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: August 01, 2024
TIME: 10:03 AM

WSR 24-16-085

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: Naloxone nasal spray as over-the-counter status. In March 2023, the United States Food and Drug Administration (FDA) approved the first 4 mg naloxone hydrochloride nasal spray as an over-the-counter (OTC) drug and has approved other naloxone nasal sprays since that time. Naloxone is an opioid antagonist used for the emergency treatment of known or suspected opioid overdose. Currently, WAC 246-945-030 incorporates the 39th edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, or "Orange Book," which has naloxone listed as a prescription drug. The Pharmacy Quality Assurance Commission (commission) considers the ongoing opioid epidemic to be a public health emergency in Washington state. In order to combat this epidemic in Washington, the commission is amending WAC 246-945-030 and adding a new section, WAC 246-945-034, classifying the 3mg and 4mg naloxone hydrochoride nasal spray as approved by the FDA for OTC distribution as an OTC drug in Washington state.

The time line for the availability of naloxone nasal spray is set by the manufacturers, although some are already available. This emergency rule prepares Washington state for the moment that the drug becomes available by manufacturers. The proposed new rule WAC 246-945-034, will also allow for expansion of different formularies if the FDA makes further changes. This preparation will allow for a faster release of the drug throughout the state, meaning this life saving drug would be in the hands of Washingtonians faster. Increasing patient access to the drug is critical to reduce opioid overdoses.

This emergency rule filing allows for the 3mg and 4mg dosage versions of naloxone spray to be prescribed as OTC products. This rule is unchanged from the previous emergency rule under WSR 24-09-013 filed on April 5, 2024. This emergency rule will be continued until the permanent rulemaking is effective.

Citation of rules affected by this order:

New: WAC 246-945-034
Repealed: None
Amended: WAC 246-945-030
Suspended: None

Statutory authority for adoption: RCW 18.64.005

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 adoption of this rule is necessary for the preservation of public health, safety, and general welfare. The opioid epidemic is a public health emergency which requires the use of the emergency rulemaking process. Observing the time requirements of notice and opportunity to comment upon adoption of a permanent rule would be contrary to the public interest. This rule will increase access to this lifesaving drug faster, which will help relieve some stress on affected communities in Washington state and attempt to reduce opioid overdoses.

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	1	Amended	1	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:

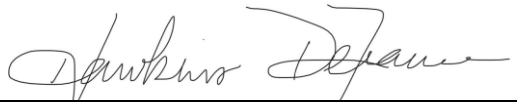
	New	0	Amended	0	Repealed	0

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	1	Amended	1	Repealed	0

Date Adopted: 8/1/2024	**Signature:** 
Name: Hawkins DeFrance, PharmD	
Title: Pharmacy Quality Assurance Commission	

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

WAC 246-945-030 Identification of legend drugs for purposes of chapter 69.41 RCW. (1) Those drugs determined by the FDA to require a prescription under federal law should be classified as legend drugs under state law because their toxicity, potential for harmful effect, methods of use, or collateral measures necessary to their use indicate they are only safe for use under the supervision of a practitioner.

(2) The commission finds that under state law, legend drugs are those drugs designated as legend drugs under federal law, as of the date of adoption of this rule, and listed in at least one of the following publications unless the drug is identified as an over-the-counter drug by the commission in WAC 246-945-034:

(a) The 39th Edition, including supplements, of the *Approved Drug Products with Therapeutic Equivalence Evaluations "Orange Book"* (available at https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book).

(b) The 2019 version, including monthly updates, of the *Approved Animal Drug Products "Green Book"* (available at https://www.fda.gov/animal-veterinary/products/approved-animal-drug-products-green-book).

(c) The 2019 *List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations "Purple Book"* (available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or).

(3) Copies of the reference material listed in subsection (2) of this section are available for public inspection at the commission's office at Department of Health, Town Center 2, 111 Israel Road S.E., Tumwater, WA 98501.

(4) The commission also identifies those ephedrine products specified in WAC 246-945-031 as legend drugs under state law.

(5) There may be changes in the marketing status of drugs after the publication of the above references. Upon application of a manufacturer or distributor, the commission may grant authority for the over-the-counter distribution of certain drugs designated as legend drugs in these references. These determinations will be made after public hearing and will be published as an amendment to this chapter.

NEW SECTION

WAC 246-945-034 Identification of the over-the-counter drugs. Although listed as a legend drug in publications that are incorporated by reference in WAC 246-945-030(2), the commission identifies the following as an over-the-counter drug in Washington:

(1) 4 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.

(2) 3 mg naloxone hydrochloride nasal spray, approved by the FDA for marketing as an OTC drug product.