FOR CONSIDERATION By the Committee on Health Policy

588-01843A-16 20167038pb

A bill to be entitled

An act relating to controlled substances; amending s. 456.42, F.S.; authorizing certain controlled substances to be electronically prescribed; amending s. 499.0121, F.S.; deleting a specified requirement in the performance of due diligence of purchasers by prescription drug wholesalers; amending s. 893.055, F.S.; authorizing the designee of a pharmacy, prescriber, or dispenser to access a patient's record in the prescription drug monitoring program's database for a specified purpose; authorizing an impaired practitioner consultant to access an impaired practitioner program participant's or referral's record in the prescription drug monitoring program's database; reenacting and amending s. 893.0551, F.S.; authorizing the designee of a health care practitioner, pharmacist, pharmacy, prescriber, or dispenser and an impaired practitioner consultant to receive certain information from the prescription drug monitoring program; providing an effective date.

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

Section 1. Subsection (2) of section 456.42, Florida Statutes, is amended to read:

456.42 Written prescriptions for medicinal drugs.—

(2) A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated in numerical, month/day/year format, or with the abbreviated month written out, or the month written out in whole, and must be either written on a standardized counterfeit-proof

prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. All controlled substances listed in Schedule II, Schedule III, Schedule IV, and Schedule V may be electronically prescribed pursuant to applicable federal law. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department that, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

Section 2. Paragraph (b) of subsection (15) of section 499.0121, Florida Statutes, is amended to read:

499.0121 Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(15) DUE DILIGENCE OF PURCHASERS.—

(b) A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. ~~A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable.~~

In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

Section 3. Paragraphs (b) and (c) of subsection (7) and subsection (12) of section 893.055, Florida Statutes, are amended to read:

893.055 Prescription drug monitoring program.—

(7)

(b) A pharmacy, prescriber, or dispenser<u>, or the designee of a pharmacy, prescriber, or dispenser,</u> shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the 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 database from the prescription drug monitoring program shall 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) The following entities are ~~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. Before ~~Prior to~~ release, a ~~the~~ request by the following entities 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 for Medicaid fraud cases involving prescribed controlled substances.

3. A law enforcement agency during active investigations of ~~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 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.

5. An impaired practitioner consultant who is retained by the department under s. 456.076 for the purpose of reviewing the database information of an impaired practitioner program participant or a referral who has agreed to be evaluated or monitored through the program and who has separately agreed in writing to the consultant's access to and review of such

information.

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.

(12) A prescriber or dispenser, or his or her designee, may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. 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 monitoring 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.

Section 4. Section 893.0551, Florida Statutes, is reenacted and amended to read:

893.0551 Public records exemption for the prescription drug monitoring program.—

(1) For purposes of this section, the terms used in this section have the same meanings as provided in s. 893.055.

(2) The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the practitioner, a pharmacist, or a pharmacy that is

contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a) Name.

(b) Address.

(c) Telephone number.

(d) Insurance plan number.

(e) Government-issued identification number.

(f) Provider number.

(g) Drug Enforcement Administration number.

(h) Any other unique identifying information or number.

(3) The department shall disclose such confidential and exempt information to the following persons or entities upon request and after using a verification process to ensure the legitimacy of the request as provided in s. 893.055:

(a) The Attorney General, or his or her designee, when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. The Attorney General's Medicaid fraud investigators may not have direct access to the department's database. The Attorney General, or his or her designee, may disclose to a criminal justice agency, as defined in s. 119.011, only the confidential and exempt information received from the department that is relevant to an identified active investigation that prompted the request for the information.

(b) The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to

prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide to a law enforcement agency pursuant to ss. 456.066 and 456.073 only information that is relevant to the specific controlled substances investigation that prompted the request for the information.

(c) A law enforcement agency that has initiated an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances and that has entered into a user agreement with the department. A law enforcement agency may request information from the department but may not have direct access to its database. The law enforcement agency may disclose to a criminal justice agency, as defined in s. 119.011, only confidential and exempt information received from the department that is relevant to an identified active investigation that prompted the request for such information.

(d) A health care practitioner, or his or her designee, who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(e) A pharmacist, or his or her designee, who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f) A patient or the legal guardian or designated health

care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.

(g) The patient's pharmacy, prescriber, or dispenser, or the designee of the pharmacy, prescriber, or dispenser, who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(h) An impaired practitioner consultant who has been authorized in writing by a participant in or referral to the impaired practitioner program to access and review information as provided in s. 893.055(7)(c)5.

(4) If the department determines consistent with its rules that a pattern of controlled substance abuse exists, the department may disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055. The law enforcement agency may disclose to a criminal justice agency, as defined in s. 119.011, only confidential and exempt information received from the department that is relevant to an identified active investigation that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

(5) Before disclosing confidential and exempt information to a criminal justice agency or a law enforcement agency pursuant to this section, the disclosing person or entity must take steps to ensure the continued confidentiality of all confidential and exempt information. At a minimum, these steps must include redacting any nonrelevant information.

(6) An agency or person who obtains any confidential and exempt information pursuant to this section must maintain the

confidential and exempt status of that information and may not disclose such information unless authorized by law. Information shared with a state attorney pursuant to paragraph (3)(a) or paragraph (3)(c) may be released only in response to a discovery demand if such information is directly related to the criminal case for which the information was requested. Unrelated information may be released only upon an order of a court of competent jurisdiction.

(7) A person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Section 5. This act shall take effect upon becoming a law.