

WSR 21-14-059

EMERGENCY RULES

DEPARTMENT OF HEALTH

(Pharmacy Quality Assurance Commission)

[Filed July 2, 2021, 9:12 a.m., effective July 2, 2021, 9:12 a.m.]

Effective Date of Rule: Immediately upon filing.

Purpose: WAC 246-945-010 Prescription labeling, records, and advertising—Minimum requirements, the pharmacy quality assurance commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the coronavirus disease (COVID-19) outbreak. This adopted emergency rule will extend WSR 21-07-016 filed on March 5, 2021. This emergency rule was originally filed on April 21, 2020, under WSR 20-09-133. It was re-filed on July 10, 2020, after the commission's new chapter went into effect under WSR 20-15-058. This emergency rule will continue the existing emergency rule amending WAC 246-945-010 to increase the duration of time a practitioner has to deliver a signed prescription of a Schedule II substance to the pharmacy from seven days to fifteen days when a prescription is dispensed in an emergency. It also defines what a "signed prescription" means and allows for a practitioner to accomplish this requirement through paper, electronic transmission, facsimile, photograph, or scanned copy. These alternative methodologies support patients, practitioners, and pharmacists' efforts to practice social distancing and to help mitigate communal spread.

Citation of Rules Affected by this Order: Amending WAC 246-945-010.

Statutory Authority for Adoption: RCW 18.64.005; chapter 69.50 RCW.

Under RCW 34.05.350 the agency for good cause finds that immediate adoption, amendment, or repeal of a rule is necessary for the preservation of the public health, safety, or general welfare, and that observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest.

Reasons for this Finding: The immediate amendment of this existing rule is necessary for the preservation of public health, safety, and general welfare. Stakeholders and leaders from the pain community have highlighted this is an immediate need for Washingtonians. This emergency rule has been in effect since April 21, 2020. This emergency rule allows more time and more avenues for complying with the requirements during the ongoing COVID-19 pandemic, reducing burdens on practitioners and pharmacists, and sustaining patient access during this difficult time. The emergency rules follow guidance from the United States Drug Enforcement Agency and will help address this problem and reduce barriers for providers and patient populations in need of Schedule II prescriptions throughout this public health emergency. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to public interest.

Number of Sections Adopted in Order to Comply with Federal Statute: New 0, Amended 0, Repealed 0; Federal Rules or Standards: New 0, Amended 0, Repealed 0; or Recently Enacted State Statutes: New 0, Amended 0, Repealed 0.

Number of Sections Adopted at the Request of a Nongovernmental Entity: New 0, Amended 0, Repealed 0.

Number of Sections Adopted on the Agency's own Initiative: New 0, Amended 1, Repealed 0.

Number of Sections Adopted in Order to Clarify, Streamline, or Reform Agency Procedures: New 0, Amended 0, Repealed 0.

Number of Sections Adopted using Negotiated Rule Making: New 0, Amended 0, Repealed 0; Pilot Rule Making: New 0, Amended 0, Repealed 0; or Other Alternative Rule Making: New 0, Amended 1, Repealed 0.

Date Adopted: June 4, 2021.

Teri Ferreira, RPh, Chair
Pharmacy Quality Assurance Commission

OTS-2391.1

AMENDATORY SECTION (Amending WSR 20-12-072, filed 6/1/20, effective 7/1/20)

WAC 246-945-010 Prescription and chart order—Minimum requirements. (1) For the purposes of this section, prescription does not include chart orders as defined in RCW 18.64.011(3).

(2) For the purposes of WAC 246-945-010 through 246-945-013, prescription includes written and electronic prescriptions.

(3) A prescription for a noncontrolled legend drug must include, but is not limited to, the following:

(a) Prescriber's name;

(b) Name of patient, authorized entity, or animal name and species;

(c) Date of issuance;

(d) Drug name, strength, and quantity;

(e) Directions for use;

(f) Number of refills (if any);

(g) Instruction on whether or not a therapeutically equivalent generic drug or interchangeable biological product may be substituted, unless substitution is permitted under a prior-consent authorization;

(h) Prescriber's manual or electronic signature, or prescriber's authorized agent signature if allowed by law; and

(i) If the prescription is written, it must be written on tamper-resistant prescription pad or paper approved by the commission pursuant to RCW 18.64.500;

(4) A prescription for a controlled substance must include all the information listed in subsection (1) of this section and the following:

(a) Patient's address;

(b) Dosage form;

(c) Prescriber's address;

(d) Prescriber's DEA registration number; and

(e) Any other requirements listed in 21 C.F.R., Chapter II.

(5) A chart order must meet the requirements of RCW 18.64.550 and any other applicable requirements listed in 21 C.F.R., Chapter II.

(6) A controlled substance listed in Schedule II can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011 unless there is an "emergency."

(a) For the purposes of this subsection, an "emergency" exists when the immediate administration of the drug is necessary for proper treatment and no alternative treatment is available, and further, it is not possible for the practitioner to provide a written or electronic prescription for the drug at that time.

(b) If a Schedule II drug is dispensed in an emergency, the practitioner must deliver a signed prescription to the dispenser within ~~((seven))~~ fifteen days after authorizing an emergency oral prescription or if delivered by mail it must be postmarked within the ~~((seven))~~ fifteen day period, and further the pharmacist must note on the prescription that it was filled on an emergency basis.

(c) For the purposes of this subsection, a "signed prescription" shall be either:

(i) A paper prescription;

(ii) An electronic prescription;

(iii) A copy of the paper prescription sent via facsimile to the pharmacy; or

(iv) A photograph or scanned copy of the paper prescription sent to the pharmacy.

(7) A controlled substance listed in Schedule III, IV, or V, can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a controlled substance listed in Schedule III, IV, or V must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

(8) A noncontrolled legend drug can only be dispensed pursuant to a valid prescription in accordance with WAC 246-945-011, or an oral prescription. An oral prescription for a noncontrolled legend drug must be promptly reduced to a written or electronic prescription that complies with WAC 246-945-011.

[Statutory Authority: RCW 18.64.005, 18.64.080, 18.130.075, 18.64.043, 18.64.044, 18.64.045, 18.64.046, 18.64.370, 18.64.460, 69.50.310, 18.64.011, 18.64.245, 18.64.470, 18.64.255, 18.64.205, 18.64.253, 18.64.410, 18.64.500, 18.64.590. WSR 20-12-072, § 246-945-010, filed 6/1/20, effective 7/1/20.]