

## **REGULATION ON SAFE STORAGE AND REPLACEMENT PROTOCOLS FOR OPIOID ANTAGONISTS**

This regulation is promulgated under the VA Department of Health in collaboration with the Department of Education, Code of Virginia, Section § 22.1-274.4:1 to promote the safe use, storage, and accessibility of opioid antagonists to prevent opioid overdose deaths.

**Purpose:** To establish standards for the safe storage of opioid antagonists and to provide mechanisms for the replacement of lost, damaged, or used supplies to ensure continuous access for individuals and entities authorized to possess and administer these medications.

### **Definitions:**

**Opioid Antagonist:** A medication, such as naloxone, approved by the U.S. Food and Drug Administration (FDA) for the reversal of opioid overdose.

**Authorized Possessor:** An individual, healthcare provider, first responder, harm reduction organization, or other entity authorized under state law to possess and administer opioid antagonists.

**Safe Storage:** The secure and appropriate storage of opioid antagonists to prevent unauthorized access, degradation, or loss, while ensuring accessibility for emergency use.

### **Section 1: Safe Storage Requirements**

#### **Storage Conditions:**

Authorized possessors shall store opioid antagonists following manufacturer guidelines, including maintaining temperatures between 59°F and 77°F (15°C to 25°C), unless otherwise specified.

Medications shall be protected from direct sunlight, moisture, and extreme temperatures to preserve efficacy.

#### **Security Measures:**

Opioid antagonists shall be stored in a secure location, such as a locked cabinet, medical kit, or other restricted-access container, to prevent theft or unauthorized use.

In public settings (e.g., the school), opioid antagonists shall be stored in clearly marked, accessible emergency kits, such as wall-mounted boxes with tamper-evident seals, to balance security and rapid access.

#### **Labeling:**

All opioid antagonist containers shall be clearly labeled with the medication name, dosage, expiration date, and emergency contact information for local poison control or health authorities.

**Training:**

Authorized possessors shall ensure that individuals responsible for storing opioid antagonists are trained in proper storage protocols and emergency response procedures, consistent with state training requirements.

**Section 2: Supply Replacement Protocols****Eligibility for Replacement:**

Authorized possessors may request replacement of opioid antagonist supplies in the following circumstances:

- a. Use of the medication in an emergency to reverse an opioid overdose.
- b. Loss or theft of the medication, provided a report is filed with local law enforcement or the administering agency within 48 hours.
- c. Damage or expiration of the medication, rendering it unusable.

**Replacement Process:**

Requests for replacement shall be submitted to Richmond Public Schools via Va Department of Health Pharmacy or an authorized distributor (e.g., pharmacy, harm reduction program) within 30 days of the qualifying event.

Requests shall include:

- a. A completed replacement request form, detailing the reason for replacement (use, loss, theft, damage, or expiration).
- b. For used doses, a brief incident report describing the overdose event, including date, time, and outcome (if known), while maintaining confidentiality of involved individuals.
- c. For lost or stolen doses, a copy of the law enforcement or agency report.
- d. For damaged or expired doses, proof of return or disposal at an authorized medication take-back site, if feasible.

**Replacement Supply:**

Approved replacements shall be provided at no cost to authorized possessors, subject to available funding or state supply programs.

Replacement doses shall be dispensed within 7 business days of request approval, unless expedited delivery is required for high-risk settings (e.g., emergency services).

**Recordkeeping:**

Authorized possessors shall maintain records of opioid antagonist inventory, including receipt, storage, use, and replacement, for a minimum of 3 years, subject to inspection by the VA Department of Health.

Distributors shall report replacement requests and fulfillments to Va Department of Health quarterly to monitor supply needs and prevent abuse.

### Section 3: Compliance and Enforcement

**Inspections:**

The VA Department of Health may conduct periodic inspections of authorized possessors' storage practices to ensure compliance with this regulation.

**Penalties:**

Failure to comply with safe storage or replacement protocols may result in:

- a. Written warnings for first offenses.
- b. Suspension of authorization to possess opioid antagonists for repeated or willful violations.
- c. Civil fines .

**Appeals:**

Authorized possessors may appeal penalties or suspensions to The Virginia Department of Health within 30 days of receiving notice.

### Section 4: Public Education

The Virginia Department of Behavioral Health and Developmental Services (DBHDS) shall develop and distribute educational materials on safe storage and replacement protocols to authorized possessors and the public.

Materials shall be available in multiple languages and accessible formats to ensure equitable access.

**Severability:** If any provision of this regulation is found invalid by a court of competent jurisdiction, the remaining provisions shall remain in full force and effect.

**Rationale and Notes:**

**Safe Storage:** The regulation balances security (to prevent theft or misuse) with accessibility (to ensure rapid use in emergencies). It aligns with FDA guidelines for naloxone storage and incorporates best practices for public access, such as tamper-evident kits.

**Replacement Protocols:** The replacement process incentivizes reporting of use or loss, ensures accountability, and maintains supply availability, particularly for high-risk communities. The no-cost replacement provision aims to reduce financial barriers, though it assumes state or grant funding.

**Compliance:** Penalties are structured to encourage adherence without overly burdening authorized possessors, especially non-profit organizations or first responders.

**Public Health Focus:** The regulation supports harm reduction by ensuring opioid antagonists remain accessible while preventing waste or misuse.

Adopted: September 18, 2025

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Cross Refs.:

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Opioid Antagonists

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