SENATE AMENDMENTS TO A-ENGROSSED HOUSE BILL 3258 (INCLUDING AMENDMENTS TO RESOLVE CONFLICTS)

By COMMITTEE ON HEALTH CARE

May 23

On page 1 of the printed A-engrossed bill, line 3, delete "431A.880,". 1 2 On page 3, after line 38, insert: "SECTION 4a. If House Bill 2395 becomes law, section 4 of this 2023 Act (amending ORS 3 431A.855) is repealed and ORS 431A.855, as amended by section 31, chapter ____, Oregon Laws 4 2023 (Enrolled House Bill 2395), is amended to read: 5 6 "431A.855. (1)(a) The Oregon Health Authority, in consultation with the Prescription Monitoring 7 Program Advisory Commission, shall establish and maintain a prescription monitoring program for 8 monitoring and reporting: 9 "(A) Except as provided in subsection (4) of this section, prescription drugs dispensed by 10 pharmacies licensed by the State Board of Pharmacy that are classified in schedules II through [IV] V under the federal Controlled Substances Act, 21 U.S.C. 811 and 812, as modified by the board 11 by rule under ORS 475.035; 12 "(B) Prescribed gabapentin [and short-acting opioid antagonists, as defined in ORS 689.681,] dis-13pensed by pharmacies; and 14 "(C) Other drugs identified by rules adopted by the authority. 15"(b)(A) To fulfill the requirements of this subsection, the authority shall establish, maintain and 16 operate an electronic system to monitor and report drugs described in paragraph (a) of this sub-17section that are dispensed by prescription. 18 "(B) The electronic system must: 19 (i) Operate and be accessible by practitioners and pharmacies 24 hours a day, seven days a 2021week; and 22"(ii) Allow practitioners to register as required under ORS 431A.877 and to apply for access to the electronic system in accordance with rules adopted by the authority under subsection (2) of this 23section. 2425"(C) [The authority may contract with a state agency or private entity to ensure the effective operation of the electronic system.] To ensure the interoperability of data contained in the electronic 26system, the authority shall contract with an information technology services vendor to pro-27vide secure connections between the electronic system and prescribers and between the 28 29 electronic system and pharmacies. The approved entity, as described by the authority by rule, is responsible for ensuring that only practitioners registered under ORS 431A.877 and 30 31pharmacies may access the electronic system. 32"(D) The authority shall contract with a state agency or private entity to ensure the effective operation of the electronic system, including the operation of any technology inte-33 grations between the electronic system and a health information technology system used by 34

1 a practitioner.

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2 "(2) In consultation with the commission, the authority shall adopt rules for the operation of the 3 electronic prescription monitoring program established under subsection (1) of this section, including 4 standards for:

5 "(a) Reporting data;

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

"(c) Ensuring accuracy and completeness of data;

8 "(d) Complying with the federal Health Insurance Portability and Accountability Act of 1996 9 (P.L. 104-191) and regulations adopted under that law, including 45 C.F.R. parts 160 and 164, federal 10 alcohol and drug treatment confidentiality laws and regulations adopted under those laws, including 11 42 C.F.R. part 2, and state health and mental health confidentiality laws, including ORS 179.505, 12 192.517 and 192.553 to 192.581;

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

"(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] V is dispensed to the patient, about the prescription monitoring program and the entry of the prescription in the electronic system; and

20 "(h) Registering practitioners with the electronic system.

21 "(3) The authority shall submit an annual report to the commission regarding the prescription 22 monitoring program established under this section.

23 "(4) The prescription and dispensing of a short-acting opioid antagonist, as defined in 24 ORS 689.681, or a drug containing pseudoephedrine or ephedrine or a salt, isomer or salt of 25 an isomer of pseudoephedrine or ephedrine is not subject to the prescription monitoring 26 program established under this section.".

27 On page 8, after line 2, insert:

28 "SECTION 6a. If House Bill 2395 becomes law, section 6 of this 2023 Act (amending ORS
431A.865) is repealed and ORS 431A.865, as amended by section 32, chapter ___, Oregon Laws
2023 (Enrolled House Bill 2395), is amended to read:

31 "431A.865. (1)(a) Except as provided under subsections (2) and (3) of this section, prescription 32 monitoring information submitted under ORS 431A.860 to the prescription monitoring program es-33 tablished in ORS 431A.855:

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

35 "(B) Is confidential and not subject to disclosure under ORS 192.311 to 192.478.

36 "(b) Except as provided under subsection (3)(a)(H) of this section, prescription monitoring infor-37 mation submitted under ORS 431A.860 to the prescription monitoring program may not be used to 38 evaluate a practitioner's professional practice.

"(2) The Oregon Health Authority may review the prescription monitoring information of an
 individual who dies from a drug overdose.

41 "(3)(a) Except as provided in paragraph (c) of this subsection, the Oregon Health Authority shall
 42 disclose prescription monitoring information reported to the authority under ORS 431A.860:

43 "(A)(i) Subject to sub-subparagraph (ii) of this subparagraph, to a practitioner or 44 pharmacist, or, if a practitioner or pharmacist authorizes the authority to disclose the information 45 to a member of the practitioner's or pharmacist's staff, to a member of the practitioner's or

1 pharmacist's staff. If a practitioner or pharmacist authorizes disclosing the information to a member 2 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 infor-3 4 mation 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 5 the purpose of evaluating the need for or providing medical or pharmaceutical treatment for a pa-6 7 tient, or if applicable, a patient's animal, to whom the practitioner or pharmacist anticipates 8 providing, is providing or has provided care.

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"(ii) The authority may not disclose the information described in this subsection to a practitioner who is a veterinarian.

11 "(B) To a dental director, medical director or pharmacy director, or, if a dental director, medical 12director or pharmacy director authorizes the authority to disclose the information to a member of 13the dental director's, medical director's or pharmacy director's staff, to a member of the dental director's, medical director's or pharmacy director's staff. If a dental director, medical director or 14 15pharmacy director authorizes disclosing the information to a member of the dental director's, med-16 ical director's or pharmacy director's staff under this subparagraph, the dental director, medical 17director or pharmacy director remains responsible for the use or misuse of the information by the 18 staff member. To receive information under this subparagraph, or to authorize the receipt of infor-19 mation by a staff member under this subparagraph:

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

"(ii) A medical director must certify that the requested information is for the purposes of overseeing the operations of a coordinated care organization, hospital, health care clinic or system of hospitals or health care clinics and ensuring the delivery of quality health care within the coordinated care organization, hospital, clinic or system.

"(iii) A pharmacy director must certify that the requested information is for the purposes of overseeing the operations of a coordinated care organization, pharmacy or system of pharmacies and ensuring the delivery of quality pharmaceutical care within the coordinated care organization, 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 technologysystem;

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

39 "(iii) The health information technology system meets any privacy and security requirements 40 and other criteria, including criteria required by the federal Health Insurance Portability and Ac-41 countability Act, established by the authority by rule.

42 "(D) To a practitioner in a form that catalogs all prescription drugs prescribed by the practi-43 tioner according to the number assigned to the practitioner by the Drug Enforcement Adminis-44 tration of the United States Department of Justice.

45 "(E) To the Chief Medical Examiner or designee of the Chief Medical Examiner, for the purpose

1 of conducting a medicolegal investigation or autopsy.

2 "(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 3 4 431A.855.

"(G) Pursuant to a valid court order based on probable cause and issued at the request of a 5 federal, state or local law enforcement agency engaged in an authorized drug-related investigation 6 7 involving a person to whom the requested information pertains.

8 "(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 9 10 action involving the applicant, licensee or registrant to whom the requested information pertains. 11

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

"(J) To the director of the division of the authority that administers the state medical 1213assistance program and the director of the division of the authority that administers the prescription drug program within the state medical assistance program, and authorized staff, 14 15after certification that the requested information is for purposes of overseeing the state 16 medical assistance program, and to the Centers for Medicare and Medicaid Services for the purpose of ensuring the prescription monitoring program meets systems certification re-1718 quirements. A disclosure under this subparagraph may be of only the minimum information 19 necessary to fulfill the intended purposes. If a director described in this subparagraph au-20thorizes disclosure to the director's staff, the authorizing director remains responsible for 21the use or misuse of the information by the staff member.

22"(b) The authority may disclose information from the prescription monitoring program that does 23not identify a patient, practitioner or drug outlet:

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

25"(B) For the purpose of educating practitioners about the prescribing of opioids and other con-26trolled substances;

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"(C) To a health professional regulatory board;

"(D) To a local public health authority, as defined in ORS 431.003; or 28

29"(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 30 431.990. 31

"(c) The authority may not disclose, except as provided in paragraph (b) of this subsection:

33 "(A) Prescription drug monitoring information to the extent that the disclosure fails to comply 34with applicable provisions of the federal Health Insurance Portability and Accountability Act of 35 1996 (P.L. 104-191) and regulations adopted under that law, including 45 C.F.R. parts 160 and 164, 36 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 37 to 192.581. 38

"(B) The sex of a patient for whom a drug was prescribed.

40 "[(C) The identity of a patient for whom a short-acting opioid antagonist, as defined in ORS 41 689.681, was prescribed.]

"(C) Prescription drug monitoring information to a practitioner who is a veterinarian.

43 "(d) The authority shall disclose information relating to a patient, and if applicable, the 44 patient's animal, maintained in the electronic system established under ORS 431A.855 to that pa-45 tient at no cost to the patient within 10 business days after the authority receives a request from 1 the patient for the information.

2 "(e)(A) A patient may request the authority to correct any information related to the patient, or if applicable, the patient's animal, that is maintained in the electronic system established un-3 4 der 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 5 information cannot be granted because the error occurred at the pharmacy where the information 6 7 was inputted, the authority shall inform the patient that the information cannot be corrected be-8 cause the error occurred at the pharmacy.

"(B) If the authority denies a patient's request to correct information under this paragraph, or 9 10 fails to grant a patient's request to correct information under this paragraph within 10 business days 11 after the authority receives the request, the patient may appeal the denial or failure to grant the 12request. Upon receiving notice of an appeal under this subparagraph, the authority shall conduct 13a 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. 14 15"(f) The information in the prescription monitoring program may not be used for any commercial

16 purpose.

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17"(g) In accordance with ORS 192.553 to 192.581 and federal laws and regulations related to pri-18 vacy, any person authorized to prescribe or dispense a prescription drug who is entitled to access 19 a patient's prescription monitoring information may discuss the information with or release the in-20formation to other health care providers involved with the patient's care for the purpose of provid-21ing safe and appropriate care coordination.

22"(4)(a) The authority shall maintain records of the information disclosed through the pre-23scription monitoring program including:

"(A) The identity of each person who requests or receives information from the program and any 24 25organization the person represents;

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

27"(C) The date and time the information was requested and the date and time the information 28was provided.

"(b) Records maintained as required by this subsection may be reviewed by the Prescription 2930 Monitoring Program Advisory Commission.

(5) Information in the prescription monitoring program that identifies an individual patient 3132must be removed no later than three years from the date the information is entered into the pro-33 gram.

34"(6) The authority shall notify the Attorney General and each individual affected by an improper 35 disclosure of information from the prescription monitoring program of the disclosure.

"(7)(a) If the authority or a person or entity required to report or authorized to receive or re-36 37 lease prescription information under this section violates this section or ORS 431A.860 or 431A.870, 38 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. 39

40 (b) Notwithstanding paragraph (a) of this subsection, the authority and a person or entity re-41 quired to report or authorized to receive or release prescription information under this section are 42immune 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 43 44 intent.

45 "(8) Nothing in ORS 431A.855 to 431A.900 requires a practitioner or pharmacist who prescribes 1 or dispenses a prescription drug to obtain information about a patient from the prescription moni-

2 toring 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 3

4 did or did not request or obtain information from the prescription monitoring program.

5 "(9) The authority shall, at regular intervals, ensure compliance of a health information technology system described in subsection (3) of this section with the privacy and security requirements 6 7 and other criteria established by the authority under subsection (3) of this section.".

Delete lines 3 through 29. 8

In line 30, delete "8" and insert "7". 9

In line 38, delete "13" and insert "12". 10

- 11 On page 9, line 7, restore the bracketed material.
- 12Delete line 8.
- 13In line 9, restore "(j)" and delete "(k)".

In line 11, delete "9" and insert "8". 14

15Delete lines 27 through 45 and delete page 10 and insert:

16 "SECTION 9. (1) Section 2 of this 2023 Act and the amendments to ORS 431A.850, 431A.855, 431A.860 and 431A.865 by sections 3 to 6 of this 2023 Act apply to prescription drugs 17 18 dispensed on or after the operative date specified in section 10 of this 2023 Act.

19 "(2) The amendments to ORS 431A.896 by section 8 of this 2023 Act apply to members of 20the Prescription Monitoring Program Prescribing Practices Review Subcommittee appointed 21on or after the operative date specified in section 10 of this 2023 Act.

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"SECTION 9a. If House Bill 2395 becomes law, section 9 of this 2023 Act is amended to read: 23"Sec. 9. (1) Section 2 of this 2023 Act and the amendments to ORS 431A.850, 431A.855, 431A.860 and 431A.865 by sections 3 to [6] 6a of this 2023 Act apply to prescription drugs dispensed on or 2425after the operative date specified in section 10 of this 2023 Act.

26"(2) The amendments to ORS 431A.896 by section 8 of this 2023 Act apply to members of the Prescription Monitoring Program Prescribing Practices Review Subcommittee appointed on or after 27the operative date specified in section 10 of this 2023 Act. 28

29"SECTION 10. (1) Section 2 of this 2023 Act and the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.890 and 431A.896 by sections 3 to 8 of this 2023 Act become 30 operative on January 1, 2025. 31

"(2) The Oregon Health Authority may take any action before the operative date specified 3233 in subsection (1) of this section that is necessary to enable the authority to exercise, on and 34after the operative date specified in subsection (1) of this section, all of the duties, functions 35 and powers conferred on the authority by section 2 of this 2023 Act and the amendments to ORS 431A.850, 431A.855, 431A.860, 431A.865, 431A.890 and 431A.896 by sections 3 to 8 of this 36 2023 Act. 37

38 "SECTION 11. This 2023 Act takes effect on the 91st day after the date on which the 2023 regular session of the Eighty-second Legislative Assembly adjourns sine die.". 39

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