Sen. Melinda Bush

Filed: 4/20/2018

AMENDMENT TO SENATE BILL 2952

AMENDMENT NO. _____. Amend Senate Bill 2952 by replacing everything after the enacting clause with the following:

"Section 5. The Illinois Controlled Substances Act is amended by changing Sections 316, 318, and 320 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) 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 next business day after the date 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 the information required 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;

(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.

(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) Within one year of the effective date of this amendatory Act of the 100th General Assembly, 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 Advisory Committee, shall adopt rules allowing licensed prescribers or pharmacists who have registered to access the Prescription Monitoring Program to authorize a <u>licensed or non-licensed</u>

designee employed in that licensed prescriber's office or a licensed designee in a licensed pharmacist's pharmacy, and who has received training in the federal Health Insurance Portability and Accountability Act 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.

(Source: P.A. 99-480, eff. 9-9-15; 100-564, eff. 1-1-18.)

(720 ILCS 570/318)

Sec. 318. Confidentiality of information.

(a) Information received by the central repository under Section 316 and former Section 321 is confidential.

(a-1) To ensure the federal Health Insurance Portability and Accountability Act privacy of an individual's prescription data reported to the Prescription Monitoring Program received from a retail dispenser under this Act, the data shall be stored and isolated from any other database and remain under the full and complete control of the Prescription Monitoring Program.

(a-2) As an active step to address the current opioid crisis in this State and to prevent and reduce addiction resulting from a sports injury or an accident, the Prescription Monitoring Program and the Department of Public Health shall coordinate a continuous review of the Prescription Monitoring

Program and the Department of Public Health data to determine if a patient may be at risk of opioid addiction. Each patient discharged from any medical facility with an International Classification of Disease, 10th edition code related to a sport or accident injury shall be subject to the data review. If the discharged patient is dispensed a controlled substance, the Prescription Monitoring Program shall alert the patient's prescriber and dispenser as to the addiction risk and urge each to follow the Centers for Disease Control and Prevention guidelines or his or her respective profession's treatment guidelines related to the patient's injury. This subsection (a-2), other than this sentence, is inoperative on or after January 1, 2024.

(b) The Department must carry out a program to protect the confidentiality of the information described in subsection (a). The Department may disclose the information to another person only under subsection (c), (d), or (f) and may charge a fee not to exceed the actual cost of furnishing the information.

(c) The Department may disclose confidential information described in subsection (a) to any person who is engaged in receiving, processing, or storing the information.

(d) The Department may release confidential information described in subsection (a) to the following persons:

(1) A governing body that licenses practitioners and is engaged in an investigation, an adjudication, or a

prosecution of a violation under any State or federal law that involves a controlled substance.

(2) An investigator for the Consumer Protection Division of the office of the Attorney General, a prosecuting attorney, the Attorney General, a deputy Attorney General, or an investigator from the office of the Attorney General, who is engaged in any of the following activities involving controlled substances:

(A) an investigation;

(B) an adjudication; or

(C) a prosecution of a violation under any State or federal law that involves a controlled substance.

(3) A law enforcement officer who is:

(A) authorized by the Illinois State Police or the office of a county sheriff or State's Attorney or municipal police department of Illinois to receive information of the type requested for the purpose of investigations involving controlled substances; or

(B) approved by the Department to receive information of the type requested for the purpose of investigations involving controlled substances; and

(C) engaged in the investigation or prosecution of a violation under any State or federal law that involves a controlled substance.

(4) Select representatives of the Department of Children and Family Services through the indirect online

request process. Access shall be established by an intergovernmental agreement between the Department of Children and Family Services and the Department of Human Services.

(e) Before the Department releases confidential information under subsection (d), the applicant must demonstrate in writing to the Department that:

(1) the applicant has reason to believe that a violation under any State or federal law that involves a controlled substance has occurred; and

(2) the requested information is reasonably related to the investigation, adjudication, or prosecution of the violation described in subdivision (1).

(f) The Department may receive and release prescription record information under Section 316 and former Section 321 to:

(1) a governing body that licenses practitioners;

(2) an investigator for the Consumer Protection Division of the office of the Attorney General, a prosecuting attorney, the Attorney General, a deputy Attorney General, or an investigator from the office of the Attorney General;

(3) any Illinois law enforcement officer who is:

(A) authorized to receive the type of information released; and

(B) approved by the Department to receive the type of information released; or

(4) prescription monitoring entities in other states per the provisions outlined in subsection (g) and (h) below;

confidential prescription record information collected under Sections 316 and 321 (now repealed) that identifies vendors or practitioners, or both, who are prescribing or dispensing large quantities of Schedule II, III, IV, or V controlled substances outside the scope of their practice, pharmacy, or business, as determined by the Advisory Committee created by Section 320.

(g) The information described in subsection (f) may not be released until it has been reviewed by an employee of the Department who is licensed as a prescriber or a dispenser and until that employee has certified that further investigation is warranted. However, failure to comply with this subsection (g) does not invalidate the use of any evidence that is otherwise admissible in a proceeding described in subsection (h).

(h) An investigator or a law enforcement officer receiving confidential information under subsection (c), (d), or (f) may disclose the information to a law enforcement officer or an attorney for the office of the Attorney General for use as evidence in the following:

(1) A proceeding under any State or federal law that involves a controlled substance.

(2) A criminal proceeding or a proceeding in juvenile court that involves a controlled substance.

(i) The Department may compile statistical reports from the

information described in subsection (a). The reports must not include information that identifies, by name, license or address, any practitioner, dispenser, ultimate user, or other person administering a controlled substance.

(j) Based upon federal, initial and maintenance funding, a prescriber and dispenser inquiry system shall be developed to assist the health care community in its goal of effective clinical practice and to prevent patients from diverting or abusing medications.

(1) An inquirer shall have read-only access to a stand-alone database which shall contain records for the previous 12 months.

(2) Dispensers may, upon positive and secure identification, make an inquiry on a patient or customer solely for a medical purpose as delineated within the federal HIPAA law.

(3) The Department shall provide a one-to-one secure link and encrypted software necessary to establish the link between an inquirer and the Department. Technical assistance shall also be provided.

(4) Written inquiries are acceptable but must include the fee and the requestor's Drug Enforcement Administration license number and submitted upon the requestor's business stationery.

(5) As directed by the Prescription Monitoring Program Advisory Committee and the Clinical Director for the

Prescription Monitoring Program, aggregate data that does not indicate any prescriber, practitioner, dispenser, or patient may be used for clinical studies.

(6) Tracking analysis shall be established and used per administrative rule.

(7) Nothing in this Act or Illinois law shall be construed to require a prescriber or dispenser to make use of this inquiry system.

(8) If there is an adverse outcome because of a prescriber or dispenser making an inquiry, which is initiated in good faith, the prescriber or dispenser shall be held harmless from any civil liability.

(k) The Department shall establish, by rule, the process by which to evaluate possible erroneous association of prescriptions to any licensed prescriber or end user of the Illinois Prescription Information Library (PIL).

(l) The Prescription Monitoring Program Advisory Committee is authorized to evaluate the need for and method of establishing a patient specific identifier.

(m) Patients who identify prescriptions attributed to them that were not obtained by them shall be given access to their personal prescription history pursuant to the validation process as set forth by administrative rule.

(n) The Prescription Monitoring Program is authorized to develop operational push reports to entities with compatible electronic medical records. The process shall be covered within

administrative rule established by the Department.

(o) Hospital emergency departments and freestanding healthcare facilities providing healthcare to walk-in patients may obtain, for the purpose of improving patient care, a unique identifier for each shift to utilize the PIL system.

(p) The Prescription Monitoring Program shall automatically create a log-in to the inquiry system when a prescriber or dispenser obtains or renews his or her controlled substance license. The Department of Financial and Professional Regulation must provide the Prescription Monitoring Program with electronic access to the license information of a prescriber or dispenser to facilitate the creation of this profile. The Prescription Monitoring Program shall send the prescriber or dispenser information regarding the inquiry system, including instructions on how to log into the system, instructions on how to use the system to promote effective clinical practice, and opportunities for continuing education for the prescribing of controlled substances. The Prescription Monitoring Program shall also send to all enrolled prescribers, dispensers, and designees information regarding the unsolicited reports produced pursuant to Section 314.5 of this Act.

(q) A prescriber or dispenser may authorize a designee to consult the inquiry system established by the Department under this subsection on his or her behalf, provided that all the following conditions are met:

(1) the designee so authorized is employed by the same hospital or health care system; is employed by the same professional practice; or is under contract with such practice, hospital, or health care system;

(2) the prescriber or dispenser takes reasonable steps to ensure that such designee is sufficiently competent in the use of the inquiry system;

(3) the prescriber or dispenser remains responsible for ensuring that access to the inquiry system by the designee is limited to authorized purposes and occurs in a manner that protects the confidentiality of the information obtained from the inquiry system, and remains responsible for any breach of confidentiality; and

(4) the ultimate decision as to whether or not to prescribe or dispense a controlled substance remains with the prescriber or dispenser.

The Prescription Monitoring Program shall send to registered designees information regarding the inquiry system, including instructions on how to log onto the system.

(r) The Prescription Monitoring Program shall maintain an Internet website in conjunction with its prescriber and dispenser inquiry system. This website shall include, at a minimum, the following information:

(1) current clinical guidelines developed by health care professional organizations on the prescribing of opioids or other controlled substances as determined by the

Advisory Committee;

(2) accredited continuing education programs related to prescribing of controlled substances;

(3) programs or information developed by health care professionals that may be used to assess patients or help ensure compliance with prescriptions;

(4) updates from the Food and Drug Administration, the Centers for Disease Control and Prevention, and other public and private organizations which are relevant to prescribing;

(5) relevant medical studies related to prescribing;

(6) other information regarding the prescription of controlled substances; and

(7) information regarding prescription drug disposal events, including take-back programs or other disposal options or events.

The content of the Internet website shall be periodically reviewed by the Prescription Monitoring Program Advisory Committee as set forth in Section 320 and updated in accordance with the recommendation of the advisory committee.

(s) The Prescription Monitoring Program shall regularly send electronic updates to the registered users of the Program. The Prescription Monitoring Program Advisory Committee shall review any communications sent to registered users and also make recommendations for communications as set forth in Section 320. These updates shall include the following information:

(1) opportunities for accredited continuing education programs related to prescribing of controlled substances;

(2) current clinical guidelines developed by health care professional organizations on the prescribing of opioids or other drugs as determined by the Advisory Committee;

(3) programs or information developed by health care professionals that may be used to assess patients or help ensure compliance with prescriptions;

(4) updates from the Food and Drug Administration, the Centers for Disease Control and Prevention, and other public and private organizations which are relevant to prescribing;

(5) relevant medical studies related to prescribing;

(6) other information regarding prescribing of controlled substances;

(7) information regarding prescription drug disposal events, including take-back programs or other disposal options or events; and

(8) reminders that the Prescription Monitoring Program is a useful clinical tool.

(Source: P.A. 99-480, eff. 9-9-15; 100-125, eff. 1-1-18.)

(720 ILCS 570/320)

Sec. 320. Advisory committee.

(a) There is created a Prescription Monitoring Program

Advisory Committee to assist the Department of Human Services in implementing the Prescription Monitoring Program created by this Article and to advise the Department on the professional performance of prescribers and dispensers and other matters germane to the advisory committee's field of competence.

(b) The Prescription Monitoring Program Advisory Committee shall consist of 12 members appointed by the Clinical Director of the Prescription Monitoring Program ~~The Clinical Director of the Prescription Monitoring Program shall appoint members to serve on the advisory committee. The advisory committee shall be~~ composed of prescribers and dispensers licensed to practice medicine in his or her respective profession as follows: 4 physicians ~~licensed to practice medicine in all its branches~~; one advanced practice registered nurse; one physician assistant; one optometrist or ophthalmologist; one dentist; one podiatric physician; and 3 pharmacists. The Advisory Committee members serving on the effective date of this amendatory Act of the 100th General Assembly shall continue to serve until January 1, 2019. Prescriber and dispenser nominations for membership on the Committee shall be submitted by their respective professional associations. If there are more nominees than membership positions for a prescriber or dispenser category, as provided in this subsection (b), the Clinical Director of the Prescription Monitoring Program shall appoint a member or members for each profession as provided in this subsection (b), from the nominations to serve on the

advisory committee. At the first meeting of the Committee in 2019 members shall draw lots for initial terms and 4 members shall serve 3 years, 4 members shall serve 2 years, and 4 members shall serve one year. Thereafter, members shall serve 3 year terms. Members may serve more than one term but no more than 3 terms. ~~The Clinical Director of the Prescription Monitoring Program may appoint a representative of an organization representing a profession required to be appointed.~~ The Clinical Director of the Prescription Monitoring Program shall serve as the Secretary ~~chair~~ of the committee.

(c) The advisory committee may appoint a chairperson and ~~its~~ other officers as it deems appropriate.

(d) The members of the advisory committee shall receive no compensation for their services as members of the advisory committee, unless appropriated by the General Assembly, but may be reimbursed for their actual expenses incurred in serving on the advisory committee.

(e) The advisory committee shall:

(1) provide a uniform approach to reviewing this Act in order to determine whether changes should be recommended to the General Assembly;

(2) review current drug schedules in order to manage changes to the administrative rules pertaining to the utilization of this Act;

(3) review the following: current clinical guidelines

developed by health care professional organizations on the prescribing of opioids or other controlled substances; accredited continuing education programs related to prescribing and dispensing; programs or information developed by health care professional organizations that may be used to assess patients or help ensure compliance with prescriptions; updates from the Food and Drug Administration, the Centers for Disease Control and Prevention, and other public and private organizations which are relevant to prescribing and dispensing; relevant medical studies; and other publications which involve the prescription of controlled substances;

(4) make recommendations for inclusion of these materials or other studies which may be effective resources for prescribers and dispensers on the Internet website of the inquiry system established under Section 318;

(5) semi-annually ~~on at least a quarterly basis,~~ review the content of the Internet website of the inquiry system established pursuant to Section 318 to ensure this Internet website has the most current available information;

(6) semi-annually ~~on at least a quarterly basis,~~ review opportunities for federal grants and other forms of funding to support projects which will increase the number of pilot programs which integrate the inquiry system with electronic health records; and

(7) semi-annually ~~on at least a quarterly basis,~~ review

communication to be sent to all registered users of the inquiry system established pursuant to Section 318, including recommendations for relevant accredited continuing education and information regarding prescribing and dispensing.

(f) The Advisory Committee shall select from its members 7 members of the Peer Review Committee composed of: ~~The Clinical Director of the Prescription Monitoring Program shall select 5 members, 3 physicians and 2 pharmacists, of the Prescription Monitoring Program Advisory Committee to serve as members of the peer review subcommittee.~~

(1) 2 physicians;

(2) one pharmacist;

(3) one dentist;

(4) one advanced practice registered nurse;

(5) one physician assistant; and

(6) one optometrist or ophthalmologist.

The purpose of the Peer Review Committee ~~peer review subcommittee~~ is to ~~advise the Program on matters germane to the advisory committee's field of competence,~~ establish a formal peer review of professional performance of prescribers and dispensers~~, and develop communications to transmit to prescribers and dispensers~~. The deliberations, information, and communications of the Peer Review Committee ~~peer review subcommittee~~ are privileged and confidential and shall not be disclosed in any manner except in accordance with current law.

(1) The Peer Review Committee ~~peer review subcommittee~~ shall periodically review the data contained within the prescription monitoring program to identify those prescribers or dispensers who may be prescribing or dispensing outside the currently accepted standard and practice ~~standards in the course~~ of their profession ~~professional practice~~. The Peer Review Committee member, whose profession is the same as the prescriber or dispenser being reviewed, shall prepare a preliminary report and recommendation for any non-action or action. The Prescription Monitoring Program Clinical Director and staff shall provide the necessary assistance and data as required.

(2) The Peer Review Committee ~~peer review subcommittee~~ may identify prescribers or dispensers who may be prescribing outside the currently accepted medical standards in the course of their professional practice and send the identified prescriber or dispenser a request for information regarding their prescribing or dispensing practices. This request for information shall be sent via certified mail, return receipt requested. A prescriber or dispenser shall have 30 days to respond to the request for information.

(3) The Peer Review Committee ~~peer review subcommittee~~ shall refer a prescriber or a dispenser to the Department of Financial and Professional Regulation in the following

situations:

(i) if a prescriber or dispenser does not respond to three successive requests for information;

(ii) in the opinion of a majority of members of the Peer Review Committee ~~peer review subcommittee~~, the prescriber or dispenser does not have a satisfactory explanation for the practices identified by the Peer Review Committee ~~peer review subcommittee~~ in its request for information; or

(iii) following communications with the Peer Review Committee ~~peer review subcommittee~~, the prescriber or dispenser does not sufficiently rectify the practices identified in the request for information in the opinion of a majority of the members of the Peer Review Committee ~~peer review subcommittee~~.

(4) The Department of Financial and Professional Regulation may initiate an investigation and discipline in accordance with current laws and rules for any prescriber or dispenser referred by the peer review subcommittee.

(5) The Peer Review Committee ~~peer review subcommittee~~ shall prepare an annual report starting on July 1, 2017. This report shall contain the following information: the number of times the Peer Review Committee ~~peer review subcommittee~~ was convened; the number of prescribers or dispensers who were reviewed by the Peer Review Committee ~~peer review committee~~; the number of requests for

information sent out by the Peer Review Committee ~~peer review subcommittee~~; and the number of prescribers or dispensers referred to the Department of Financial and Professional Regulation. The annual report shall be delivered electronically to the Department and to the General Assembly. The report to the General Assembly shall be filed with the Clerk of the House of Representatives and the Secretary of the Senate in electronic form only, in the manner that the Clerk and the Secretary shall direct. The report prepared by the Peer Review Committee ~~peer review subcommittee~~ shall not identify any prescriber, dispenser, or patient.

(Source: P.A. 99-480, eff. 9-9-15; 100-513, eff. 1-1-18.)

Section 99. Effective date. This Act takes effect upon becoming law.".