A-Engrossed
Senate Bill 355

Ordered by the Senate April 16
Including Senate Amendments dated April 16

Sponsored by Senators MORRISETTE, KRUSE, BATES

SUMMARY

The following summary is not prepared by the sponsors of the measure and is not a part of the body thereof subject to consideration by the Legislative Assembly. It is an editor's brief statement of the essential features of the measure.

Requires State Board of Pharmacy to establish electronic prescription monitoring program for information reported by **certain** pharmacies regarding dispensing of certain prescription drugs. Restricts access to and limits use of reported information. Provides certain immunities from civil liability relating to reporting or use of information.

Authorizes board to impose on individual violator of program and related provisions maximum penalty of $250 and on drug outlet violator maximum penalty of $1,000.

Requires licensees of certain boards to pay $25 annual fee for prescribing and dispensing controlled substances. Establishes Electronic Prescription Monitoring Fund consisting of portion of fees. Appropriates moneys in fund to State Board of Pharmacy for purpose of administering program.

Creates Prescription Monitoring Program Advisory Commission.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to an electronic prescription monitoring program; appropriating money; and declaring an emergency.

Whereas the ability to identify and inhibit the diversion of prescription drugs must be improved; and

Whereas the appropriate use of prescription drugs for legitimate medical purposes must be protected; and

Whereas the goal of this 2009 Act is to improve the ability to identify and inhibit the diversion of prescription drugs, while promoting appropriate utilization of prescription drugs for legitimate medical purposes; and

Whereas the creation and operation of an electronic system to track prescriptions of controlled substances would improve the ability to identify and inhibit the diversion of prescription drugs but would not adversely effect prescriptions issued for legitimate medical purposes; and

Whereas the purpose of this 2009 Act is to authorize the development, implementation, operation and evaluation of an electronic system for the monitoring of prescription drugs to accomplish the goal of this 2009 Act; now, therefore,

Be It Enacted by the People of the State of Oregon:

SECTION 1. Sections 2 to 10 of this 2009 Act are added to and made a part of ORS chapter 689.

SECTION 2. As used in sections 2 to 10 of this 2009 Act:

(1) "Health professional regulatory board" has the meaning given that term in ORS 676.160.

NOTE: Matter in **boldfaced** type in an amended section is new; matter [*italic and bracketed*] is existing law to be omitted. New sections are in **boldfaced** type.

(2) "Prescription" has the meaning given that term in ORS 475.005.

SECTION 3. (1)(a) The State Board of Pharmacy, in consultation with the Prescription Monitoring Program Advisory Commission, shall establish and maintain a prescription monitoring program for monitoring and reporting prescription drugs dispensed by pharmacies in Oregon that are classified in schedules II through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified under ORS 475.035.

(b)(A) To fulfill the requirements of this subsection, the board shall establish, maintain and operate an electronic system to monitor and report drugs described in paragraph (a) of this subsection that are dispensed by prescription.

(B) The system must operate and be accessible by practitioners and pharmacies 24 hours a day, seven days a week.

(C) The board may contract with a state agency or private entity to ensure the effective operation of the electronic system.

(2) In consultation with the commission, the board shall adopt rules for the operation of the electronic prescription monitoring program established under subsection (1) of this section, including but not limited to standards for:

(a) Reporting data;

(b) Providing maintenance, security and disclosure of data;

(c) Ensuring accuracy and completeness of data;

(d) Complying with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.518 to 192.529;

(e) Ensuring accurate identification of persons or entities requesting information from the database;

(f) Assessing civil penalties for failing to report or for intentional wrongful disclosure of data; and

(g) Accepting printed or nonelectronic reports from pharmacies that do not have the capability to provide electronic reports.

(3) The board shall submit an annual report to the commission regarding the prescription monitoring program established under this section.

SECTION 4. (1) Not later than one week after dispensing a prescription drug subject to the prescription monitoring program established under section 3 of this 2009 Act, a pharmacy shall electronically report to the State Board of Pharmacy the:

(a) Name, address and date of birth of the patient;

(b) Identification of the pharmacy dispensing the prescription drug;

(c) Identification of the practitioner who prescribed the drug;

(d) Identification of the prescription drug by a national drug code number;

(e) Date of origin of the prescription;

(f) Date the drug was dispensed;

(g) Quantity of drug dispensed; and

(h) Other relevant information as required by rules adopted by the board.

(2) Notwithstanding subsection (1) of this section, the board may not:

(a) Require the reporting of prescription drugs administered directly to a patient or dis-

pensed pursuant to ORS 127.800 to 127.897; or

(b) Collect or use Social Security numbers in the prescription monitoring program.

(3) Upon receipt of the data reported pursuant to subsection (1) of this section, the board shall record the data in the electronic system operated pursuant to the prescription monitoring program.

(4)(a) The board may grant a pharmacy a waiver of the electronic submission requirement of subsection (1) of this section for good cause as determined by the board. The waiver shall state the format, method and frequency of the alternate nonelectronic submissions from the pharmacy and the duration of the waiver.

(b) As used in this subsection, "good cause" includes financial hardship.

(5) This section does not apply to pharmacies in institutions as defined in ORS 179.010.

SECTION 5. (1)(a) Except as provided under subsection (2) of this section, prescription monitoring information submitted under section 4 of this 2009 Act to the prescription monitoring program established in section 3 of this 2009 Act:

(A) Is protected health information under ORS 192.518 to 192.529.

(B) Is not subject to disclosure pursuant to ORS 192.410 to 192.505.

(b) Except as provided under subsection (2)(a)(D) of this section, prescription monitoring information submitted under section 4 of this 2009 Act to the prescription monitoring program may not be used to evaluate a practitioner's professional practice.

(2)(a) If prescription monitoring information disclosures comply with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.518 to 192.529, the State Board of Pharmacy shall disclose the information:

(A) To a practitioner or pharmacist who certifies that the requested information is for the purpose of evaluating the need for or providing medical or pharmaceutical treatment for a patient to whom the practitioner or pharmacist anticipates providing, is providing or has provided care.

(B) To designated representatives of the board or any vendor or contractor with whom the board has contracted to establish or maintain the electronic system of the prescription monitoring program.

(C) Pursuant to a valid court order based on probable cause and issued at the request of a federal, state or local law enforcement agency engaged in an authorized drug-related investigation involving a person to whom the requested information pertains.

(D) To a health professional regulatory board that certifies in writing that the requested information is necessary for an investigation related to licensure, renewal or disciplinary action involving the applicant, licensee or registrant to whom the requested information pertains.

(E) To a prescription monitoring program of another state if the confidentiality, security and privacy standards of the requesting state are determined by the State Board of Pharmacy to be equivalent to those of the board.

(b) The board may disclose information from the prescription monitoring program that does not identify a patient, practitioner or drug outlet:

(A) For educational, research or public health purposes; and

(B) To officials of the Department of Human Services who are conducting special epidemiologic morbidity and mortality studies in accordance with ORS 432.060 and rules adopted under ORS 431.110.

(c) The board shall disclose information relating to a patient to that patient if requested in accordance with procedures established by the board. The information shall be disclosed to the patient within 10 business days of the request being received by the board, and the patient may make a request to the board up to once every six months. A patient may request the board to correct any information about the patient that is erroneous.

(d) In accordance with ORS 192.518 to 192.529 and federal privacy regulations, any person authorized to prescribe or dispense a prescription drug and who is entitled to access a patient's prescription monitoring information may discuss or release the information to other health care providers involved with the patient's care, in order to provide safe and appropriate care coordination.

(3)(a) The board shall maintain records of the information disclosed through the prescription monitoring program including, but not limited to:

(A) The identification of each person who requests or receives information from the program and the organization, if any, the person represents;

(B) The information released to each person or organization; and

(C) The date and time the information was requested and the date and time the information was provided.

(b) Records maintained as required by this subsection may be reviewed by the Prescription Monitoring Program Advisory Commission.

(4) Information in the prescription monitoring program that identifies an individual patient must be removed no later than three years from the date the information is entered into the program.

(5) A pharmacy required to report information to the board, or a person authorized under this section to obtain or use information from the prescription monitoring program, is immune from civil liability arising out of the reporting or release of the information if the pharmacy or person reports, obtains or uses the data in good faith.

(6) The board and the commission are immune from civil liability arising from the inaccuracy of any information submitted under section 4 of this 2009 Act to the prescription monitoring program.

(7) Nothing in sections 2 to 10 of this 2009 Act requires a practitioner or pharmacist who prescribes or dispenses a prescription drug to obtain information about a patient from the prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses a prescription drug may not be held liable for damages in any civil action on the basis that the practitioner or pharmacist did or did not request or obtain information from the prescription monitoring program.

SECTION 6. A pharmacist may not refuse to fill a valid prescription solely because the pharmacist cannot receive patient information from the prescription monitoring program established under section 3 of this 2009 Act at the time the patient requests that the prescription be filled.

SECTION 7. (1) In addition to any other penalty provided by law, the State Board of Pharmacy may impose a civil penalty for any violation of sections 4 to 6 of this 2009 Act. A civil penalty imposed under this section may not exceed $250 for each violation by an indi-

vidual and $1,000 for each violation by a drug outlet.

(2) Civil penalties recovered under this section shall be deposited in the State Board of Pharmacy Account established in ORS 689.139.

(3) Civil penalties under this section shall be imposed as provided in ORS 183.745.

(4) Notwithstanding ORS 183.745, the person to whom the notice is addressed has 10 days from the date of service of the notice to make written application for a hearing before the board.

SECTION 8. (1) As used in this section, "board" means:

(a) The Oregon Medical Board;

(b) The Oregon Board of Dentistry;

(c) The Board of Naturopathic Examiners;

(d) The Oregon State Board of Nursing;

(e) The Oregon Board of Optometry; and

(f) The State Board of Pharmacy.

(2) The State Board of Pharmacy may accept grants, donations, gifts or moneys from any source for expenditures consistent with the purposes of sections 2 to 10 of this 2009 Act.

(3)(a) In addition to other licensing fees imposed by a board on licensees, a board shall adopt rules imposing a fee of $25 per year on each person licensed by the board who is authorized to prescribe or dispense controlled substances. A board shall collect the fee at the same time the board collects other licensing fees imposed on licensees.

(b) A board shall retain 10 percent of the fees collected under paragraph (a) of this subsection to cover the costs of accounting and collection of the fees.

(c) On the first day of each calendar quarter, a board shall transmit 90 percent of the fees collected under paragraph (a) of this subsection during the preceding calendar quarter to the Electronic Prescription Monitoring Fund established in section 11 of this 2009 Act.

SECTION 9. (1) The Prescription Monitoring Program Advisory Commission is created for the purposes of:

(a) Studying issues related to the prescription monitoring program established under section 3 of this 2009 Act;

(b) Reviewing the program's annual report and making recommendations to the State Board of Pharmacy regarding the operation of the program; and

(c) Developing criteria that should be used to evaluate program data.

(2) The commission shall consist of 15 members appointed by the board as follows:

(a) A person nominated by the Pain Management Commission;

(b) A person nominated by the Oregon State Pharmacy Association;

(c) A person nominated by the Oregon Dental Association;

(d) A physician nominated by the Oregon Medical Association;

(e) A doctor of osteopathy nominated by the Osteopathic Physicians and Surgeons of Oregon;

(f) A person nominated by the Oregon Nurses Association;

(g) A person nominated by the Oregon Association of Naturopathic Physicians;

(h) A person nominated by the Oregon Board of Dentistry;

(i) A physician nominated by the Oregon Medical Board;

(j) A person nominated by the Board of Naturopathic Examiners;

(k) A person nominated by the Oregon State Board of Nursing;

(L) A person nominated by the State Board of Pharmacy;

(m) A member of the public nominated by the State Board of Pharmacy;

(n) A person nominated by a health professional licensing board that regulates addiction counselors; and

(o) A person nominated by the Department of Human Services from a division of the department responsible for administering addiction services.

SECTION 10. (1) The term of office of each member of the Prescription Monitoring Program Advisory Commission is four years, but a member serves at the pleasure of the State Board of Pharmacy. Before the expiration of the term of a member, the board shall appoint a successor whose term begins on July 1 next following. A member is eligible for reappointment. If there is a vacancy for any cause, the board shall make an appointment to become immediately effective.

(2) The commission shall elect one of its members to serve as chairperson.

(3) The commission shall meet at least once annually at a time and place specified by the chairperson of the commission. The commission may meet at other times and places specified by the call of the chairperson or of a majority of the members of the commission.

(4) The commission may adopt rules necessary for the operation of the commission.

(5) A majority of the members of the commission constitutes a quorum for the transaction of business.

(6) Official action by the commission requires the approval of a majority of the members of the commission.

(7) The board shall provide staff support to the commission.

(8) Members of the commission are not entitled to compensation, but may be reimbursed for actual and necessary travel and other expenses incurred by them in the performance of their official duties in the manner and amounts provided for in ORS 292.495. Claims for expenses incurred in performing functions of the commission shall be paid out of funds appropriated to the board for that purpose.

(9) All agencies of state government, as defined in ORS 174.111, are directed to assist the commission in the performance of its duties and, to the extent permitted by laws relating to confidentiality, to furnish such information and advice as the members of the commission consider necessary to perform their duties.

SECTION 11. The Electronic Prescription Monitoring Fund is established in the State Treasury, separate and distinct from the General Fund. The Electronic Prescription Monitoring Fund consists of moneys transmitted to the fund under section 8 of this 2009 Act. Interest earned by the fund shall be credited to the fund. Moneys in the fund are continuously appropriated to the State Board of Pharmacy for the purpose of carrying out the provisions of sections 2 to 10 of this 2009 Act.

SECTION 12. Notwithstanding the term of office specified by section 10 of this 2009 Act, the members first appointed to the Prescription Monitoring Program Advisory Commission shall determine by lot at the first meeting of the commission the initial terms of office for commission members as follows:

(1) Five shall serve for a term ending July 1, 2010.

(2) Five shall serve for a term ending on July 1, 2011.

(3) Five shall serve for a term ending on July 1, 2012.

SECTION 13. (1) Sections 4 to 6 of this 2009 Act become operative on July 1, 2010.

(2) The State Board of Pharmacy may take any action before the operative date in subsection (1) of this section that is necessary to enable the board to exercise on or after the operative date in subsection (1) of this section, all of the duties, functions and powers conferred on the board by sections 4 to 6 of this 2009 Act.

SECTION 14. This 2009 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect on its passage.