Sen. David Koehler

Filed: 4/27/2023

AMENDMENT TO SENATE BILL 285

AMENDMENT NO. _____. Amend Senate Bill 285 by replacing everything after the enacting clause with the following:

"Section 5. The Illinois Controlled Substances Act is amended by changing Sections 316 and 317 and by adding Section 316.1 as follows:

(720 ILCS 570/316)

Sec. 316. Prescription Monitoring Program.

(a) The Department must provide for a Prescription Monitoring Program for Schedule II, III, IV, and V controlled substances that includes the following components and requirements:

(1) The dispenser must transmit to the central repository, in a form and manner specified by the Department, the following information:

(A) The recipient's name and address.

(B) The recipient's date of birth and gender.

(C) The national drug code number of the controlled substance dispensed.

(D) (Blank). ~~The date the controlled substance is dispensed.~~

(E) The quantity of the controlled substance dispensed and days supply.

(F) The dispenser's United States Drug Enforcement Administration registration number.

(G) The prescriber's United States Drug Enforcement Administration registration number.

(H) The dates the controlled substance prescription is filled.

(I) The payment type used to purchase the controlled substance (i.e. Medicaid, cash, third party insurance).

(J) The patient location code (i.e. home, nursing home, outpatient, etc.) for the controlled substances other than those filled at a retail pharmacy.

(K) Any additional information that may be required by the department by administrative rule, including but not limited to information required for compliance with the criteria for electronic reporting of the American Society for Automation and Pharmacy or its successor.

(2) The information required to be transmitted under

this Section must be transmitted not later than the end of the business day on which a controlled substance is dispensed, or at such other time as may be required by the Department by administrative rule.

(3) A dispenser must transmit electronically, as provided by Department rule, the information required to be transmitted under this Section. ~~by:~~

~~(A) an electronic device compatible with the receiving device of the central repository;~~

~~(B) a computer diskette;~~

~~(C) a magnetic tape; or~~

~~(D) a pharmacy universal claim form or Pharmacy Inventory Control form.~~

(3.5) The requirements of paragraphs (1), (2), and (3) of this subsection also apply to opioid treatment programs that are licensed or certified by the Department of Human Services' Division of Substance Use Prevention and Recovery and are authorized by the federal Drug Enforcement Administration to prescribe Schedule II, III, IV, or V controlled substances for the treatment of opioid use disorders. Opioid treatment programs shall attempt to obtain written patient consent, shall document attempts to obtain the written consent, and shall not transmit information without patient consent. Documentation obtained under this paragraph shall not be utilized for law enforcement purposes, as proscribed under 42 CFR 2, as

amended by 42 U.S.C. 290dd-2. Treatment of a patient shall not be conditioned upon his or her written consent.

(4) The Department may impose a civil fine of up to $100 per day for willful failure to report controlled substance dispensing to the Prescription Monitoring Program. The fine shall be calculated on no more than the number of days from the time the report was required to be made until the time the problem was resolved, and shall be payable to the Prescription Monitoring Program.

(a-5) Notwithstanding subsection (a), a licensed veterinarian is exempt from the reporting requirements of this Section. If a person who is presenting an animal for treatment is suspected of fraudulently obtaining any controlled substance or prescription for a controlled substance, the licensed veterinarian shall report that information to the local law enforcement agency.

(b) The Department, by rule, may include in the Prescription Monitoring Program certain other select drugs that are not included in Schedule II, III, IV, or V. The Prescription Monitoring Program does not apply to controlled substance prescriptions as exempted under Section 313.

(c) The collection of data on select drugs and scheduled substances by the Prescription Monitoring Program may be used as a tool for addressing oversight requirements of long-term care institutions as set forth by Public Act 96-1372. Long-term care pharmacies shall transmit patient medication

profiles to the Prescription Monitoring Program monthly or more frequently as established by administrative rule.

(d) The Department of Human Services shall appoint a full-time Clinical Director of the Prescription Monitoring Program.

(e) (Blank).

(f) It is the responsibility of any new, ceased, or unconnected healthcare facility and its selected Electronic Health Records System or Pharmacy Management System to make contact with and ensure integration with the Prescription Monitoring Program. As soon as practicable after the effective date of this amendatory Act of the 103rd General Assembly, the Department shall adopt rules requiring Electronic Health Records Systems and Pharmacy Management Systems to interface, by January 1, 2024, with the Prescription Monitoring Program to ensure that providers have access to specific patient records during the treatment of their patients. The Department shall identify actions to be taken if a prescriber's Electronic Health Records System and Pharmacy Management Systems does not effectively interface with the Prescription Monitoring Program once the Prescription Monitoring Program is aware of the non-integrated connection. ~~Within one year of January 1, 2018 (the effective date of Public Act 100-564), the Department shall adopt rules requiring all Electronic Health Records Systems to interface with the Prescription Monitoring Program application program on or before January 1,~~

~~2021 to ensure that all providers have access to specific patient records during the treatment of their patients. These rules shall also address the electronic integration of pharmacy records with the Prescription Monitoring Program to allow for faster transmission of the information required under this Section. The Department shall establish actions to be taken if a prescriber's Electronic Health Records System does not effectively interface with the Prescription Monitoring Program within the required timeline.~~

(g) The Department, in consultation with the Prescription Monitoring Program Advisory Committee, shall adopt rules allowing licensed prescribers or pharmacists who have registered to access the Prescription Monitoring Program to authorize a licensed or non-licensed designee employed in that licensed prescriber's office or a licensed designee in a licensed pharmacist's pharmacy who has received training in the federal Health Insurance Portability and Accountability Act and 42 CFR 2 to consult the Prescription Monitoring Program on their behalf. The rules shall include reasonable parameters concerning a practitioner's authority to authorize a designee, and the eligibility of a person to be selected as a designee. In this subsection (g), "pharmacist" shall include a clinical pharmacist employed by and designated by a Medicaid Managed Care Organization providing services under Article V of the Illinois Public Aid Code under a contract with the Department of Healthcare and Family Services for the sole

purpose of clinical review of services provided to persons covered by the entity under the contract to determine compliance with subsections (a) and (b) of Section 314.5 of this Act. A managed care entity pharmacist shall notify prescribers of review activities.

(Source: P.A. 101-81, eff. 7-12-19; 101-414, eff. 8-16-19; 102-527, eff. 8-20-21; 102-813, eff. 5-13-22.)

(720 ILCS 570/316.1 new)

Sec. 316.1. Access to the integration of pharmacy records with the Prescription Monitoring Program.

(a) Subject to the requirements and limitations set out in this Section and in administrative rule, the Department shall not require, either expressly or effectively, Electronic Health Records Systems, pharmacies, or other providers to utilize a particular entity or system for access to the integration of pharmacy records with the Prescription Monitoring Program.

(1) Any entity or system for integration (transmitting the data maintained by the Prescription Monitoring Program) into an Electronic Health Records System, Certified Health IT Module, Pharmacy Dispensing System, or Pharmacy Management System must meet applicable requirements outlined in administrative rule, including, but not limited to, the following:

(A) enter into a data sharing agreement with the

Department of Human Services, Prescription Monitoring Program;

(B) all security requirements noted within this Section, administrative rule, and all other applicable State and federal security and privacy requirements;

(C) the Prescription Monitoring Program shall have administrative control over the approval of each site and individual integration point and the Prescription Monitoring Program shall have the ability to disable individual integration points, at no additional cost to the State;

(D) interstate data sharing shall be completed with written authorization from the Prescription Monitoring Program;

(E) data available from the Prescription Monitoring Program shall not be stored, cached, or sold and the State may inspect and review an entity or system for integration to assure and confirm the same, subject to a reasonable non-disclosure agreement, as permitted by State law, to protect the entity's or system's trade secrets or other proprietary information;

(F) analysis of data shall only be allowed with express written permission from the Prescription Monitoring Program; and

(G) access to audit data, shall be available in

hourly to real-time increments at no cost to the State.

(2) Electronic Health Record Systems, Certified Health IT Modules, Pharmacy Management Systems, and Pharmacy Dispensing Systems integrated with the Prescription Monitoring Program must meet applicable requirements outlined in rule, including, but not limited to, the following:

(A) provide their customers (healthcare entity, pharmacy, provider, prescriber, dispenser, etc.) the choice of approved integration vendor, meeting the requirements of this Section and administrative rule, or direct connect to the Illinois Prescription Monitoring Program;

(B) provide their customers with access to the data provided by the customer's chosen integration vendor as allowed under State and federal statute; and

(C) follow all State and federal security and privacy standards.

(3) Customers required to integrate under State or federal law must meet the requirements outlined in administrative rule, including, but not limited to, the following:

(A) the customer retains the choice of which integration vendor or direct connect is utilized to connect to the Illinois Prescription Monitoring

Program; and

(B) customers seeking to contract with a new integration vendor, shall enter into a memorandum of understanding with the Prescription Monitoring Program.

(b) The Illinois Prescription Monitoring Program may exercise the power, by rule, to require Memoranda of Understanding with all customers. The general contents of the memorandum of understanding shall be set out in rule and shall include, but not be limited to:

(1) the acknowledgment and choice of the customer of the method of integration with the Prescription Monitoring Program and

(2) the data use and other requirements on the customer in accessing and using the Prescription Monitoring Program.

A fee cannot be levied as part of a memorandum of understanding required by the Department under this Section.

(c) Non-compliance by the Integration Vendor, Electronic Health Record System, Certified Health IT Module, Pharmacy Management System or Pharmacy Dispensing System, customer, or any parties required to comply with this Section may result in the party being prohibited from serving as entity or system for integration with the Prescription Monitoring Program, termination of contracts, agreements, or other business relationships. The Department shall institute appropriate cure

notices, as necessary to remedy non-compliance.

(720 ILCS 570/317)

Sec. 317. Central repository for collection of information.

(a) The Department must designate a central repository for the collection of information transmitted under Section 316 and former Section 321.

(b) The central repository must do the following:

(1) Create a database for information required to be transmitted under Section 316 in the form required under rules adopted by the Department, including search capability for the following:

(A) A recipient's name and address.

(B) A recipient's date of birth and gender.

(C) The national drug code number of a controlled substance dispensed.

(D) (Blank). ~~The dates a controlled substance is dispensed.~~

(E) The quantities and days supply of a controlled substance dispensed.

(F) A dispenser's Administration registration number.

(G) A prescriber's Administration registration number.

(H) The dates the controlled substance

prescription is filled.

(I) The payment type used to purchase the controlled substance (i.e. Medicaid, cash, third party insurance).

(J) The patient location code (i.e. home, nursing home, outpatient, etc.) for controlled substance prescriptions other than those filled at a retail pharmacy.

(2) Provide the Department with a database maintained by the central repository. The Department of Financial and Professional Regulation must provide the Department with electronic access to the license information of a prescriber or dispenser.

(3) Secure the information collected by the central repository and the database maintained by the central repository against access by unauthorized persons.

All prescribers shall designate one or more medical specialties or fields of medical care and treatment for which the prescriber prescribes controlled substances when registering with the Prescription Monitoring Program.

No fee shall be charged for access by a prescriber or dispenser.

(Source: P.A. 99-480, eff. 9-9-15.)

Section 99. Effective date. This Act takes effect upon becoming law, except that Section 316.1 takes effect July 1,

2024.".