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NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 333
OREGON HEALTH AUTHORITY
PUBLIC HEALTH DIVISION

FILED
11/22/2024 11:29 AM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Prescription Drug Monitoring Program reporting requirements and information request

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/23/2024 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

A public rulemaking hearing may be requested in writing by 10 or more people, or by a group with 10 or more members, within 21 days following the publication of the Notice of Proposed Rulemaking in the Oregon Bulletin or 28 days from the date the Notice was sent to people on the agency mailing list, whichever is later. If sufficient hearing requests are received, the notice of the date and time of the rulemaking hearing must be published in the Oregon Bulletin at least 14 days before the hearing.

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NEED FOR THE RULE(S)

House Bill 3258 (Oregon Laws 2023, chapter 438) was passed by the 2023 Oregon Legislature and made minor alterations to the Prescription Drug Monitoring Program (PDMP) statute. Two changes that must be reflected in rule:

- Add schedule V drugs and fields related to veterinarian prescribed drugs to be reported to the PDMP. The PDMP currently collects schedule II-IV drugs, however, schedule V drugs have also been shown to carry risk for abuse and overdose, especially when combined with other medications. Collecting these drugs in the PDMP will improve providers' knowledge of the patient's comprehensive prescription history prior to prescribing. Similarly, collecting veterinarian prescribed drugs and new fields to properly categorize them within the PDMP will improve providers' knowledge of additional risk factors facing their patients.
- Add the director of the division of the Oregon Health Authority responsible for the state medical assistance program to be allowed to submit requests for information from the program. This is similar to other oversight roles (coordinated care organization (CCO) directors, medical directors) that are allowed to submit requests for data to oversee their entities.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

HB 3258 (Oregon Laws 2023, chapter 438):
https://olis.oregonlegislature.gov/liz/2023R1/Downloads/MeasureDocument/HB3258
OAR chapter 333, division 23:
https://secure.sos.state.or.us/oard/displayDivisionRules.action?selectedDivision=1238
ORS chapter 431A: https://www.oregonlegislature.gov/bills_laws/ors/ors431A.html

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

These proposed rules have limited impact on racial or health equity in the state. The new drugs to be collected have a

smaller abuse potential than the drugs currently being collected in the PDMP and will not significantly increase barriers for marginalized groups.

FISCAL AND ECONOMIC IMPACT:

There is no anticipated fiscal or economic impact of the proposed changes.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) There is no anticipated cost of compliance impact to state agencies, units of local government, or the public with the proposed changes.

(2)(a) Approximately 800 pharmacies would be impacted by the new collection requirements. The implementation level of effort is low, all approximately 800 pharmacies are already reporting to the PDMP, these changes require small changes be made to the reporting selections. No new trainings or advanced alterations are required.

(b) None. There is no additional reporting, recordkeeping or administrative activities required for compliance. Implementation of these changes can be monitored using existing reports and staff.

(c) None. There are no equipment, supplies, labor, or increased administration required for compliance.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were not involved in the development of the rules because the proposed rule changes are to align with changes made to statute and there is no room for interpretation of the bill language.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? NO IF NOT, WHY NOT?

These proposed rule changes are to align with changes made to statute and there is no room for interpretation of the bill language.

RULES PROPOSED:
333-023-0810, 333-023-0820

AMEND: 333-023-0810

RULE SUMMARY: Amending OAR 333-023-0810 to include schedule V drugs in the list of drugs reported to the Prescription Drug Monitoring Program (PDMP). Currently schedule II-IV are listed. OAR 333-023-0810 is also amended to include name, species, and sex for animals when applicable. Addition of these fields will allow veterinarian prescribed drugs to be properly labeled and categorized within the PDMP.

CHANGES TO RULE:

333-023-0810
Reporting Requirements ¶

(1) Not later than 72 hours after dispensing a controlled substance a pharmacy shall electronically report to the ~~Authority~~Oregon Health Authority (Authority) the following information for prescription drugs dispensed that

are classified in schedules II through ~~I~~V 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:¶
(a) Patient's full name, address, phone number, date of birth, and sex;¶
(b) Pharmacy Drug Enforcement Administration Registration Number (or other identifying number in lieu of such registration number);¶
(c) Prescriber name and Drug Enforcement Administration Registration Number (or other identifying number in lieu of such registration number);¶
(d) Identification of the controlled substance using a national drug code number;¶
(e) Prescription number;¶
(f) Date the prescription was written;¶
(g) Date the drug was dispensed;¶
(h) Number of metric units dispensed;¶
(i) Number of days supplied;¶
(j) Number of refills authorized by the prescriber and the number of the fill of the prescription;¶
(k) ICD-10, if it is provided by the prescriber with the prescription; ~~and~~ ¶
(l) Reason for prescription, if it is provided by the prescriber with the prescription; and¶
(m) If applicable, the species, name and sex of the animal for which the prescription drug was prescribed.¶
(2) A pharmacy located outside of the state and licensed by the Oregon Board of Pharmacy shall electronically report the required information for controlled substances dispensed to residents of Oregon.¶
(3) A pharmacy shall submit data formatted in the American Society for Automation in Pharmacy (ASAP) 2016 version 4 release 2a specification standard.¶
(4) Data submitted by a pharmacy shall meet criteria prescribed by the Authority before it is uploaded into the system.¶
(5) A pharmacy shall be responsible for the correction of errors in the submitted data. Corrections shall be submitted no later than one week after the data was submitted.¶
(6) A pharmacy that has not dispensed any controlled substances during a seven-day reporting period must submit a zero report to the Authority at the end of the reporting period.¶
(7) A pharmacy that does not dispense any controlled substances or any controlled substances directly to a patient may request a waiver from the Authority for exemption from the reporting requirement. A pharmacy requesting a no reporting waiver shall submit to the Authority a written waiver request form provided by the Authority.¶
(8) If the Authority approves or denies the no reporting waiver request, the Authority shall provide written notification of approval or denial to the pharmacy. The duration of the waiver shall be two years at which time the pharmacy must reapply.¶
(9) A pharmacy may request a waiver from the Authority for exemption from the electronic reporting method. A pharmacy requesting an electronic reporting waiver shall submit to the Authority a written waiver request form provided by the Authority that contains the reason for the requested waiver.¶
(10) The Authority may grant a waiver of the electronic reporting requirement for good cause as determined by the Authority. Good cause includes financial hardship and not having an automated recordkeeping system.¶
(a) If the Authority approves the electronic reporting waiver, the Authority shall provide written notification to the pharmacy. The Authority shall determine an alternative reporting method for the pharmacy granted a waiver. The duration of the waiver shall be two years at which time the pharmacy must reapply.¶
(b) If the Authority denies the electronic reporting waiver, the Authority shall provide written notification to the pharmacy explaining why the request was denied. The Authority may offer alternative suggestions for reporting to facilitate participation in the program.
Statutory/Other Authority: ORS 431A.855
Statutes/Other Implemented: ORS 431A.855, 431A.860

AMEND: 333-023-0820

RULE SUMMARY: Amending OAR 333-023-0820 to include the director of the division of the Oregon Health Authority responsible for the state medical assistance program as a party allowed to submit a request for information from the Prescription Drug Monitoring Program (PDMP). Medical, pharmacy, dental, and coordinated care organization (CCO) directors are allowed to request PDMP information to assist in overseeing their respective organizations. House Bill 3258 added the director of the state medical assistant program and the amendment to this rule adds that role.

CHANGES TO RULE:

333-023-0820
Information Access ¶

(1) System Access. Only the following individuals or entities may access the system:¶
(a) Practitioners and pharmacists authorized to prescribe or dispense controlled substances;¶
(b) Delegates of practitioners or pharmacists;¶
(c) Designated representatives of the ~~Authority~~Oregon Health Authority (Authority) and any vendor contracted to establish or maintain the system;¶
(d) State Medical Examiner and designees of the State Medical Examiner; or¶
(e) Medical, dental, and pharmacy directors. ¶
(2) All entities or individuals who request access from the Authority for the creation of user accounts shall agree to terms and conditions of use of the system.¶
(3) All delegates must be authorized by a practitioner or pharmacist with an active system account.¶
(4) The Authority shall monitor the system for unusual and potentially unauthorized use. When such use is detected, the user account shall be immediately deactivated.¶
(5) The vendor, a practitioner, a medical director, a dental director, a pharmacy director, a pharmacist, a pharmacy, or an approved entity shall report to the Authority within 24 hours any suspected breach of the system or unauthorized access.¶
(6) When the Authority is informed of any suspected breach of the system or unauthorized access, the Authority shall notify the Authority's Information Security Office and investigate.¶
(7) If patient data is determined to have been breached or accessed without proper authorization, the Authority shall notify all affected patients, the Attorney General, and the applicable health professional regulatory board as soon as possible but no later than 30 days from the date of the final determination that a breach or unauthorized access occurred. Notice shall be made by first class mail to a patient or a patient's next of kin if the patient is deceased. The notice shall include:¶
(a) The date the breach or unauthorized access was discovered and the date the Authority believes the breach or unauthorized access occurred;¶
(b) The data that was breached or accessed without proper authorization; ¶
(c) Steps the individual can take to protect him or herself from identity or medical identity theft;¶
(d) Mitigation steps taken by the Authority; and¶
(e) Steps the Authority will take to reasonably ensure such a breach does not occur in the future.¶
(8) Practitioner, Pharmacist, Medical Director, Dental Director, Pharmacy Director, and Delegate Access. A practitioner, pharmacist, medical director, pharmacy director, or delegate who chooses to request access to the system shall apply for a user account as follows:¶
(a) Complete and submit an application provided by the Authority that includes identifying information and credentials; and¶
(b) Agree to terms and conditions of use of the system that defines the limits of access, allowable use of patient information, and penalties for misuse of the system.¶
(9) State Medical Examiner Access. The State Medical Examiner or his or her designee shall apply for a user account as required in section (8) of this rule and indicate their license type as Medical Examiner. For purposes of ORS 431A.865 and these rules, a designee of the State Medical Examiner is an individual who has authority to conduct a medicolegal investigation or autopsy on behalf of the State Medical Examiner under ORS chapter 146. ¶
(10) The Authority shall compare the licensure requirements between Oregon practitioners and similarly licensed professionals in California, Idaho, and Washington. The Authority's determination of similar licensure requirements shall be based upon scope of practice and formulary.¶
(11) The Authority shall review each application to authenticate before granting approval of a new account.¶
(12) If the Authority learns that an applicant has provided inaccurate or false information on an application, the Authority shall deny access to the system or terminate access to the system if access has already been established. The Authority may send written notification to the appropriate health professional regulatory board or oversight

entity.¶
(13) A practitioner or pharmacist who is an authorized system user shall notify the Authority when his or her license or DEA registration has been limited, revoked, or voluntarily retired. A practitioner or pharmacist who changes or terminates employment shall notify the Authority of that change.¶
(14) When the Authority learns that a practitioner or pharmacist's license has been limited or revoked, the Authority shall deny further access to the system.¶
(15) When a delegate for any reason is no longer authorized as a delegate by a practitioner or pharmacist, the practitioner or pharmacist shall revoke the delegation and notify the Authority.¶
(16) When the account of a delegate is inactive for more than six months, the account shall be deactivated by the Authority.¶
(17) When for any reason access of a designee of the State Medical Examiner must be revoked, the State Medical Examiner shall notify the Authority.¶
(18) Each time a practitioner or pharmacist makes a non-health IT integrated patient query he or she shall certify that requests are in connection with the treatment of a patient in his or her care and agree to terms and conditions of use of the system.¶
(19) Each time the State Medical Examiner or designee of the State Medical Examiner makes a patient query he or she shall certify that requests are for the purpose of conducting a specific medicolegal investigation or autopsy where there is reason to believe controlled substances contributed to the death and agree to terms and conditions of use of the system.¶
(20) Each time a delegate makes a non-health IT integrated patient query he or she shall certify that requests are in connection with the treatment of a patient of the practitioner or pharmacist for whom the delegate is conducting the query, agree to terms and conditions of use, and indicate the authorizing practitioner or pharmacist for whom the delegate is conducting the query.¶
(21) Practitioners and pharmacists with delegates must conduct monthly audits of delegate use to monitor for potential misuse of the system.¶
(22) When a practitioner or pharmacist learns of any potential unauthorized use of the system or system data by a delegate, the practitioner or pharmacist shall:¶
(a) Revoke the delegation; and¶
(b) Notify the Authority of the potential unauthorized use.¶
(23) When the State Medical Examiner learns of any potential unauthorized use of the system or system data by a designee, the State Medical Examiner shall notify the Authority.¶
(24) When the Authority learns of any potential unauthorized use of the system or system data, the Authority shall revoke the user's access to the system, notify the Authority's Information Security Office, and investigate.¶
(a) If the Authority determines unauthorized use occurred, the Authority shall send written notification to the appropriate health professional regulatory board, the Attorney General and all affected individuals.¶
(b) If the Authority determines unauthorized use did not occur, the Authority shall reinstate access to the system.¶
(25) The Authority shall send written notification to a user or a potential user when an account has been deactivated or access has been denied.¶
(26) Patient Access. A patient may request a report of the patient's own controlled substance record. The patient shall mail to the Authority a request that contains the following documents:¶
(a) A signed and dated patient request form provided by the Authority; and¶
(b) A copy of the patient's current valid U.S. driver's license or other valid government issued photo identification.¶
(27) The Authority shall review the personal information submitted and verify that the patient's identification and request match before taking further action.¶
(28) If the Authority cannot verify the information, the Authority shall send written notification to the patient explaining why the request cannot be processed.¶
(29) After the Authority has verified the request, the Authority shall query the system based upon the patient information provided in the request and securely send the report to the patient at no cost to the patient. The report shall include:¶
(a) A list of controlled substances dispensed to the patient including the dates of dispensation, the practitioners who prescribed the controlled substances, and the pharmacies that dispensed them; and¶
(b) A list of users who accessed the system for information on that specific patient with the date of each instance of access.¶
(30) If no data is found that matches the patient identified in the request, the Authority shall send written notification to the patient explaining possible reasons why no patient data was identified.¶
(31) A patient may send written notification to the Authority if he or she believes unauthorized access to his or her information has occurred. The notification shall include the patient's name, who is suspected to have gained

unauthorized access to the patient's information, what information is suspected to have been accessed by unauthorized use, when the suspected unauthorized access occurred, and why the patient suspects the access was unauthorized. The Authority shall treat such patient notifications as potential unauthorized use of the system.¶
(32) A patient may request that the Authority correct information in a patient record report as follows:¶
(a) The patient shall specify in writing to the Authority what information in the report the patient considers incorrect.¶
(b) When the Authority receives a request to correct a patient's information in the system, the Authority shall make a note in the system that the information is contested and verify the accuracy of the system data with the vendor. The vendor shall verify that the data obtained from the query is the same data received from the pharmacy.¶
(c) If the data is verified incorrect, the Authority shall correct the errors in consultation with the vendor and pharmacy and document the correction. The Authority shall send to the patient the corrected report.¶
(d) If the vendor verifies the data is correct, the Authority shall send written notification informing the patient that the request for correction is denied. The notice shall inform the patient of his or her rights as are applicable to the prescription drug monitoring program, the process for filing an appeal, and if there are no appeal rights, how to otherwise address or resolve the issue.¶
(33) The Authority shall respond to all patient requests within 10 business days after the Authority receives a request. Each response shall include information that informs the patient of his or her rights as are applicable to the prescription drug monitoring program.¶
(34) If the Authority denies a patient's request to correct information, or fails to grant a patient's request within 10 business days after the Authority receives the request, a patient may appeal the denial or failure by requesting a contested case hearing. The appeal shall be filed within 30 days after the request to correct information is denied. The appeal process is conducted pursuant to ORS chapter 183 and the Attorney General's Uniform and Model Rules of Procedure for the Office of Administrative Hearings (OAH), OAR 137-003-0501 through 137-003-0700.¶
(35) Law Enforcement Access. A state or local law enforcement agency engaged in an authorized drug-related investigation of an individual may request from the Authority controlled substance information pertaining to the individual to whom the information pertains. The request shall be pursuant to a valid court order based on probable cause.¶
(36) A law enforcement agency shall submit to the Authority a request that contains the following:¶
(a) A form provided by the Authority specifying the information requested; and¶
(b) A copy of the court order documents.¶
(37) The Authority shall review the law enforcement request.¶
(a) If the form is complete and the court order is valid, the Authority shall query the system for the requested information and securely provide a report to the law enforcement agency.¶
(b) If the request or court order is not valid, the Authority shall respond to the law enforcement agency providing an explanation for the denial.¶
(38) Health Professional Regulatory Board Access. A health professional regulatory board investigating an individual regulated by the board may request from the Authority controlled substance information pertaining to the member.¶
(a) A health professional regulatory board shall submit to the Authority a form provided by the Authority specifying the information requested. The board's executive director shall certify 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.¶
(b) The Authority shall review the regulatory board request.¶
(A) If a request is valid, the Authority shall query the system for the requested information and securely provide a report to the health professional regulatory board.¶
(B) If a request is not valid, the Authority shall respond to the health professional regulatory board providing an explanation for the denial.¶
(39) Researcher Access. The Authority may provide de-identified data for research purposes to a researcher. A researcher shall submit a research data request form provided by the Authority.¶
(a) The request shall include but is not limited to a thorough description of the study aims, data use, data storage, data destruction, and publishing guidelines.¶
(b) The Authority shall approve or deny research data requests based on application merit.¶
(c) If a request is approved, the requestor shall sign a data use agreement provided by the Authority.¶
(d) The Authority shall provide the minimum data set necessary that does not identify individuals.¶
(e) The Authority may charge researchers a reasonable fee for services involved in data access.¶
(40) A medical, dental, or pharmacy director may request information from the system for the sole purpose of overseeing their organization's quality assessment and improvement activities. Such access is strictly limited

pursuant ORS 431A.865 sections (1)(b) and (2)(a) and only for quality assessment and improvement activities defined under 45 CFR 164.501 and is not permitted for the purpose of determining prior authorization or reducing healthcare costs to their respective organizations.¶
(41) The director of the division of the Authority that administers the state medical assistance program may request information from the system. The director must certify that the requested information if for the sole purpose of overseeing the state medical assistance program.
Statutory/Other Authority: ORS 431A.855
Statutes/Other Implemented: ORS 431A.865, ORS 431A.855