

House Bill 2519

Sponsored by Representative BUEHLER; Representatives KENY-GUYER, NOSSE, Senators MONNES ANDERSON, STEINER HAYWARD (Pre-session 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 **as introduced**.

Requires pharmacy to report de-identified 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.

Becomes operative January 1, 2018.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to the program used to monitor the dispensing of prescription drugs; creating new pro-
3 visions; amending ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.875 and 431A.880; and de-
4 claring an emergency.

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

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

7 431A.850. As used in ORS 431A.855 to 431A.900:

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

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

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

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

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

18 [(4)] (6) "Practitioner" means:

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

20 (b) An individual licensed to practice a profession in California, Idaho or Washington, if the
21 requirements for licensure are similar, as determined by the Oregon Health Authority, to the re-
22 quirements for being licensed as a practitioner as defined in ORS 689.005.

23 [(5)] (7) "Prescription" has the meaning given that term in ORS 475.005.

24 [(6)] (8) "Prescription drug" has the meaning given that term in ORS 689.005.

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

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.

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

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

7 **(B) Prescribed naloxone dispensed by pharmacies.**

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

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

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

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

18 (a) Reporting data;

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

20 (c) Ensuring accuracy and completeness of data;

21 (d) Complying with the federal Health Insurance Portability and Accountability Act of 1996 (P.L.
 22 104-191) and regulations adopted under [it] **that law**, including 45 C.F.R. parts 160 and 164, federal
 23 alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including
 24 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505,
 25 192.517 and 192.553 to 192.581;

26 (e) Ensuring accurate identification of persons or entities requesting information from the da-
 27 tabase;

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

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

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

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

36 431A.860. (1) Not later than 72 hours after dispensing a prescription drug that is subject to the
 37 prescription monitoring program established under ORS 431A.855, a pharmacy shall electronically
 38 report to the Oregon Health Authority:

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

42 (A) The name, address, **phone number**, date of birth [and], sex **and last four digits of the**
 43 **Social Security number** of the patient for whom the prescription drug was prescribed; **and**

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

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

1 prescription drug was dispensed;

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

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

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

6 (f) The quantity of the prescription drug dispensed;

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

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

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

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

13 (B) Collect or use **complete** Social Security numbers in the prescription monitoring program;
14 or

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

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

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

21 (4)(a) The authority may, for good cause as determined by the authority, grant a pharmacy a
22 waiver of the requirement that the information to be reported under subsection (1) of this section
23 be submitted electronically. The waiver must state the format, method and frequency of the alter-
24 nate nonelectronic submissions from the pharmacy and the duration of the waiver.

25 (b) As used in this subsection, “good cause” includes financial hardship.

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

27 **SECTION 4.** ORS 431A.865, as amended by section 1, chapter 100, Oregon Laws 2016, is
28 amended to read:

29 431A.865. (1)(a) Except as provided under subsection (2) of this section, prescription monitoring
30 information submitted under ORS 431A.860 to the prescription monitoring program established in
31 ORS 431A.855:

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

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

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

37 (2)(a) To the extent that the law or regulation is applicable to the prescription monitoring pro-
38 gram, if a disclosure of prescription monitoring information, other than the sex of a patient for
39 whom a drug was prescribed, complies with the federal Health Insurance Portability and Account-
40 ability Act of 1996 (P.L. 104-191) and regulations adopted under [*it*] **that law**, including 45 C.F.R.
41 parts 160 and 164, federal alcohol and drug treatment confidentiality laws and regulations, including
42 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505,
43 192.517 and 192.553 to 192.581, the Oregon Health Authority shall disclose the information:

44 (A) To a practitioner or pharmacist, or, if a practitioner or pharmacist authorizes the authority
45 to disclose the information to a member of the practitioner’s or pharmacist’s staff, to a member of

1 the practitioner's or pharmacist's staff. If a practitioner or pharmacist authorizes disclosing the in-
 2 formation to a member of the practitioner's or pharmacist's staff under this subparagraph, the
 3 practitioner or pharmacist remains responsible for the use or misuse of the information by the staff
 4 member. To receive information under this subparagraph, or to authorize the receipt of information
 5 by a staff member under this subparagraph, a practitioner or pharmacist must certify that the re-
 6 quested information is for the purpose of evaluating the need for or providing medical or pharma-
 7 ceutical treatment for a patient to whom the practitioner or pharmacist anticipates providing, is
 8 providing or has provided care.

9 **(B) To a medical director or pharmacy director, or, if a medical director or pharmacy**
 10 **director authorizes the authority to disclose the information to a member of the medical**
 11 **director's or pharmacy director's staff, to a member of the medical director's or pharmacy**
 12 **director's staff. If a medical director or pharmacy director authorizes disclosing the infor-**
 13 **mation to a member of the medical director's or pharmacy director's staff under this sub-**
 14 **paragraph, the medical director or pharmacy director remains responsible for the use or**
 15 **misuse of the information by the staff member. To receive information under this subpara-**
 16 **graph, or to authorize the receipt of information by a staff member under this subparagraph,**
 17 **a medical director must certify that the requested information is for the purposes of over-**
 18 **seeing the operations of a hospital, health care clinic or system of hospitals or health care**
 19 **clinics and ensuring the delivery of quality health care within the hospital, clinic or system.**
 20 **To receive information under this subparagraph, or to authorize the receipt of information**
 21 **by a staff member under this subparagraph, a pharmacy director must certify that the re-**
 22 **quested information is for the purposes of overseeing the operations of a pharmacy or sys-**
 23 **tem of pharmacies and ensuring the delivery of quality pharmaceutical care within the**
 24 **pharmacy or system.**

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

- 29 (i) The practitioner or pharmacist or a member of the practitioner's or pharmacist's staff is au-
 30 thorized to access the information in the health information technology system;
- 31 (ii) The information is not permanently retained in the health information technology system,
 32 except for purposes of conducting audits and maintaining patient records; and
- 33 (iii) The health information technology system meets any privacy and security requirements and
 34 other criteria, including criteria required by the federal Health Insurance Portability and Account-
 35 ability Act, established by the authority by rule.

36 [(C)] (D) To a practitioner in a form that catalogs all prescription drugs prescribed by the
 37 practitioner according to the number assigned to the practitioner by the Drug Enforcement Admin-
 38 istration of the United States Department of Justice.

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

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

44 [(F)] (G) Pursuant to a valid court order based on probable cause and issued at the request of
 45 a federal, state or local law enforcement agency engaged in an authorized drug-related investigation

1 involving a person to whom the requested information pertains.

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

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

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

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

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

13 **(C) To a health professional regulatory board;**

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

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

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

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

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

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

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

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

42 (A) The identity of each person who requests or receives information from the program and any
 43 organization the person represents;

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

45 (C) The date and time the information was requested and the date and time the information was

1 provided.

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

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

6 (5) The authority shall notify the Attorney General and each *[affected]* individual *[of]* **affected**
7 **by** an improper disclosure of information from the prescription monitoring program.

8 (6)(a) If the authority or a person or entity required to report or authorized to receive or release
9 *[controlled substance]* prescription information under this section violates this section or ORS
10 431A.860 or 431A.870, a person injured by the violation may bring a civil action against the au-
11 thority, person or entity and may recover damages in the amount of \$1,000 or actual damages,
12 whichever is greater.

13 (b) Notwithstanding paragraph (a) of this subsection, the authority and a person or entity re-
14 quired to report or authorized to receive or release *[controlled substance]* prescription information
15 under this section are immune from civil liability for violations of this section or ORS 431A.860 or
16 431A.870 unless the authority, person or entity acts with malice, criminal intent, gross negligence,
17 recklessness or willful intent.

18 (7) Nothing in ORS 431A.855 to 431A.900 requires a practitioner or pharmacist who prescribes
19 or dispenses a prescription drug to obtain information about a patient from the prescription moni-
20 toring program. A practitioner or pharmacist who prescribes or dispenses a prescription drug may
21 not be held liable for damages in any civil action on the basis that the practitioner or pharmacist
22 did or did not request or obtain information from the prescription monitoring program.

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

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

27 431A.875. If a practitioner or pharmacist authorized to obtain *[controlled substance]* prescription
28 information from the *[prescription monitoring]* **electronic** system established under ORS 431A.855
29 discloses or uses information obtained from the **electronic** system in violation of ORS 431A.865, the
30 Oregon Health Authority shall report the individual to the appropriate health professional regula-
31 tory board.

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

33 431A.880. (1) As used in this section, “board” means:

- 34 (a) The Oregon Medical Board;
- 35 (b) The Oregon Board of Dentistry;
- 36 (c) The Oregon Board of Naturopathic Medicine;
- 37 (d) The Oregon State Board of Nursing;
- 38 (e) The Oregon Board of Optometry; and
- 39 (f) The State Board of Pharmacy.

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

45 **(b) Except as otherwise required by the authority by rule, a board is required to provide**

1 **the authority with licensing information under paragraph (a) of this subsection only once for**
 2 **purposes of qualifying the licensee to report information to, or receive information from, the**
 3 **prescription monitoring program.**

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

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

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

12 **(c) On the first day of each calendar quarter, a board shall transmit 90 percent of the fees col-**
 13 **lected under paragraph (a) of this subsection during the preceding calendar quarter to the Elec-**
 14 **tronic Prescription Monitoring Fund established in ORS 431A.885.**

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

16 **SECTION 7. The amendments to ORS 431A.860 by section 3 of this 2017 Act apply to**
 17 **prescription drugs for which the prescription was prescribed on or after the operative date**
 18 **specified in section 8 of this 2017 Act.**

19 **SECTION 8. (1) The amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.875**
 20 **and 431A.880 by sections 1 to 6 of this 2017 Act become operative January 1, 2018.**

21 **(2) The Oregon Health Authority and a board, as defined in ORS 431A.880, may take any**
 22 **action before the operative date specified in subsection (1) of this section that is necessary**
 23 **to enable the authority or the board to exercise, on and after the operative date specified in**
 24 **subsection (1) of this section, all the duties, powers and functions conferred on the authority**
 25 **or the board by the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.875 and**
 26 **431A.880 by sections 1 to 6 of this 2017 Act.**

27 **SECTION 9. This 2017 Act being necessary for the immediate preservation of the public**
 28 **peace, health and safety, an emergency is declared to exist, and this 2017 Act takes effect**
 29 **on its passage.**

30 _____