A-Engrossed
House Bill 2518

Ordered by the House April 21
Including House Amendments dated April 21

Sponsored by Representative BUEHLER; Representatives KENY-GUYER, NOSSE, Senators MONNES ANDERSON, STEINER HAYWARD (Presession filed.)

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 pharmacy to report deidentified information to prescription monitoring program upon dispensing prescribed naloxone.

Requires pharmacy to report certain other identifying information to prescription monitoring program upon dispensing prescribed controlled substance classified in schedules II through IV.

Requires information to be disclosed from prescription monitoring program to medical director or pharmacy director. Requires information to be disclosed from prescription monitoring program for certain other purposes.

Requires licensing information of licensees who are authorized to prescribe or dispense controlled substances to be provided to Oregon Health Authority for purpose of qualifying licensees to report information to, or receive information from, prescription monitoring program.

Specifies that authority may require person requesting deidentified information from prescription monitoring program to enter into data use agreement with authority.

Requires authority, not less than once per year, to develop, through use of prescription monitoring program, criteria by which practitioner may be required to receive education or training on prescribing of opioids or opiates. Creates Prescription Monitoring Program Prescribing Practices Review Subcommittee for purposes of advising authority on development of criteria, reviewing practitioner's history to determine whether practitioner meets criteria and directing authority to provide educational material to practitioner who meets criteria.

Provides that [*Director of the Oregon Health*] authority may enter into agreements governing sharing and use of information reported to prescription monitoring program with regulatory authorities of other states that administer prescription monitoring programs.

Becomes operative January 1, 2018.

Declares emergency, effective on passage.

A BILL FOR AN ACT

Relating to programs used to monitor the dispensing of prescription drugs; creating new provisions; amending ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.875 and 431A.880; and declaring an emergency.

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

SECTION 1. ORS 431A.850 is amended to read:

431A.850. As used in ORS 431A.855 to 431A.900:

(1) "Dispense" and "dispensing" have the meanings given those terms in ORS 689.005.

(2) "Drug outlet" has the meaning given that term in ORS 689.005.

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

(4) "Medical director" means a physician employed by a hospital, health care clinic or system of hospitals or health care clinics for the purposes of overseeing the operations of the hospital, clinic or system and ensuring the delivery of quality health care within the hospital, clinic or system.

(5) "Pharmacist" means:

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.

(a) A pharmacist as defined in ORS 689.005; or

(b) An individual licensed to practice pharmacy in another state, if the requirements for licensure are similar, as determined by the Oregon Health Authority, to the requirements for being licensed as a pharmacist as defined in ORS 689.005.

(6) "Pharmacy director" means a pharmacist employed by a pharmacy or system of pharmacies for the purposes of overseeing the operations of the pharmacy or system and ensuring the delivery of quality pharmaceutical care within the pharmacy or system.

[*(4)*] **(7)** "Practitioner" means:

(a) A practitioner as defined in ORS 689.005; or

(b) An individual licensed to practice a profession in [*California, Idaho or Washington,*] **another state,** if the requirements for licensure are similar, as determined by the [*Oregon Health*] authority, to the requirements for being licensed as a practitioner as defined in ORS 689.005.

[*(5)*] **(8)** "Prescription" has the meaning given that term in ORS 475.005.

[*(6)*] **(9)** "Prescription drug" has the meaning given that term in ORS 689.005.

SECTION 2. ORS 431A.855 is amended to read:

431A.855. (1)(a) The Oregon Health Authority, in consultation with the Prescription Monitoring Program Advisory Commission, shall establish and maintain a prescription monitoring program for monitoring and reporting**:**

(A) Prescription drugs dispensed by pharmacies [*in Oregon*] **licensed by the State Board of Pharmacy** that are classified in schedules II through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified by the [*State Board of Pharmacy*] **board** by rule under ORS 475.035[.]**; and**

(B) Prescribed naloxone dispensed by pharmacies.

(b)(A) To fulfill the requirements of this subsection, the authority 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 **electronic** system must operate and be accessible by practitioners and pharmacies 24 hours a day, seven days a week.

(C) The authority 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 authority 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*] **that law**, 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 192.553 to 192.581;

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

(f) Accepting printed or nonelectronic reports from pharmacies that do not have the capability to provide electronic reports; and

(g) Notifying a patient, before or when a drug classified in schedules II through IV is dispensed to the patient, about the prescription monitoring program and the entry of the prescription in the **electronic** system.

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

SECTION 3. ORS 431A.860 is amended to read:

431A.860. (1) Not later than 72 hours after dispensing a prescription drug that is subject to the prescription monitoring program established under ORS 431A.855, a pharmacy shall electronically report to the Oregon Health Authority:

(a) **If the prescription drug is classified in schedules II through IV under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified by the State Board of Pharmacy by rule under ORS 475.035:**

(A) The name, address, **phone number,** date of birth and sex of the patient for whom the prescription drug was prescribed; **and**

(B) The payment method used to pay for the prescription drug;

(b) The identity of the pharmacy that dispensed the prescription drug and the date on which the prescription drug was dispensed;

(c) The identity of the practitioner who prescribed the prescription drug and the date on which the prescription drug was prescribed;

(d) The national drug code number for the prescription drug;

(e) The prescription number assigned to the prescription drug;

(f) The quantity of the prescription drug dispensed;

(g) The number of days for which the prescription drug was dispensed; and

(h) The number of refills of the prescription authorized by the practitioner and the number of the refill that the pharmacy dispensed.

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

(A) Require the reporting of prescription drugs administered directly to a patient or dispensed pursuant to ORS 127.800 to 127.897;

(B) Collect or use Social Security numbers in the prescription monitoring program; or

(C) Disclose under ORS 431A.865 (2)(a) the sex of the patient for whom a drug was prescribed.

(b) The sex of the patient for whom a drug was prescribed may be disclosed only for the purpose of research or epidemiological study under ORS 431A.865 (2)(b).

(3) Upon receipt of the data reported pursuant to subsection (1) of this section, the authority shall record the data in the electronic system established[*, maintained and operated pursuant to*] **under** ORS 431A.855.

(4)(a) The authority may, for good cause as determined by the authority, grant a pharmacy a waiver of the requirement that the information to be reported under subsection (1) of this section be submitted electronically. The waiver must 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 4. ORS 431A.865, as amended by section 1, chapter 100, Oregon Laws 2016, is amended to read:

431A.865. (1)(a) Except as provided under subsection (2) of this section, prescription monitoring information submitted under ORS 431A.860 to the prescription monitoring program established in

ORS 431A.855:

(A) Is protected health information under ORS 192.553 to 192.581.

(B) Is **confidential and** not subject to disclosure [*pursuant to*] **under** ORS 192.410 to 192.505.

(b) Except as provided under subsection [*(2)(a)(G)*] **(2)(a)(H)** of this section, prescription monitoring information submitted under ORS 431A.860 to the prescription monitoring program may not be used to evaluate a practitioner's professional practice.

(2)(a) To the extent that the law or regulation is applicable to the prescription monitoring program, if a disclosure of prescription monitoring information, other than the sex of a patient for whom a drug was prescribed, complies with the federal Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations adopted under [*it*] **that law**, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.553 to 192.581, the Oregon Health Authority shall disclose the information:

(A) To a practitioner or pharmacist, or, if a practitioner or pharmacist authorizes the authority to disclose the information to a member of the practitioner's or pharmacist's staff, to a member of the practitioner's or pharmacist's staff. If a practitioner or pharmacist authorizes disclosing the information to a member of the practitioner's or pharmacist's staff under this subparagraph, the practitioner or pharmacist remains responsible for the use or misuse of the information by the staff member. To receive information under this subparagraph, or to authorize the receipt of information by a staff member under this subparagraph, a practitioner or pharmacist must certify 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 a medical director or pharmacy director, or, if a medical director or pharmacy director authorizes the authority to disclose the information to a member of the medical director's or pharmacy director's staff, to a member of the medical director's or pharmacy director's staff. If a medical director or pharmacy director authorizes disclosing the information to a member of the medical director's or pharmacy director's staff under this subparagraph, the medical director or pharmacy director remains responsible for the use or misuse of the information by the staff member. To receive information under this subparagraph, or to authorize the receipt of information by a staff member under this subparagraph, a medical director must certify that the requested information is for the purposes of overseeing the operations of a hospital, health care clinic or system of hospitals or health care clinics and ensuring the delivery of quality health care within the hospital, clinic or system. To receive information under this subparagraph, or to authorize the receipt of information by a staff member under this subparagraph, a pharmacy director must certify that the requested information is for the purposes of overseeing the operations of a pharmacy or system of pharmacies and ensuring the delivery of quality pharmaceutical care within the pharmacy or system.

[*(B) In accordance with subparagraph (A) of this paragraph, to a practitioner or pharmacist or to a member of the practitioner's or pharmacist's staff through a health information technology system that is used by the practitioner or pharmacist or a member of the practitioner's or pharmacist's staff to access information about patients if:*]

[*(i) The practitioner or pharmacist or a member of the practitioner's or pharmacist's staff is authorized to access the information in the health information technology system;*]

(C) In accordance with subparagraphs (A) and (B) of this paragraph, to an individual described in subparagraphs (A) and (B) of this paragraph through a health information technology system that is used by the individual to access information about patients if:

(i) The individual is authorized to access the information in the health information technology system;

(ii) The information is not permanently retained in the health information technology system, except for purposes of conducting audits and maintaining patient records; and

(iii) The health information technology system meets any privacy and security requirements and other criteria, including criteria required by the federal Health Insurance Portability and Accountability Act, established by the authority by rule.

[*(C)*] **(D)** To a practitioner in a form that catalogs all prescription drugs prescribed by the practitioner according to the number assigned to the practitioner by the Drug Enforcement Administration of the United States Department of Justice.

[*(D)*] **(E)** To the State Medical Examiner or designee of the State Medical Examiner, for the purpose of conducting a medicolegal investigation or autopsy.

[*(E)*] **(F)** To designated representatives of the authority or any vendor or contractor with whom the authority has contracted to establish or maintain the electronic system [*of the prescription monitoring program*] **established under ORS 431A.855**.

[*(F)*] **(G)** 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.

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

[*(H) To a prescription monitoring program of another state if the confidentiality, security and privacy standards of the requesting state are determined by the authority to be equivalent to those of the authority.*]

(I) Pursuant to an agreement entered into under section 12 of this 2017 Act.

(b) The authority 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;

(B) For the purpose of educating practitioners about the prescribing of opioids and other controlled substances;

(C) To a health professional regulatory board;

[*(B)*] **(D)** To a local public health authority, as defined in ORS 431.003; or

[*(C)*] **(E)** To officials of the authority who are conducting special epidemiologic morbidity and mortality studies in accordance with ORS 413.196 and rules adopted under ORS 431.001 to 431.550 and 431.990.

(c) The [*Oregon Health*] authority shall disclose information relating to a patient maintained in the electronic system [*operated pursuant to the prescription monitoring program*] **established under ORS 431A.855** to that patient at no cost to the patient within 10 business days after the authority receives a request from the patient for the information.

(d)(A) A patient may request the authority to correct any information [*about the patient*] **related to the patient that is maintained in the electronic system established under ORS 431A.855** that is erroneous. The authority shall grant or deny a request to correct information within 10

business days after the authority receives the request. **If a request to correct information cannot be granted because the error occurred at the pharmacy where the information was inputted, the authority shall inform the patient that the information cannot be corrected because the error occurred at the pharmacy.**

(B) If the authority denies a patient's request to correct information under this paragraph, or fails to grant a patient's request to correct information under this paragraph within 10 business days after the authority receives the request, the patient may appeal the denial or failure to grant the request. Upon receiving notice of an appeal under this subparagraph, the authority shall conduct a contested case hearing as provided in ORS chapter 183. Notwithstanding ORS 183.450, the authority has the burden in the contested case hearing of establishing that the information [*included in the prescription monitoring program*] is correct.

(e) The information in the prescription monitoring program may not be used for any commercial purpose.

(f) In accordance with ORS 192.553 to 192.581 and federal [*privacy regulations,*] **laws and regulations related to privacy,** any person authorized to prescribe or dispense a prescription drug [*and*] who is entitled to access a patient's prescription monitoring information may discuss **the information with** or release the information to other health care providers involved with the patient's care for the [*purposes*] **purpose** of providing safe and appropriate care coordination.

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

(A) The identity of each person who requests or receives information from the program and any organization 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) The authority shall notify the Attorney General and each [*affected*] individual [*of*] **affected by** an improper disclosure of information from the prescription monitoring program **of the disclosure**.

(6)(a) If the authority or a person or entity required to report or authorized to receive or release [*controlled substance*] prescription information under this section violates this section or ORS 431A.860 or 431A.870, a person injured by the violation may bring a civil action against the authority, person or entity and may recover damages in the amount of $1,000 or actual damages, whichever is greater.

(b) Notwithstanding paragraph (a) of this subsection, the authority and a person or entity required to report or authorized to receive or release [*controlled substance*] prescription information under this section are immune from civil liability for violations of this section or ORS 431A.860 or 431A.870 unless the authority, person or entity acts with malice, criminal intent, gross negligence, recklessness or willful intent.

(7) Nothing in ORS 431A.855 to 431A.900 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.

(8) The authority shall, at regular intervals, ensure compliance of a health information technology system described in subsection (2) of this section with the privacy and security requirements and other criteria established by the authority [*by rule*] under subsection (2) of this section.

SECTION 5. ORS 431A.875 is amended to read:

431A.875. If a practitioner or pharmacist authorized to obtain [*controlled substance*] prescription information from the [*prescription monitoring*] **electronic** system established under ORS 431A.855 discloses or uses information obtained from the **electronic** system in violation of ORS 431A.865, the Oregon Health Authority shall report the individual to the appropriate health professional regulatory board.

SECTION 6. ORS 431A.880 is amended to read:

431A.880. (1) As used in this section, "board" means:

(a) The Oregon Medical Board;

(b) The Oregon Board of Dentistry;

(c) The Oregon Board of Naturopathic Medicine;

(d) The Oregon State Board of Nursing;

(e) The Oregon Board of Optometry; and

(f) The State Board of Pharmacy.

(2)(a) At the time of issuing or renewing a license, a board shall provide the Oregon Health Authority with the licensing information of each person licensed by the board who is authorized to prescribe or dispense controlled substances. The authority shall use the licensing information to qualify the licensee to report information to, or receive information from, the prescription monitoring program established under ORS 431A.855.

(b) A board by rule may adopt exceptions to the requirement described in paragraph (a) of this subsection.

[*(2)(a)*] **(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.*] **administering this section.**

(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 ORS 431A.885.

(4) A board may adopt rules necessary for the administration of this section.

SECTION 7. Sections 8 to 12 of this 2017 Act are added to and made a part of ORS 431A.855 to 431A.900.

SECTION 8. (1) The Oregon Health Authority may require a person requesting prescription monitoring program information under ORS 431A.865 (2)(b) to enter into a data use agreement under which the person:

(a) Describes the proposed use for the information;

(b) Agrees to any terms and conditions imposed on transferring the information;

(c) Agrees to any limitations imposed on using the information;

(d) Agrees to any terms and conditions imposed on keeping the information; and

(e) Agrees to destroy the information after completing the proposed use for the information.

(2) In determining whether to enter into an agreement under this section, the authority shall:

(a) Evaluate the merits of the request for information;

(b) Determine whether the person making the request has the technical competence needed to meet any terms, conditions or limitations imposed under subsection (1) of this section and the ability to complete the proposed use for the information;

(c) If the proposed use for the information involves research, ensure that the proposed use has been approved by any involved institutional review board; and

(d) Consider any other factor that the authority determines is relevant.

(3) Using the factors described in subsection (2) of this section, the authority shall evaluate any agreement entered into under this section at least once per year for the purpose of determining whether to renew the agreement.

SECTION 9. (1) Not less than once per year, the Oregon Health Authority, in consultation with the Prescription Monitoring Program Advisory Commission created under ORS 431A.890 and the Prescription Monitoring Program Prescribing Practices Review Subcommittee established under section 10 of this 2017 Act, shall develop, through the use of prescription monitoring information, criteria by which a practitioner may be required to receive education or training on the prescribing of opioids or opiates.

(2) Criteria developed under subsection (1) of this section must include:

(a) Prescribing a high volume of opioids or opiates classified in schedules II and III;

(b) Prescribing an above-average amount of doses of opioids or opiates classified in schedules II and III to a high number of patients; and

(c) Simultaneously prescribing opioids or opiates classified in schedules II and III with other drugs classified in schedules II and III.

(3) In developing the criteria developed under subsection (1) of this section, the authority must take into consideration the total quantity and volume of opioids and opiates classified in schedules II and III prescribed by each practitioner.

(4) The subcommittee may review, through the use of prescription monitoring information that does not identify a patient, a practitioner's prescribing history for the three years immediately preceding the date of the review to determine whether a practitioner meets the criteria developed under subsection (1) of this section.

(5) After performing the review described in subsection (4) of this section, the subcommittee may direct the authority to provide to a practitioner who meets the criteria developed under subsection (1) of this section educational information about prescribing opioids and opiates, as determined appropriate by the authority.

(6) Prescription monitoring information used for purposes of this section and the data created through the use of prescription monitoring information pursuant to this section:

(a) Are confidential and not subject to public disclosure under ORS 192.410 to 192.505; and

(b) Are not admissible as evidence in a civil or criminal proceeding.

SECTION 10. (1) The Prescription Monitoring Program Prescribing Practices Review Subcommittee is established as a subcommittee of the Prescription Monitoring Program Advisory Commission created under ORS 431A.890, for the purpose of advising the Oregon Health Authority and the commission on interpreting prescription information, understand-

ing the clinical aspects of prescribing practices and evaluating prescribing practices.

(2)(a) The authority shall appoint the number of members to the subcommittee that the authority determines is necessary to fulfill the functions of the subcommittee.

(b) Members of the subcommittee must be practitioners who:

(A) Hold a valid license issued in this state or a valid emeritus license issued in this state;

(B) Are registered with the federal Drug Enforcement Administration to prescribe drugs classified in schedules II through IV; and

(C) Have at least five years of experience prescribing drugs classified in schedules II through IV.

(c) To the extent feasible, the authority shall appoint one member to the subcommittee for each type of practitioner in this state that prescribes drugs classified in schedules II through IV.

SECTION 11. The Oregon Health Authority shall coordinate with health professional regulatory boards to make resources available to practitioners regarding the best methods to change prescribing practices with respect to opioids and opiates and to incorporate alternative pain management options into prescribing practices.

SECTION 12. The Oregon Health Authority may enter into agreements governing the sharing and use of information described in ORS 431A.860 (1) with the authorities of other states that administer prescription monitoring programs. An agreement entered into under this section must adhere to the disclosure limitations listed under ORS 431A.865 (2). An agreement entered into under this section may:

(1) Provide for the transmission of information between electronic systems, provided that any electronic system to which the Oregon Health Authority transmits information meets the confidentiality, security and privacy standards adopted by the authority under ORS 431A.855; or

(2) Provide for the transmission of information to practitioners or pharmacists licensed to practice in another state.

SECTION 13. The amendments to ORS 431A.860 by section 3 of this 2017 Act apply to prescription drugs for which the prescription was prescribed on or after the operative date specified in section 15 of this 2017 Act.

SECTION 14. Notwithstanding the operative date specified in section 15 of this 2017 Act, a pharmacy is not required to electronically report the phone number of the patient for whom a prescription drug was prescribed or the payment method used to pay for a prescription drug, as described in ORS 431A.860 (1), for prescription drugs dispensed before July 1, 2018.

SECTION 15. (1) Sections 8 to 12 of this 2017 Act and the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.875 and 431A.880 by sections 1 to 6 of this 2017 Act become operative January 1, 2018.

(2) The Oregon Health Authority and a board, as defined in ORS 431A.880, may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the authority or the board to exercise, on and after the operative date specified in subsection (1) of this section, all the duties, powers and functions conferred on the authority or the board by sections 8 to 12 of this 2017 Act and the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.875 and 431A.880 by sections 1 to 6 of this 2017 Act.

SECTION 16. This 2017 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2017 Act takes effect on its passage.
