HB 2257-1
(LC 633)
1/30/19 (SCT/ps)

Requested by HOUSE COMMITTEE ON HEALTH CARE (at the request of Governor Kate Brown)

PROPOSED AMENDMENTS TO
HOUSE BILL 2257

On page 1 of the printed bill, line 2, after "drugs;" insert "creating new provisions; amending ORS 431A.850, 431A.855, 431A.860, 431A.865 and 431A.867;".

On page 2, after line 15, insert:

"(2) In establishing the requirements under this section, the advisory group shall:

"(a) Solicit input from stakeholders, including state agencies, unions representing substance use disorder treatment providers and others; and

"(b) Consider relevant factors, including but not limited to the geographic accessibility of treatment, culturally appropriate treatment options, the language needs of potential treatment patients and the needs of substance use disorder treatment providers.

"(3) The advisory group shall research and determine how to maximize all sources of federal funding that is available for treatment programs described in this section.

"(4) The advisory group may adopt rules to carry out this section.".

In line 16, delete "(2)" and insert "(5)".

Delete lines 22 through 28 and insert:

"SECTION 7. (1) The Oregon Health Authority shall prohibit public payers of health insurance, when reimbursing the cost of treating substance use disorders, including opioid and opiate addiction, from

requiring prior authorization of payment during the first 30 days of treatment.

"(2) The authority may adopt rules to carry out this section.

"SECTION 8. Section 7 of this 2019 Act applies to the provision of treatment services that begins on and after the operative date specified in section 20 (1) of this 2019 Act.".

On page 3, after line 17, insert:

"(3) Sterile needles and syringes and other items provided by a syringe service program may not be considered 'drug paraphernalia,' as that term is defined in ORS 475.525.".

Delete lines 20 through 26 and insert:

"SECTION 15. ORS 431A.850. As used in ORS 431A.855 to 431A.900:

"**(1) 'Dental managing director' means a dentist, as defined in ORS 679.010, employed by a dental clinic or office, or a system of dental clinics or offices, for the purpose of overseeing the operations of the dental clinic or office, or the system of dental clinics or offices, and ensuring the delivery of quality dental care within the clinic, office or system.**

"[*(1)*] **(2)** 'Dispense' and 'dispensing' have the meanings given those terms in ORS 689.005.

"[*(2)*] **(3)** 'Drug outlet' has the meaning given that term in ORS 689.005.

"[*(3)*] **(4)** 'Health professional regulatory board' means a health professional regulatory board, as defined in ORS 676.160, the Long Term Care Administrators Board, the Board of Licensed Dietitians and the Behavior Analysis Regulatory Board.

"[*(4)*] **(5)** 'Medical director' means a physician employed by a **coordinated care organization,** 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)*] **(6)** 'Pharmacist' means:

"(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)*] **(7)** '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.

"[*(7)*] **(8)** 'Practitioner' means:

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

"(b) An individual licensed to practice a profession in another state, if the requirements for licensure are similar, as determined by the authority, to the requirements for being licensed as a practitioner as defined in ORS 689.005.

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

"[*(9)*] **(10)** 'Prescription drug' has the meaning given that term in ORS 689.005. ORS 431A.850, as amended by section 14, chapter 61, Oregon Laws 2018, is amended to read:

"SECTION 16. ORS 431A.855, as amended by section 8, chapter 45, Oregon Laws 2018, 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 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 board by rule under ORS 475.035; and

"(B) Prescribed **gabapentin and** 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:

"(i) Operate and be accessible [*by practitioners and pharmacies*] 24 hours a day, seven days a week**, to practitioners, pharmacies and the dental director appointed by the authority under ORS 413.083**; and

"(ii) Allow practitioners to register as required under section 7, chapter 45, Oregon Laws 2018, and to apply for access to the electronic system in accordance with rules adopted by the authority under subsection (2) of this section.

"(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 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 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;

"(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; and

"(h) Registering practitioners with the electronic system.

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

"SECTION 17. 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, the name, address, phone number, date of birth and sex of the patient for whom the prescription drug was prescribed;

"(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**; and**

"(i) The diagnosis code used by the practitioner and the reason for the prescription.

"(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 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 non-electronic 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 18. ORS 431A.865 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 under ORS 192.311 to 192.478.

"(b) Except as provided under subsection (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 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 **dental managing director,** medical director or pharmacy director, or, if a **dental managing director,** medical director or pharmacy director authorizes the authority to disclose the information to a member of the **dental managing director's,** medical director's or pharmacy director's staff, to a member of the **dental managing director's,** medical director's or pharmacy director's staff. If a **dental managing director,** medical direc-

tor or pharmacy director authorizes disclosing the information to a member of the **dental managing director's,** medical director's or pharmacy director's staff under this subparagraph, the **dental managing director,** 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[*,*]**:**

"(i) A dental managing director must certify that the requested information is for the purposes of overseeing the operations of a dental clinic or office, or a system of dental clinics or offices, and ensuring the delivery of quality dental care within the clinic, office or system.

"(ii) 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,*]

"**(iii)** 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.

"(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.

"(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.

"(E) To the Chief Medical Examiner or designee of the Chief Medical Examiner, for the purpose of conducting a medicolegal investigation or autopsy.

"(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 established under ORS 431A.855.

"(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.

"(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.

"(I) Pursuant to an agreement entered into under ORS 431A.869.

"**(J) To a dental managing director, medical director, pharmacy director, practitioner or pharmacist for the purposes of evaluating the prescription of opioids and other controlled substances by practitioners and for making comparisons of prescriptions for opioids and other controlled substances between similarly situated practitioners.**

"(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;

"(D) To a local public health authority, as defined in ORS 431.003; or

"(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 authority shall disclose information relating to a patient maintained in the electronic system 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 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 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 laws and regulations related to privacy, any person authorized to prescribe or dispense a prescription drug 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 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:

"(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 individual 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 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 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 under subsection (2) of this section.

"SECTION 19. ORS 431A.867 is amended to read:

"431A.867. (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*] **Ensure that the agreement will benefit the health and safety of Oregonians**;

"(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 20. (1) Sections 1 to 14 of this 2019 Act and the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865 and 431A.867 by sections 15 to 19 of this 2019 Act become operative on January 1, 2020.

"(2) The Department of Corrections and the Oregon Health Authority may take any action before the operative date specified in subsection (1) of this section that is necessary to enable the department and the authority to exercise, on and after the operative date specified in subsection (1) of this section, all of the duties, functions and powers conferred on the department and the authority by sections 1 to 14 of this 2019 Act and the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865 and 431A.867 by sections 15 to 19 of this 2019 Act.".

In line 27, delete "16" and insert "21".
