B-Engrossed Senate Bill 34

Ordered by the House June 6 Including Senate Amendments dated March 26 and House Amendments dated June 6

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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 database for information reported by pharmacies regarding dispensing of certain controlled substances. Restricts access to and limits use of information in database. Provides immunity to pharmacist or practitioner who did or did not request or obtain information from database.

Authorizes Attorney General to impose civil penalty on practitioner or pharmacist who violates confidentiality, security or privacy standards of controlled substance prescription information database.

Provides that pharmacist may not refuse to fill valid controlled substance prescription solely because pharmacist cannot receive patient information from database.

Creates Electronic Prescription Drug Database Advisory Commission.

Declares emergency, effective on passage.

A BILL FOR AN ACT

- Relating to electronic prescription drug database; and declaring an emergency.
- Be It Enacted by the People of the State of Oregon: 3
- SECTION 1. Sections 2 to 5, 9 and 10 of this 2007 Act are added to and made a part of 4 ORS chapter 689. 5
 - SECTION 2. As used in sections 2 to 5, 9 and 10 of this 2007 Act:
 - (1) "Controlled substance" means a drug classified in Schedule II, III or IV under the federal Controlled Substances Act, 21 U.S.C. 811 to 812, as modified under ORS 475.035.
- (2) "Health professional regulatory board" has the meaning given that term in ORS 9 10 676,160.
 - SECTION 3. (1)(a) The State Board of Pharmacy shall establish and maintain a database for electronically reporting the dispensing of controlled substances.
 - (b) The board may contract with a state agency or with a private entity to ensure the effective operation of the database established under this section.
- (2) The board shall adopt rules for the operation of the electronic prescription drug database established under subsection (1) of this section, including but not limited to standards 16 for:
 - (a) Reporting data electronically and nonelectronically;
- (b) Providing maintenance, security and disclosure of data; 19
 - (c) Ensuring accuracy and completeness of data;
 - (d) Ensuring accurate identification of persons or entities requesting information from

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.

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- (e) Assessing civil penalties under ORS 689.832 for failing to report or for wrongful disclosure of data by a person required to report under section 4 of this 2007 Act; and
 - (f) Notifying patients that:
- (A) Before a patient receives a medication authorized by a prescription for a controlled substance, information about the prescription will be entered in the database;
- (B) There has been a request to search the database for information about the patient; and
- (C) The patient may review the information in the database about the patient every six months at no cost.
- SECTION 4. (1) Not later than one week after dispensing a controlled substance, a pharmacy shall report to the State Board of Pharmacy the:
 - (a) Name, address and date of birth of the patient;
 - (b) Name of the drug outlet dispensing the controlled substance;
- (c) Name of the practitioner who prescribed the controlled substance;
- (d) Identification of the controlled substance by a national drug code number;
- 17 (e) Date of origin of the prescription;
 - (f) Date the controlled substance was dispensed;
- 19 (g) Quantity dispensed; and
- 20 (h) Other relevant information as required by rules adopted by the State Board of Phar-21 macy.
 - (2) Notwithstanding subsection (1) of this section, the State Board of Pharmacy may not:
 - (a) Require the reporting of controlled substances administered directly to a patient or dispensed pursuant to ORS 127.800 to 127.897; or
 - (b) Collect or use Social Security numbers in the electronic prescription drug database.
 - (3) Upon receipt of the data reported pursuant to subsection (1) of this section, the State Board of Pharmacy shall record the data in the electronic prescription drug database established under section 3 of this 2007 Act.
 - (4) The information in the database is health care information that is confidential and may be disclosed by the State Board of Pharmacy only as authorized by the federal Health Insurance Portability and Accountability Act privacy regulations, 45 C.F.R. parts 160 and 164, and ORS 192.518 to 192.526:
 - (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 current patient for whom the practitioner or pharmacist is prescribing or dispensing, or is considering prescribing or dispensing, a controlled substance;
 - (b) Pursuant to a valid court order 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;
 - (c) To a health professional regulatory board that certifies 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;
 - (d) Upon request, to an individual who is the recipient of a prescription for a controlled substance entered into the database or to the individual's attorney within 10 days of the request; or

- (e) To a practitioner or pharmacist to whom the requested information pertains.
- (5) The State Board of Pharmacy shall maintain records on the information disclosed from the database, including but not limited to:
- (a) The identification of each individual who requests or receives information from the database and what organization, if any, that individual represents;
 - (b) The information released to each individual or organization;

- (c) The date and time the information was requested and the date and time the information was provided; and
 - (d) Records of the details of all requests made for law enforcement purposes.
- (6) Records maintained as required by subsection (5)(d) of this section are subject to disclosure as a public record, except that information that can be used to identify individual patients may not be released.
- (7) The State Board of Pharmacy shall notify the Attorney General and each individual affected by the improper release of information from the database.
- (8)(a) Data from the database that do not identify a patient, practitioner or drug outlet may be released by the State Board of Pharmacy for educational, research or public information purposes.
- (b) Data in the database that identify an individual patient shall be removed from the database three years from the data is entered into the database.
- (9)(a) The State Board of Pharmacy, or a person or entity required to report or authorized to receive or release controlled substance prescription information under this section, is immune from civil liability unless the board, person or entity acts with malice, criminal intent, gross negligence, recklessness or willful intent in a manner that violates the provisions of this section.
- (b) If a person, the board or an entity acts in the manner described in paragraph (a) of this subsection, the person, board or entity is subject to a civil penalty of \$1,000 or for actual damages, whichever is greater.
- (10) Reports from the database established under section 3 of this 2007 Act may not be used as evidence in any criminal or civil proceeding.
- (11) Nothing in this section requires a pharmacist or a practitioner who prescribes a controlled substance to obtain information about a patient from the database established under section 3 of this 2007 Act. A pharmacist or a practitioner who prescribes a controlled substance may not be held liable for damages in any civil action on the basis that the pharmacist or practitioner did or did not request or obtain information from the database.
- (12)(a) An individual who has had controlled substance prescription information entered into the database may request the State Board of Pharmacy to ensure the removal of any erroneous information and may appeal the board's decision not to remove the erroneous information.
- (b) Upon the receipt of an appeal under paragraph (a) of this subsection, the board shall conduct a contested case hearing as provided under ORS chapter 183.
- (c) The board has the burden of establishing that the information included in the database was properly included in the database.
- (13) The information collected in the database may not be used for any commercial purpose.
 - SECTION 5. The State Board of Pharmacy may accept grants, donations, gifts or moneys

from any source for expenditures consistent with the purposes of sections 3 and 4 of this 2007 Act. Any moneys received under this section shall be paid into the State Treasury and credited to the State Board of Pharmacy Account.

<u>SECTION 6.</u> (1) The Electronic Prescription Drug Database Advisory Commission is created for the purposes of:

- (a) Studying issues related to the electronic prescription drug database established under section 3 of this 2007 Act.
 - (b) Making recommendations to the State Board of Pharmacy about:
- (A) Which controlled substances should be subject to the reporting requirements of section 4 of this 2007 Act; and
- (B) The criteria that should be used to evaluate the data regarding those controlled substances.
- (2) The Electronic Prescription Drug Database Advisory Commission shall consist of 12 members selected as follows:
- (a) The President of the Senate shall appoint one member from among the members of the Senate, one public member from a group that represents patients' rights or interests and one public member with expertise in consumer privacy protection.
- (b) The Speaker of the House of Representatives shall appoint one member from among the members of the House of Representatives, one public member from a group that advocates for privacy of medical records and one public member with expertise in security for electronic databases.
 - (c) The State Board of Pharmacy shall appoint six members as follows:
- (A) One member from a list of pharmacists licensed to practice pharmacy in this state submitted by the State Board of Pharmacy.
- (B) One member from a list of physicians licensed to practice in this state submitted by the Board of Medical Examiners.
- (C) One member from a list of dentists licensed to practice dentistry in this state submitted by the Oregon Board of Dentistry.
- (D) One member from a list of nurses licensed to practice nursing in this state submitted by the Oregon State Board of Nursing.
- (E) One member from a list of naturopaths licensed to practice naturopathic medicine in this state submitted by the Board of Naturopathic Examiners.
- (F) One member from a list of nominees submitted by the Pain Management Commission. SECTION 7. (1) The term of office of each member of the Electronic Prescription Drug Database Advisory Commission is four years, but a member serves at the pleasure of the appointing authority. Before the expiration of the term of a member, the appointing authority 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 appointing authority 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 trans-

1 action of business.

- (6) Official action by the commission requires the approval of a majority of the members of the commission.
 - (7) The State Board of Pharmacy shall provide staff support to the commission.
- (8) Members of the commission who are not members of the Legislative Assembly 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 State Board of Pharmacy 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 8. Notwithstanding the term of office specified by section 7 of this 2007 Act, the members first appointed to the Electronic Prescription Drug Database Advisory Commission shall determine by lot at the first meeting of the commission the initial terms of office for commission members as follows:
 - (1) Four shall serve for a term ending July 1, 2008.
 - (2) Four shall serve for a term ending on July 1, 2009.
 - (3) Four shall serve for a term ending on July 1, 2010.
- SECTION 9. (1) A practitioner or pharmacist authorized to obtain controlled substance prescription information from the database established under section 3 of this 2007 Act who knowingly discloses or uses information obtained from the database in violation of section 4 of this 2007 Act shall be reported to the appropriate health professional regulatory board for consideration of disciplinary action under the authority of that board.
- (2)(a) In addition to any other penalty imposed by law, the Attorney General may impose a civil penalty not to exceed \$10,000 for each violation of section 4 of this 2007 Act. Each improper release of information in violation of section 4 of this 2007 Act shall be considered a separate offense.
- (b) Civil penalties imposed under this subsection shall be imposed as provided in ORS 183.745.
- (c) The Department of Justice may adopt rules required to carry out the provisions of this subsection.
- (3) The remedies prescribed in this section are cumulative and in addition to any other applicable criminal, civil or administrative penalties.
- <u>SECTION 10.</u> A pharmacist may not refuse to fill a valid controlled substance prescription presented to the pharmacist solely because the pharmacist cannot receive patient information from the database established under section 3 of this 2007 Act at the time the patient requests that the controlled substance prescription be filled.
- SECTION 11. (1) Section 4 of this 2007 Act becomes operative on the date that the database required to be established by section 3 of this 2007 Act begins continuous operation 24 hours a day, seven days a week, and is capable of responding immediately to inquiries for information from the database by authorized users.
 - (2) The State Board of Pharmacy shall notify the Legislative Counsel when the database

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4 5 meets the requirements of subsection (1) of this section. SECTION 12. This 2007 Act being necessary for the immediate preservation of the public peace, health and safety, an emergency is declared to exist, and this 2007 Act takes effect on its passage.