



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: December 08, 2023

TIME: 8:42 AM

WSR 24-01-021

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 hydrochloride nasal spray as approved by the FDA for OTC distribution as an OTC drug in Washington state.

The timeline 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 section of chapter 246-945 WAC would also allow for expansion of different formularies if the FDA makes further changes. This preparation would 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 over-the-counter products. The previous emergency rule filing on this topic, filed as WSR 23-17-059 on August 11, 2023, only allowed the 4 mg nasal spray under the brand name Narcan to be prescribed as an OTC product, but the FDA broadened the classification of allowed naloxone products since that previous filing.

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 would increase access to this lifesaving drug faster, which would 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
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The number of sections adopted on the agency's own initiative:


New	0	Amended	0	Repealed	0
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The number of sections adopted in order to clarify, streamline, or reform agency procedures:

New	0	Amended	0	Repealed	0
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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: December 8, 2023	Signature: 
Name: Kenneth Kenyon, PharmD, BCPS	
Title: Pharmacy Quality Assurance Commission Chair	