A bill to be entitled

An act relating to the prescription drug monitoring program; amending s. 456.072, F.S.; providing additional grounds for discipline of a licensee of the Department of Health by a regulatory board; amending s. 893.055, F.S.; revising definitions; revising provisions relating to the database of controlled substance dispensing information; revising program funding requirements; requiring a prescriber to access and view certain patient information in the database before initially prescribing a controlled substance; providing requirements related to the release of identifying information; revising information retention requirements; revising provisions required in a contract with a direct-support organization; requiring the state to use certain properties and funds to support the program; providing for the adoption of specific rules by the department; providing an effective date.

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

Section 1. Paragraph (oo) is added to subsection (1) of section 456.072, Florida Statutes, to read:

456.072 Grounds for discipline; penalties; enforcement.—

(1) The following acts shall constitute grounds for which

the disciplinary actions specified in subsection (2) may be taken:

(oo) Failing to comply with the requirements of s. 893.055(8) by failing to access the prescription drug monitoring program database upon each initial visit and view the patient's prescription drug history before issuing a prescription for a controlled substance listed in s. 893.03(2), (3), or (4) to the patient.

Section 2. Section 893.055, Florida Statutes, is amended to read:

(Substantial rewording of section. See s. 893.055, F.S., for present text.)

893.055 Prescription drug monitoring program.—

(1) As used in this section and s. 893.0551, the term:

(a) "Active investigation" means an open investigation conducted by a law enforcement agency with a reasonable, good faith belief that it will lead to the filing of criminal charges or that is ongoing and for which there is a reasonable, good faith anticipation of obtaining an arrest or prosecution in the foreseeable future.

(b) "Administer" means to obtain and give a single dose of a medicinal drug to a patient for her or his consumption.

(c) "Controlled substance" means a substance named or described in s. 893.03(2), (3), or (4).

(d) "Dispense" means to transfer possession of one or more doses of a medicinal drug to the ultimate consumer or her or his

agent.

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

(f) "Health care practitioner" means a person licensed as a physician or physician assistant under chapter 458, as an osteopathic physician or physician assistant under chapter 459, as a podiatric physician under chapter 461, as an optometrist under chapter 463, as an advanced registered nurse practitioner under chapter 464, as a pharmacist under chapter 465, or as a dentist under chapter 466.

(g) "Law enforcement agency" means the Department of Law Enforcement, a Florida sheriff's department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and the agents and officers of which are empowered by law to conduct criminal investigations and make arrests.

(h) "Patient advisory report" means information provided by the program to a health care practitioner, dispenser, or patient concerning the dispensing of a controlled substance to a patient.

(i) "Pharmacy" means an entity permitted under chapter 465 as a pharmacy, as defined in s. 465.003(11), and a nonresident pharmacy registered under s. 465.0156.

(j) "Program" means the prescription drug monitoring program created under this section.

(2)(a) The department shall establish and maintain a database of controlled substance dispensing information. The database shall be used to provide information regarding dispensed prescriptions of controlled substances to persons with direct and indirect access to such information pursuant to this section. The database must meet the standards of the American Society for Automation in Pharmacy and must comply with the Health Insurance Portability and Accountability Act and all other relevant state and federal privacy and security laws and regulations. A transmission of information required by this section must comply with relevant state and federal privacy and security laws and regulations.

(b) The department shall designate a program manager to administer the program and ensure the program's integrity and compliance with this section. The program manager and each member of the authorized program and support staff must undergo a level 2 background screening pursuant to s. 435.04 as a condition of employment.

(c) The program shall be funded only by federal grants or private funding received by the state. The department may not commit funds for the program without ensuring that funding is available. The department shall cooperate with the direct-support organization established in subsection (16) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private funds for the program if the costs of doing so are nonmaterial. For purposes of this paragraph,

nonmaterial costs include, but are not limited to, costs for postage and department personnel assigned to research or apply for a grant. Funds provided by prescription drug manufacturers may not be used to establish or administer the program.

(d) To the extent that funding is provided for the program through federal grant funds, other nonstate grant funds, gifts, donations, or other private funds, the department shall study the feasibility of enhancing the program for the purposes of supporting public health initiatives and improving statistical reporting. The study shall be conducted to reduce drug abuse and further the safety and quality of health care services by improving prescribing and dispensing practices related to controlled substances and incorporating advances in technology.

(e) The department shall comply with s. 287.057 for the procurement of any goods or services required by this section.

(3) Within 7 days after the date that a prescription substance is dispensed, a dispenser shall submit to the database the following information. The department shall establish a reporting procedure and format by rule and may authorize an extension of time to report such information for cause as defined by rule:

(a) The prescribing health care practitioner's full name, federal Drug Enforcement Administration registration number, and National Provider Identifier or other appropriate identifier.

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

(c) The date that the prescription was written.

(d) The date that the prescription was filled and the method of payment. The department may not include credit card numbers or other account numbers in the database.

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

(f) The full name, federal Drug Enforcement Administration number, and address of the pharmacy or other location from which the controlled substance was dispensed or, if the controlled substance was dispensed by a health care practitioner other than a pharmacist, the health care practitioner's full name, federal Drug Enforcement Administration registration number, National Provider Identifier or other appropriate identifier, and address.

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

(4) A dispenser shall submit the information required by this section electronically, or by another method established by rule, in a format approved by the department. The cost to the dispenser to submit the information required by this section may not be material or extraordinary.

(5) The following acts of a health care practitioner or dispenser are exempt from reporting under this section:

(a) Administering or dispensing a controlled substance to a patient in a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the

developmentally disabled.

(b) Administering or dispensing a controlled substance within the Department of Corrections health care system.

(c) Administering or dispensing a controlled substance to a person under the age of 16.

(d) Dispensing a one-time, 72-hour emergency supply of a controlled substance to a patient.

(6) A person who knowingly and willfully 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.

(7) A dispenser or her or his agent, before dispensing a controlled substance to a person not known to the dispenser, shall require the person purchasing or receiving the controlled substance to present identification issued by the state or the Federal Government that contains the person's photograph, printed name, and signature, or a document considered acceptable identification under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

(a) If the person does not have such identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescribing health care practitioner or her or his agent. Verification of health plan eligibility of the person purchasing or receiving the controlled substance satisfies the requirement of this subsection.

(b) This subsection does not apply in an institutional setting or in a long-term care facility, including, but not

limited to, an assisted living facility or a hospital to which patients are admitted.

(8)(a) The program manager, and program and support staff only as directed or authorized by the program manager, shall have direct access to the database for program management in support of the requirements of this section.

(b) A health care practitioner or dispenser shall have direct access to information in the database which relates to a patient of that health care practitioner or dispenser for the purpose of reviewing the patient's controlled substance prescription history. A prescribing health care practitioner must access the database and view a patient's prescription drug history before issuing a prescription for a controlled substance to the patient upon each initial visit. A health care practitioner or dispenser acting in good faith is immune from any civil, criminal, or administrative liability for receiving or using information from the database. This section does not create a private cause of action and a person may not recover damages against a health care practitioner or dispenser who is authorized to access information from the database for accessing or failing to access such information.

(9) The following entities may not have direct access to information in the database but may request information from the program:

(a) The department for the purpose of an active investigation of a health care practitioner or dispenser who is

authorized to prescribe, administer, or dispense controlled substances.

(b) The Attorney General for the purpose of an active investigation of Medicaid fraud involving prescriptions of controlled substances.

(c) A law enforcement agency for the purpose of an active investigation regarding potential criminal activity, fraud, or theft involving prescriptions of controlled substances.

(d) A patient or the legal guardian or health care surrogate, as defined in s. 765.101(16), of an incapacitated patient. The department shall verify the identity of the incapacitated patient or the legal guardian or health care surrogate. Verification is also required for a request to change an incapacitated patient's prescription drug history or other information in the database.

(10) Upon receipt of a request from a law enforcement agency for information from the database, the program manager shall verify that the request is authentic and authorized. The program manager may release confidential and exempt information to the law enforcement agency only after the request is verified and is accompanied by an order of a court of competent jurisdiction compelling release of the information.

(11) The program manager, upon determining a pattern consistent with the rules established under subsection (17) evidencing controlled substance abuse or diversion and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or

(8)(b) has occurred, may provide relevant information to the appropriate law enforcement agency.

(12) An authorized person or entity receiving information from the database under subsection (9) may maintain the information for no more than 24 months before purging the information from official records. Information may be maintained for more than 24 months if it is pertinent to an active investigation or criminal prosecution.

(13) Information contained in the database is not discoverable or admissible in any civil or administrative action, except in an investigation or disciplinary proceeding conducted by the department.

(14) A person who participates in preparing, reviewing, issuing, or any other activity related to a patient advisory report may not be permitted or required to testify in any civil action as to any finding, recommendation, evaluation, opinion, or other action taken in connection with preparing, reviewing, or issuing such a report.

(15) The department shall report performance measures annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by December 1. Department staff may not have direct access to information in the database for the purpose of reporting performance measures. To measure performance and undertake public health care and safety initiatives, department staff may request data from the database that does not contain patient, health care

practitioner, or dispenser identifying information. Performance measures may include, but are not limited to:

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

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

(c) Increased coordination among partners participating in the program.

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

(16) The department may establish a direct-support organization to provide assistance, funding, and promotional support for the activities authorized for the program.

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

1. A Florida not-for-profit corporation 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 or

provide funding to or for the benefit of the program.

(b) The State Surgeon General shall appoint a board of directors for the direct-support organization consisting of at least five members. Members of the board shall serve at the pleasure of the State Surgeon General. The State Surgeon General shall provide guidance to members of the board to ensure that funds received by the direct-support organization are not from inappropriate sources. An inappropriate source includes, but is not limited to, a donor, grantor, person, or organization that may benefit from the purchase of goods or services by the department for the program.

(c) The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:

1. Department approval of the articles of incorporation, bylaws, and annual budgets.

2. Department certification that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the program. Such certification must be made annually and reported in the official minutes of a direct-support organization board meeting.

3. The reversion, without penalty, to the state of all funds and property held in trust by the direct-support organization for the benefit of the program if the direct-support organization ceases to exist or if the contract is terminated. The state shall use all funds and property reverted

to it to support the program.

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

5. The disclosure of the material provisions of the contract to a donor of a gift, contribution, or bequest, including such disclosure on all promotional and fundraising publications, and an explanation to the donor of the distinction between the department and the direct-support organization.

6. The direct-support organization's collecting, expending, and providing of funds to the department for the operation of the program.

7. The reversion to the department of any funds of the direct-support organization held by the department in a separate depository account received from rentals of facilities and properties managed by the department for use by the direct-support organization.

(d) The direct-support organization may collect and expend funds for the function of its board of directors, as approved by the department, and provide funds to the department for:

1. Establishing and administering the database, including hardware and software.

2. Conducting studies on the efficiency and effectiveness of the program, including the feasibility study described in paragraph (2)(d).

3. Future enhancements of the program.

4. User training for the program, including the distribution of materials to promote public awareness and education and conducting workshops or other meetings for health care practitioners, pharmacists, and others.

5. Travel expenses incurred by the board.

6. Administrative costs.

7. Fulfilling all other requirements necessary to operate the program.

(e) The department may authorize, without charge, appropriate use of its administrative services, property, and facilities by the direct-support organization.

(f) The department may not authorize the use of any of its administrative services, property, or facilities by a direct-support organization if the organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

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

(h) The direct-support organization is not a lobbying firm for purposes of s. 11.045.

(17) The department shall adopt rules to administer this section. Such rules shall include procedures for reporting

information to the database and accessing information in the database. The department shall also adopt rules identifying the indicators of controlled substance abuse or diversion. The department may adopt rules to govern the use of its administrative services, property, or facilities by the direct-support organization established under subsection (16).

Section 3. This act shall take effect July 1, 2014.