RULE-MAKING ORDER
EMERGENCY RULE ONLY

CR-103E (December 2017)
(Implements RCW 34.05.350 and 34.05.360)

CODE REVISER USE ONLY

OFFICE OF THE CODE REVISER
STATE OF WASHINGTON
FILED

DATE: April 21, 2020
TIME: 11:19 AM

WSR 20-09-133

Agency: Department of Health- Pharmacy Quality Assurance Commission

Effective date of rule:

Emergency Rules

☒ Immediately upon filing.

☐ Later (specify)

Any other findings required by other provisions of law as precondition to adoption or effectiveness of rule?

☐ Yes ☒ No If Yes, explain:

Purpose: WAC 246-887-020 - Uniform Controlled Substances Act. The Pharmacy Quality Assurance Commission (commission) is adopting emergency rules to reduce burdens on practitioners prescribing Schedule II substances during the COVID-19 outbreak. The emergency rule amends WAC 246-887-020 and increases the duration of time a practitioner has to deliver a signed prescription when authorizing an emergency prescription of a Schedule II substance to the pharmacy from seven days to fifteen days. 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:

New: None
Repealed: None
Amended: WAC 246-887-020
Suspended: None

Statutory authority for adoption: RCW 18.64.005; Chapter 69.50 RCW

Other authority:

EMERGENCY RULE

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.

☐ That state or federal law or federal rule or a federal deadline for state receipt of federal funds requires immediate adoption of a rule.

Reasons for this finding: The immediate amendment of these existing rules 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 will allow more time and more avenues for complying with the requirements during the COVID-19 pandemic, reducing burdens on practitioners and pharmacists during this difficult time and sustaining patient access. The emergency rules will help address this problem and reduce barriers for providers and patient populations requiring 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 the public interest and the Governor's order.

Note: If any category is left blank, it will be calculated as zero. No descriptive text.

Count by whole WAC sections only, from the WAC number through the history note. A section may be counted in more than one category.

The 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
Recently enacted state statutes:	New	0	Amended	0	Repealed	0

The number of sections adopted at the request of a nongovernmental entity:

	New	0	Amended	0	Repealed	0

The number of sections adopted on the agency's own initiative:

	New	0	Amended	1	Repealed	0

The number of sections adopted in order to clarify, streamline, or reform agency procedures:

	New	0	Amended	0	Repealed	0

The number of sections adopted using:

Negotiated rule making:	New	0	Amended	0	Repealed	0
Pilot rule making:	New	0	Amended	0	Repealed	0
Other alternative rule making:	New	0	Amended	1	Repealed	0

Date Adopted: 04/21/2020	**Signature:** 
Name: Tim Lynch	
Title: Chair, Pharmacy Quality Assurance Commission	

AMENDATORY SECTION (Amending WSR 19-06-068, filed 3/5/19, effective 4/5/19)

WAC 246-887-020 Uniform Controlled Substances Act. (1) The pharmacy quality assurance commission (commission) adopts Title 21 of the Code of Federal Regulations. The following sections do not apply: Section 1301.13, section 1301.33, section 1301.35-.46, section 1303, section 1308.41-.45, and section 1316.31-.67. Any inconsistencies between Title 21 of the Code of Federal Regulations sections 1300 through 1321 and chapter 246-887 WAC should be resolved in favor of chapter 246-887 WAC. Further, nothing in these rules applies to the production, processing, distribution, or possession of marijuana as authorized and regulated by the Washington state liquor and cannabis board.

(2) Registration. A separate registration is required for each place of business, as defined in 21 C.F.R. 1301.12 where controlled substances are manufactured, distributed or dispensed. Application for registration must be made on forms supplied by the commission, and all requested information must be supplied unless the information is not applicable, which must be indicated by the applicant. An applicant for registration must hold the appropriate wholesaler, manufacturer or pharmacy license provided for in chapter 18.64 RCW.

(3) Every registrant shall be required to keep inventory records required by 21 C.F.R. 1304.04 and must maintain said inventory records for a period of two years from the date of inventory. Such registrants are further required to keep a record of receipt and distribution of controlled substances. Such record shall include:

(a) Invoices, orders, receipts, etc. showing the date, supplier and quantity of drug received, and the name of the drug;

(b) Distribution records; i.e., invoices, etc. from wholesalers and manufacturers and prescriptions records for dispensers;

(c) In the event of a significant loss or theft, two copies of DEA 106 (report of theft or loss of controlled substances) must be transmitted to the federal authorities and a copy must be sent to the commission;

(d) For transfers of controlled substances from one dispenser to another, a record of the transfer must be made at the time of transfer indicating the drug, quantity, date of transfer, who it was transferred to and from whom. Said record must be retained by both the transferee and the transferor. These transfers can only be made in emergencies pursuant to 21 C.F.R. 1307.11.

(4) The records must be maintained separately for Schedule II drugs. The records for Schedule III, IV and V drugs may be maintained either separately or in a form that is readily retrievable from the business records of the registrant.

(5) A federal order form is required for each distribution of a Schedule I or II controlled substance, and said forms along with other records required to be kept must be made readily available to authorized employees of the commission.

(6) Schedule II drugs require that a dispenser have a signed prescription in his possession prior to dispensing said drugs. An exception is permitted in an "emergency." 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 physician to provide a written or electronic prescription for the drug at that time. 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.

(7) For the purposes of subsection (6) of this section, a "signed prescription" shall be either:

(a) A paper prescription;

(b) An electronic prescription;

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

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

(8) A prescription for a substance included in Schedule II may not be refilled.

((~~(8)~~)) (9) A prescription for a substance included in Schedule II may not be filled more than six months after the date the prescription was issued.

((~~(9)~~)) (10) Except when dispensed directly by a practitioner authorized to prescribe or administer a controlled substance, other than a pharmacy, to an ultimate user, a substance included in Schedule III, IV, or V, which is a prescription drug as determined under RCW 69.04.560, may not be dispensed without a written, oral, or electronically communicated prescription of a practitioner. Any oral prescription must be promptly reduced to writing. The prescription for a substance included in Schedule III, IV, or V may not be filled or refilled more than six months after the date issued by the practitioner or be refilled more than five times, unless the practitioner issues a new prescription.