

B-Engrossed
Senate Bill 355

Ordered by the Senate June 25
Including Senate Amendments dated April 16 and June 25

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.] **Requires Department of Human Services to establish and maintain prescription monitoring program for monitoring and reporting certain prescription drugs dispensed by pharmacies.** 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.] **Authorizes Attorney General to impose civil penalty up to maximum of \$10,000 for each violation of program.**

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. **Continuously** appropriates moneys in fund to *[State Board of Pharmacy]* **department** for purpose of administering program.

Creates Prescription Monitoring Program Advisory Commission.

Increases biennial expenditure limitation for payment of expenses for health services from fees, moneys or other revenues, including Miscellaneous Receipts, but excluding lottery funds and federal funds, collected or received by department.

Increases certain biennial expenditure limitation for payment of expenses from federal funds collected or received by department.

Declares emergency, effective on passage.

A BILL FOR AN ACT

1
2 Relating to an electronic prescription monitoring program; appropriating money; limiting expen-
3 ditures; and declaring an emergency.

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

5 **SECTION 1. As used in sections 2 to 11 of this 2009 Act:**

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

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

8 (3) "Health professional regulatory board" has the meaning given that term in ORS
9 **676.160.**

10 (4) "Practitioner" has the meaning given that term in ORS 689.005.

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

12 (6) "Prescription drug" has the meaning given that term in ORS 689.005.

13 **SECTION 2. (1)(a) The Department of Human Services, in consultation with the Pre-**
14 **scription Monitoring Program Advisory Commission, shall establish and maintain a pre-**
15 **scription monitoring program for monitoring and reporting prescription drugs dispensed by**
16 **pharmacies in Oregon that are classified in schedules II through IV under the federal Con-**
17 **trolled Substances Act, 21 U.S.C. 811 and 812, as modified under ORS 475.035.**

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 **(b)(A) To fulfill the requirements of this subsection, the department shall establish,**
2 **maintain and operate an electronic system to monitor and report drugs described in para-**
3 **graph (a) of this subsection that are dispensed by prescription.**

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

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

8 **(2) In consultation with the commission, the department shall adopt rules for the oper-**
9 **ation of the electronic prescription monitoring program established under subsection (1) of**
10 **this section, including but not limited to standards for:**

11 **(a) Reporting data;**

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

13 **(c) Ensuring accuracy and completeness of data;**

14 **(d) Complying with the federal Health Insurance Portability and Accountability Act of**
15 **1996 (P.L. 104-191) and regulations adopted under it, including 45 C.F.R. parts 160 and 164,**
16 **federal alcohol and drug treatment confidentiality laws and regulations adopted under those**
17 **laws, including 42 C.F.R. part 2, and state health and mental health confidentiality laws, in-**
18 **cluding ORS 179.505, 192.517 and 192.518 to 192.529;**

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

21 **(f) Accepting printed or nonelectronic reports from pharmacies that do not have the ca-**
22 **pability to provide electronic reports; and**

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

26 **(3) The department shall submit an annual report to the commission regarding the pre-**
27 **scription monitoring program established under this section.**

28 **SECTION 3. (1) Not later than one week after dispensing a prescription drug subject to**
29 **the prescription monitoring program established under section 2 of this 2009 Act, a pharmacy**
30 **shall electronically report to the Department of Human Services the:**

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

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

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

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

35 **(e) Date of origin of the prescription;**

36 **(f) Date the drug was dispensed; and**

37 **(g) Quantity of drug dispensed.**

38 **(2) Notwithstanding subsection (1) of this section, the department may not:**

39 **(a) Require the reporting of prescription drugs administered directly to a patient or dis-**
40 **dispensed pursuant to ORS 127.800 to 127.897; or**

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

42 **(3) Upon receipt of the data reported pursuant to subsection (1) of this section, the de-**
43 **partment shall record the data in the electronic system operated pursuant to the pre-**
44 **scription monitoring program.**

45 **(4)(a) The department may grant a pharmacy a waiver of the electronic submission re-**

1 requirement of subsection (1) of this section for good cause as determined by the department.
2 The waiver shall state the format, method and frequency of the alternate nonelectronic
3 submissions from the pharmacy and the duration of the waiver.

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

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

6 **SECTION 4.** (1)(a) Except as provided under subsection (2) of this section, prescription
7 monitoring information submitted under section 3 of this 2009 Act to the prescription moni-
8 toring program established in section 2 of this 2009 Act:

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

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

11 (b) Except as provided under subsection (2)(a)(D) of this section, prescription monitoring
12 information submitted under section 3 of this 2009 Act to the prescription monitoring pro-
13 gram may not be used to evaluate a practitioner's professional practice.

14 (2)(a) If a disclosure of prescription monitoring information complies with the federal
15 Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191) and regulations
16 adopted under it, including 45 C.F.R. parts 160 and 164, federal alcohol and drug treatment
17 confidentiality laws and regulations adopted under those laws, including 42 C.F.R. part 2, and
18 state health and mental health confidentiality laws, including ORS 179.505, 192.517 and 192.518
19 to 192.529, the Department of Human Services shall disclose the information:

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

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

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

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

34 (E) To a prescription monitoring program of another state if the confidentiality, security
35 and privacy standards of the requesting state are determined by the department to be
36 equivalent to those of the department.

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

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

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

42 (c) The department shall disclose information relating to a patient maintained in the
43 electronic system operated pursuant to the prescription monitoring program established
44 under section 2 of this 2009 Act to that patient at no cost to the patient within 10 business
45 days after the department receives a request from the patient for the information.

1 (d)(A) A patient may request the department to correct any information about the pa-
2 tient that is erroneous. The department shall grant or deny a request to correct information
3 within 10 business days after the department receives the request.

4 (B) If the department denies a patient's request to correct information under this para-
5 graph, or fails to grant a patient's request to correct information under this paragraph
6 within 10 business days after the department receives the request, the patient may appeal
7 the denial or failure to grant the request. Upon receipt of an appeal under this subpara-
8 graph, the department shall conduct a contested case hearing as provided in ORS chapter
9 183. Notwithstanding ORS 183.450, in the contested case hearing, the department has the
10 burden of establishing that the information included in the prescription monitoring program
11 is correct.

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

14 (f) In accordance with ORS 192.518 to 192.529 and federal privacy regulations, any person
15 authorized to prescribe or dispense a prescription drug and who is entitled to access a pa-
16 tient's prescription monitoring information may discuss or release the information to other
17 health care providers involved with the patient's care, in order to provide safe and appro-
18 priate care coordination.

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

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

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

24 (C) The date and time the information was requested and the date and time the infor-
25 mation was provided.

26 (b) Records maintained as required by this subsection may be reviewed by the Pre-
27 scription Monitoring Program Advisory Commission.

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

31 (5) The department shall notify the Attorney General and each affected individual of an
32 improper disclosure of information from the prescription monitoring program.

33 (6)(a) If the department or a person or entity required to report or authorized to receive
34 or release controlled substance prescription information under this section violates section
35 3, 4 or 5 of this 2009 Act, a person injured by the violation may bring a civil action against
36 the department, person or entity and may recover damages in the amount of \$1,000 or actual
37 damages, whichever is greater.

38 (b) Notwithstanding paragraph (a) of this subsection, the department and a person or
39 entity required to report or authorized to receive or release controlled substance pre-
40 scription information under this section are immune from civil liability for violations of
41 section 3, 4 or 5 of this 2009 Act unless the department, person or entity acts with malice,
42 criminal intent, gross negligence, recklessness or willful intent.

43 (7) Nothing in sections 2 to 11 of this 2009 Act requires a practitioner or pharmacist who
44 prescribes or dispenses a prescription drug to obtain information about a patient from the
45 prescription monitoring program. A practitioner or pharmacist who prescribes or dispenses

1 a prescription drug may not be held liable for damages in any civil action on the basis that
2 the practitioner or pharmacist did or did not request or obtain information from the pre-
3 scription monitoring program.

4 **SECTION 5.** A pharmacist may not refuse to fill a valid prescription solely because the
5 pharmacist cannot receive patient information from the prescription monitoring program
6 established under section 2 of this 2009 Act at the time the patient requests that the pre-
7 scription be filled.

8 **SECTION 6.** (1) In addition to any other penalty provided by law, the Attorney General
9 may impose a civil penalty not to exceed \$10,000 for each violation of section 3, 4 or 5 of this
10 2009 Act. Each improper release of information from the prescription monitoring program
11 in violation of section 4 of this 2009 Act is a separate violation.

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

13 (3) The Department of Justice may adopt rules as required to carry out the provisions
14 of this section.

15 (4) Penalties recovered under this section shall be paid into the State Treasury and
16 credited to the General Fund.

17 **SECTION 7.** The Department of Human Services shall report a practitioner or
18 pharmacist authorized to obtain controlled substance prescription information from the
19 prescription monitoring system established under section 2 of this 2009 Act who discloses or
20 uses information obtained from the system in violation of section 4 of this 2009 Act to the
21 health professional regulatory board responsible for the practitioner or pharmacist.

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

- 23 (a) The Oregon Medical Board;
- 24 (b) The Oregon Board of Dentistry;
- 25 (c) The Board of Naturopathic Examiners;
- 26 (d) The Oregon State Board of Nursing;
- 27 (e) The Oregon Board of Optometry; and
- 28 (f) The State Board of Pharmacy.

29 (2)(a) In addition to other licensing fees imposed by a board on licensees, a board shall
30 adopt rules imposing a fee of \$25 per year on each person licensed by the board who is au-
31 thorized to prescribe or dispense controlled substances. A board shall collect the fee at the
32 same time the board collects other licensing fees imposed on licensees.

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

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

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

40 (a) Studying issues related to the prescription monitoring program established under
41 section 2 of this 2009 Act;

42 (b) Reviewing the program's annual report and making recommendations to the Depart-
43 ment of Human Services regarding the operation of the program; and

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

45 (2) The commission shall consist of 11 members appointed by the department as follows:

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

2 (b) A person who dispenses controlled substances nominated by an association repre-
3 senting pharmacists;

4 (c) A practicing dentist nominated by an association representing dentists;

5 (d) A practicing physician nominated by an association representing physicians;

6 (e) A practicing doctor of osteopathy nominated by an association representing
7 osteopathic physicians and surgeons;

8 (f) A nurse authorized to prescribe controlled substances nominated by an association
9 representing nurses;

10 (g) A practicing naturopathic physician nominated by an association representing
11 naturopathic physicians;

12 (h) A practicing optometrist, nominated by an association representing optometrists;

13 (i) A person nominated by the department from a division of the department responsible
14 for administering addiction services; and

15 (j) Two members of the public nominated by the department, one of whom must be an
16 expert in information technology.

17 **SECTION 10.** (1) The term of office of each member of the Prescription Monitoring Pro-
18 gram Advisory Commission is four years, but a member serves at the pleasure of the De-
19 partment of Human Services. Before the expiration of the term of a member, the department
20 shall appoint a successor whose term begins on July 1 next following. A member is eligible
21 for reappointment. If there is a vacancy for any cause, the department shall make an ap-
22 pointment to become immediately effective.

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

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

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

28 (5) A majority of the members of the commission constitutes a quorum for the trans-
29 action of business.

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

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

33 (8) Members of the commission are not entitled to compensation, but may be reimbursed
34 for actual and necessary travel and other expenses incurred by them in the performance of
35 their official duties in the manner and amounts provided for in ORS 292.495. Claims for ex-
36 penses incurred in performing functions of the commission shall be paid out of funds appro-
37 priated to the department for that purpose.

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

42 **SECTION 11.** (1) The Electronic Prescription Monitoring Fund is established in the State
43 Treasury, separate and distinct from the General Fund. The Electronic Prescription Moni-
44 toring Fund consists of moneys transmitted to the fund under section 8 of this 2009 Act and
45 any other moneys deposited in accordance with law. Interest earned by the fund shall be

1 credited to the fund. Moneys in the fund are continuously appropriated to the Department
2 of Human Services for the purpose of carrying out the provisions of sections 2 to 11 of this
3 2009 Act.

4 (2) The Department of Human Services may accept grants, donations, gifts or moneys
5 from any source for deposit into the fund established by this section.

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

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

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

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

13 **SECTION 13.** (1) Sections 3 to 5 of this 2009 Act become operative on July 1, 2010.

14 (2) The Department of Human Services may take any action before the operative date in
15 subsection (1) of this section that is necessary to enable the department to exercise, on or
16 after the operative date in subsection (1) of this section, all of the duties, functions and
17 powers conferred on the department by sections 3 to 5 of this 2009 Act.

18 **SECTION 14.** (1) If the Legislative Assembly is meeting in special session in February
19 2010, the Department of Human Services shall report to the Joint Committee on Ways and
20 Means on the implementation of the prescription monitoring program under sections 2 to 11
21 of this 2009 Act. The report shall include, but need not be limited to, the status of the elec-
22 tronic system required by section 2 of this 2009 Act and the content of rules adopted under
23 section 2 of this 2009 Act.

24 (2) If the Legislative Assembly is not meeting in special session in February 2010, the
25 department shall submit the report described in subsection (1) of this section to the Speaker
26 of the House of Representatives and the President of the Senate by February 15, 2010.

27 **SECTION 15.** Notwithstanding any other law limiting expenditures, the limitation on
28 expenditures established by section 2 (3), chapter __, Oregon Laws 2009 (Enrolled Senate
29 Bill 5529), for the biennium beginning July 1, 2009, as the maximum limit for payment of ex-
30 penses for health services from fees, moneys or other revenues, including Miscellaneous
31 Receipts, but excluding lottery funds and federal funds, collected or received by the Depart-
32 ment of Human Services, is increased by \$250,000 for the purpose of carrying out the pro-
33 visions of sections 2 to 11 of this 2009 Act.

34 **SECTION 16.** Notwithstanding any other law limiting expenditures, the limitation on
35 expenditures established by section 4 (3), chapter __, Oregon Laws 2009 (Enrolled Senate
36 Bill 5529), for the biennium beginning July 1, 2009, as the maximum limit for payment of ex-
37 penses from certain federal funds collected or received by the Department of Human Ser-
38 vices, is increased by \$10,000 for the purpose of carrying out the provisions of sections 2 to
39 11 of this 2009 Act.

40 **SECTION 17.** This 2009 Act being necessary for the immediate preservation of the public
41 peace, health and safety, an emergency is declared to exist, and this 2009 Act takes effect
42 on its passage.