WSR 21-01-123
EXPEDITED RULES
DEPARTMENT OF HEALTH
[Filed December 15, 2020, 10:48 a.m.]

Title of Rule and Other Identifying Information: WAC 246-470-030, 246-470-052, and 246-470-053, the department of health (DOH) is proposing changes to the prescription monitoring program (PMP) that would bring the rule language into alignment with statutory changes resulting from SSB 5380 (chapter 314, Laws of 2019), including amendments to timelines for submission of information by dispensers, and eliminating requirements for facilities or entities to be trading partners with the state's health information exchange.

Purpose of the Proposal and Its Anticipated Effects, Including Any Changes in Existing Rules: The proposal brings the rules into alignment with the statute. The proposed rules clarify that dispensers shall submit information to the PMP as soon as possible, but not later than one business day. The proposal also removes language that requires a facility or entity to be a trading partner with the state's health information exchange (HIE) in order to have access to the PMP.

Reasons Supporting Proposal: The proposed changes are necessary in order to bring rules into alignment with statutory changes. In SSB 5380, section 23, the legislature removed the requirement for a facility or entity to be a trading partner with the HIE in order for DOH to share data with them. Furthermore, section 21 of SSB 5380 makes edits that clarify that a dispenser shall submit information to the PMP as soon as possible, but not later than one business day.

Statutory Authority for Adoption: RCW 70.225.025.

Statute Being Implemented: RCW 70.25.040 and 70.225.020 as amended by SSB 5380.

Rule is not necessitated by federal law, federal or state court decision.

Name of Proponent: DOH, governmental.

Name of Agency Personnel Responsible for Drafting, Implementation, and Enforcement: Carly Bartz-Overman, 111 Israel Road S.W., Tumwater, WA 98501, 360-236-3044.

This notice meets the following criteria to use the expedited adoption process for these rules:

Adopts or incorporates by reference without material change federal statutes or regulations, Washington state statutes, rules of other Washington state agencies, shoreline master programs other than those programs governing shorelines of statewide significance, or, as referenced by Washington state law, national consensus codes that generally establish industry standards, if the material adopted or incorporated regulates the same subject matter and conduct as the adopting or incorporating rule.

This notice meets the following criteria to use the expedited repeal process for these rules:

The statute on which the rule is based has been repealed and has not been replaced by another statute providing statutory authority for the rule.

Explanation of the Reason the Agency Believes the Expedited Rule-Making Process is Appropriate: This proposal qualifies for expedited rule making under RCW 34.05.353 (1)(b) as it adopts without material change language from Washington state statute. The proposed rule also qualifies under RCW 34.05.353 (2)(a) because it repeals requirements

that are based on statutory requirements that have been repealed in SSB 5380.

NOTICE

THIS RULE IS BEING PROPOSED UNDER AN EXPEDITED RULE-MAKING PROCESS THAT WILL ELIMINATE THE NEED FOR THE AGENCY TO HOLD PUBLIC HEARINGS, PREPARE A SMALL BUSINESS ECONOMIC IMPACT STATEMENT, OR PROVIDE RESPONSES TO THE CRITERIA FOR A SIGNIFICANT LEGISLATIVE RULE. IF YOU OBJECT TO THIS USE OF THE EXPEDITED RULE-MAKING PROCESS, YOU MUST EXPRESS YOUR OBJECTIONS IN WRITING AND THEY MUST BE SENT TO Carly Bartz-Overman, DOH, P.O. Box 47852, Olympia, WA 98504, phone 360-236-3044, email https://fortress.wa.gov/doh/policyreview, AND RECEIVED BY February 22, 2021.

December 14, 2020
Jessica Todorovich
Chief of Staff
for John Wiesman, DrPH, MPH
Secretary

OTS-2599.1

AMENDATORY SECTION (Amending WSR 16-15-014, filed 7/8/16, effective 8/8/16)

WAC 246-470-030 Data submission requirements for dispensers. (1) A dispenser shall provide to the department the dispensing information required by RCW 70.225.020 and this section for all scheduled II, III, IV, and V controlled substances and for drugs identified by the pharmacy quality assurance commission under WAC 246-470-020. Only drugs dispensed for more than one day use must be reported.

(2) Dispenser identification number. A dispenser shall acquire and maintain an identification number issued to dispensing pharmacies by the National Council for Prescription Drug Programs or a prescriber identifier issued to authorized prescribers of controlled substances by the Drug Enforcement Administration, United States Department of Justice.

(3) Submitting data. A dispenser shall submit data to the department electronically, ((~~not~~)) as soon as readily available, but no later than one business day from the date of dispensing, and in the format required by the department. When the dispenser has not dispensed any drugs during a business day which require reporting, then within seven days the dispenser shall report that no drugs requiring reporting were dispensed. The notification shall be in a format established by the department.

(a) A dispenser shall submit for each dispensing the following information and any additional information required by the department:

(i) Patient identifier. A patient identifier is the unique identifier assigned to a particular patient by the dispenser;

(ii) Name of the patient for whom the prescription is ordered including first name, middle initial, last name, and generational suffixes, if any;

(iii) Patient date of birth;

(iv) Patient address;
(v) Patient gender and species code;
(vi) Drug dispensed;
(vii) Date of dispensing;
(viii) Quantity and days supply dispensed;
(ix) Refill and partial fill information;
(x) Prescriber identifiers including the National Provider Identifier and the Drug Enforcement Administration number including any suffix used;
(xi) Prescription issued date;
(xii) Dispenser identifiers including the Drug Enforcement Administration number and the National Provider Identifier;
(xiii) Prescription fill date and number;
(xiv) Source of payment indicated by one of the following:
(A) Private pay (cash, change, credit card, check);
(B) Medicaid;
(C) Medicare;
(D) Commercial insurance;
(E) Military installations and veterans affairs;
(F) Workers compensation;
(G) Indian nations;
(H) Other;
(xv) When practicable, the name of the person picking up or dropping off the prescription as verified by valid photographic identification; and
(xvi) The prescriber's and dispenser's business phone numbers.
(b) A nonresident, licensed pharmacy that delivers controlled substances, as defined in RCW 18.64.360, is required to submit only the transactions for patients with a Washington state zip code.
(c) Data submission requirements do not apply to:
(i) The department of corrections or pharmacies operated by a county for the purpose of providing medications to offenders in state or county correctional institutions who are receiving pharmaceutical services from a state or county correctional institution's pharmacy. A state or county correctional institution's pharmacy must submit data to the program related to each offender's current prescriptions for controlled substances upon the offender's release from a state or county correctional institution.
(ii) Medications provided to patients receiving inpatient services provided at hospitals licensed under chapter 70.41 RCW or patients of such hospitals receiving services at the clinics, day surgery areas, or other settings within the hospital's license where the medications are administered in single doses; or medications provided to patients receiving outpatient services provided at ambulatory surgical facilities licensed under chapter 70.230 RCW.

[Statutory Authority: RCW 70.225.020, 70.225.025, and 70.225.040. WSR 16-15-014, § 246-470-030, filed 7/8/16, effective 8/8/16. Statutory Authority: RCW 70.225.020 and 70.225.025. WSR 14-07-099, § 246-470-030, filed 3/18/14, effective 4/18/14; WSR 13-12-025, § 246-470-030, filed 5/28/13, effective 6/28/13. Statutory Authority: Chapter 70.225 RCW and 2007 c 259. WSR 11-16-041, § 246-470-030, filed 7/27/11, effective 8/27/11.]

AMENDATORY SECTION (Amending WSR 18-17-048, filed 8/8/18, effective 9/8/18)

WAC 246-470-052 Facility and provider group access to information from the program. (1) Access.

(a) A health care facility or entity may have access to prescription monitoring information for the purpose of providing medical or pharmaceutical care to the patients of the facility or entity or for quality improvement purposes ((~~only under the following conditions:~~

~~(i)~~)), provided that the facility or entity is licensed by the department, operated by the federal government, or a federally recognized Indian tribe((~~; and~~

~~(ii) The facility or entity is a trading partner with the state's health information exchange~~)).

(b) A health care provider group of five or more prescribers may have access to prescription monitoring information for the purpose of providing medical or pharmaceutical care to the patients, or for quality improvement purposes, ((~~only under the following conditions:~~

~~(i)~~)) provided that all prescribers in the provider group are licensed by the department, the provider group is operated by the federal government or a federally recognized Indian tribe((~~; and~~

~~(ii) The provider group is a trading partner with the state's health information exchange~~)).

(2) Registration for access. A facility or entity identified in subsection (1)(a) of this section or a provider group of five or more prescribers identified in subsection (1)(b) of this section may register for access by using the registration process established by the department.

(3) Verification by the department. The department or its designee shall verify the authentication and identity of the facility, entity, or provider group before allowing access to any prescription monitoring information.

(4) Procedure for accessing prescription information. A facility, entity, or provider group identified in subsection (1) of this section must access information from the program electronically through ((~~the state health information exchange~~)) a method approved by the department.

(5) If the connection between the facility, entity, or provider group and the ((~~health information exchange~~)) program is compromised, the facility, entity, or provider group shall notify the department's designee by telephone and in writing as soon as reasonably possible.

(6) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must be consistent with the mandate as outlined in RCW 70.225.040 and this chapter.

[Statutory Authority: RCW 70.225.020, 70.225.025, 70.225.040, and 2017 c 297. WSR 18-17-048, § 246-470-052, filed 8/8/18, effective 9/8/18. Statutory Authority: Chapter 70.225 RCW and 2016 c 104, and 2015 c 259. WSR 17-18-103, § 246-470-052, filed 9/6/17, effective 10/7/17.]

AMENDATORY SECTION (Amending WSR 18-17-048, filed 8/8/18, effective 9/8/18)

WAC 246-470-053 The coordinated care electronic tracking program access to information from the program. (1) Access. The coordinated

care electronic tracking program may have access to data for the purposes of:

(a) Providing program data to emergency department personnel when the patient registers in the emergency department; and

(b) Providing notice to the patient's providers, appropriate care coordination staff, and prescribers listed in the patient's prescription monitoring program record when the patient has experienced a controlled substance overdose event.

(2) Registration for access. The coordinated care electronic tracking program may register for access by using the registration process established by the department.

(3) Verification by the department. The department or its designee shall verify the authentication and identity of the coordinated care electronic tracking program before allowing access to any prescription monitoring information.

(4) Procedure for accessing prescription data. The coordinated care electronic tracking program must access data from the program electronically through ((~~the state health information exchange~~)) a method approved by the department. The data shall only be retained long enough by the tracking program to create the report needed by emergency department personnel when the patient registered or to provide notice of an overdose event.

(5) If the secure connection between the coordinated care electronic tracking program and the ((~~state health information exchange~~)) program is compromised, the coordinated care electronic tracking program shall notify the department's designee by telephone and in writing as soon as reasonably possible.

(6) All requests for, uses of, and disclosures of prescription monitoring information by authorized persons must be consistent with the mandate as outlined in RCW 70.225.040 and this chapter.

[Statutory Authority: RCW 70.225.020, 70.225.025, 70.225.040, and 2017 c 297. WSR 18-17-048, § 246-470-053, filed 8/8/18, effective 9/8/18.]