December 1, 2010, the department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that

provides prescription information to a patient's health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser 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 (ASAP). The electronic system shall also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), the National All Schedules Prescription Electronic Reporting (NASPER) Act's minimum requirements for authentication of a practitioner that requests information in the prescription drug monitoring program database and certification of the purpose for which information is requested, and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise

subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b)1. The department's prescription drug monitoring program shall:

a. Provide reports directly to the Department of Law Enforcement without review by the department or a regulatory board so that the Department of Law Enforcement may investigate whether any violation of law has occurred regarding controlled substances in Schedule II, Schedule III, or Schedule IV; and

b. Report, if applicable, the information to the appropriate state attorney or other law enforcement agency in accordance with state law.

The parameters for such reports shall be adopted by rule of the department and developed after consultation with the Department of Law Enforcement, the Florida Medical Association, and the Florida Osteopathic Medical Association.

2. The department, when the direct support organization receives at least $20,000 in nonstate moneys or the state receives at least $20,000 in federal grants for the prescription drug monitoring program, and in consultation with the Office of Drug Control, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of

information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Office of Drug Control, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

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

(d) The department shall establish a method to allow corrections to the database when notified by a health care practitioner or pharmacist.

(3) The pharmacy dispensing the controlled substance 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 and consistent with an ASAP-approved format, the following information for inclusion in the database:

(a) The name of the prescribing practitioner, 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, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.

(c) The full 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 full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f) The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g) Other appropriate identifying information as determined by department rule.

(h) The number of refills ordered and whether the drug was dispensed as a refill of a prescription or was a first-time request.

(5) When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(a) A health care practitioner when 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 when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

~~(c) A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.~~

(c)~~(d)~~ A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

(d)~~(e)~~ A health care practitioner when administering ~~or dispensing~~ a controlled substance directly to a patient ~~person~~ under the age of 16 if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(e)~~(f)~~ A pharmacist or a dispensing practitioner when dispensing a one-time, 48-hour ~~72-hour~~ emergency resupply of a controlled substance to a patient.

(7)(a) A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. 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)1. In order for a pharmacy, prescriber, practitioner, or dispenser to ~~shall~~ have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, practitioner, or dispenser, the pharmacy, prescriber, practitioner, or dispenser shall register with the department by submitting a registration document provided by the department ~~in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history~~. The registration document must be notarized before it is submitted to the department. Before a pharmacy, prescriber, practitioner, or dispenser is granted access to information in the prescription drug monitoring program's database, the submitted document must be approved by the department. Upon approval, the department shall grant the registrant access to the appropriate information in the prescription drug monitoring program's database.

2. Other access to the program's database shall be limited to the program ~~program's~~ manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt

information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the prescription drug monitoring program database must submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

(c) Except as provided in subparagraph (2)(b)1., the following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:

1. The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled

substance investigation involving a designated person for one or more prescribed controlled substances.

2. The Attorney General or the Agency for Health Care Administration for Medicaid fraud cases or Medicaid investigations involving prescribed controlled substances.

3. A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4. A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The patient's phone number and a copy of a government-issued photo identification must be provided in person to the program manager along with the notarized request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate

regulatory board.

(d) The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:

1. Department staff for the purpose of calculating performance measures pursuant to subsection (8).

2. The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.

(e) All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

(8) After the prescription drug monitoring system has been operational for 18 months, the State Surgeon General shall enter into reciprocal agreements for the sharing of prescription drug monitoring information with any other state or states that have compatible prescription drug monitoring programs. If the State

Surgeon General evaluates the prescription drug monitoring program of another state as authorized in this subsection, priority shall be given to a state that is contiguous with the borders of this state.

(a) In determining compatibility, the State Surgeon General shall consider:

1. The essential purposes of the program and the success of the program in fulfilling those purposes.

2. The safeguards for privacy of patient records and the success of the program in protecting patient privacy.

3. The persons authorized to view the data collected by the program.

4. The schedules of the controlled substances monitored.

5. The data required to be submitted on each prescription.

6. Any implementation criteria deemed essential for a thorough comparison.

(b) The State Surgeon General shall review any agreement on an annual basis to determine its continued compatibility with the prescription drug monitoring program in this state.

(c) Any agreement between the State Surgeon General and another state shall prohibit the sharing of information about a resident of this state or a practitioner, pharmacist, or other prescriber for any purposes not otherwise authorized by this section or s. 893.0551.

Section 2. Present subsections (4), (5), and (6) of section 893.0551, Florida Statutes, are renumbered as subsections (5), (6), and (7), respectively, and a new subsection (4) is added to that section, to read:

893.0551 Public records exemption for the prescription drug

monitoring program.—

(4) The department may disclose confidential and exempt information contained in records held by the department under s. 893.055 if the State Surgeon General has entered into a reciprocal agreement for the sharing of prescription drug monitoring information with any other state that has compatible prescription drug monitoring programs, as provided under s. 893.055(8).

Section 3. This act shall take effect July 1, 2010.