

14 DEPARTMENT OF HEALTH AND HUMAN SERVICES
118 OFFICE OF SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES
Chapter 19: RULES GOVERNING COMMUNITY-BASED DRUG OVERDOSE PREVENTION PROGRAMS

RULES GOVERNING COMMUNITY-BASED DRUG OVERDOSE PREVENTION PROGRAMS

STATE OF MAINE



DEPARTMENT OF HEALTH AND
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OFFICE OF SUBSTANCE ABUSE
AND MENTAL HEALTH SERVICES

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SECTION 1. Introduction

This rule describes policies and procedures related to the establishment of Overdose Prevention Programs and the storage, dispensing, and distribution of Naloxone Hydrochloride in Community-based Agency settings.

SECTION 2. Authority

This rule is authorized by 22 M.R.S. § 2353.

SECTION 3. Definitions

- A. Community-based Agency:** Any agency, coalition, association, or organization, that has registered as a corporation or other business organization with the Office of the Secretary of State and that is in good standing with that office, or any municipality, local or county government entity. The Community-based Agency must in some capacity provide services to populations at high risk for drug overdose.
- B. Healthcare Professional:** Any individual licensed under Title 32 of the Maine Revised Statutes who is authorized to prescribe Naloxone Hydrochloride within the scope of professional competency.
- C. Medical Supplies Necessary to Administer Naloxone Hydrochloride:** Items intended to facilitate the administration of Naloxone Hydrochloride, including but not limited to syringes, atomizers, rescue breathing masks, rubber gloves, alcohol pads, and educational inserts.
- D. Naloxone Hydrochloride:** An opioid antagonist approved by the United States Food and Drug Administration that when administered can temporarily stop or reverse the effects of an Opioid-related Drug Overdose.
- E. Opioid-related Drug Overdose:** A condition including, but not limited to, extreme physical illness, decreased level of consciousness, respiratory depression, coma or death resulting from the consumption or use of an opioid, or another substance with which an opioid was combined, or a condition that a reasonable person would believe to be an Opioid-related Drug Overdose that requires medical assistance.
- F. Overdose Prevention Program:** A program established by a Community-based Agency that has the goal of increasing awareness of opioid use and overdose prevention.
- G. Standing Order:** A written order for a medication authorizing the dispensing of the medication when specified predetermined conditions have been met. Consistent with 22 M.R.S. § 2353(2), a Standing Order for Naloxone Hydrochloride allows a Healthcare Professional to issue an order without the Healthcare Professional necessarily interacting directly with the ultimate recipient of the medication.

SECTION 4. Policies and Procedures

A. Standing Orders

1. Any Healthcare Professional who is authorized by law in the State of Maine to prescribe Naloxone Hydrochloride and who is acting within the scope of professional competency may issue a Standing Order for the supply of Naloxone Hydrochloride to an eligible Community-based Agency as described in Section 4.B below.
2. At a minimum, the Standing Order shall:
 - a. Include the name of the Community-based Agency that will store, dispense, and distribute the supply of Naloxone Hydrochloride.
 - b. Specify that the following individuals are eligible to receive Naloxone Hydrochloride from the Community-based Agency: an individual at risk of experiencing an Opioid-related Drug Overdose, a member of an individual's immediate family or a friend of the individual or another person in a position to assist the individual if the individual is at risk of experiencing an Opioid-related Drug Overdose.
 - c. Include the delivery method of Naloxone Hydrochloride, such as auto-injector, intranasal, or intermuscular.
3. The Community-based Agency must retain copies of any Standing Orders written for the agency under this rule and such copies must be available for review by the Department of Health and Human Services or its authorized agents upon request. Any request by the Department for copies of such records must be provided at no expense to the Department.
4. Although not required, the Healthcare Professional issuing the Standing Order for Naloxone Hydrochloride may be an employee or contractor of the Community-based Agency. In the event the Healthcare Professional issuing the Standing Order is not an employee or contractor of the Community-based Agency, the Healthcare Professional and Community-based Agency must enter a signed written agreement indicating a mutual understanding that the Community-based Agency will store, dispense, and distribute the Naloxone Hydrochloride in accordance with these rules. The Community-based Agency shall make this agreement available for review by the Department upon request.

B. Eligible Community-based Agencies

1. Any Community-based Agency may request, for the purpose of establishing and maintaining an Overdose Prevention Program, a Standing Order for Naloxone Hydrochloride be provided by a Healthcare Professional.

2. Any Community-based Agency that receives Naloxone Hydrochloride pursuant to the Standing Order may through its Overdose Prevention Program:
 - a. Store and dispense Naloxone Hydrochloride as described in Section 4.C;
 - b. Distribute unit-of-use packages of Naloxone Hydrochloride and the Medical Supplies Necessary to Administer Naloxone Hydrochloride as described in Section 4.D.
3. The Community-based Agency's Overdose Prevention Program must have internal written operating procedures which include protocols for contacting and engaging with emergency medical services when appropriate, and must make these procedures available to the Department upon request.
4. The Community-based Agency's Overdose Prevention Program must have protocols in place for referring individuals who are at risk of experiencing an Opioid-related Drug Overdose and who are ready and willing to engage in treatment to treatment programs.

C. Storage and Dispensing of Naloxone Hydrochloride

1. Any Community-based Agency with an Overdose Prevention Program and an active Standing Order as described in Section 4.A may store and dispense Naloxone Hydrochloride for the purpose of providing ready access of the medication to individuals eligible to receive Naloxone Hydrochloride pursuant to the Standing Order.
2. The Community-based Agency must have written protocols for the appropriate and safe storage of Naloxone Hydrochloride, including but not limited to, protocols on appropriate storage temperatures, inventory tracking, and ensuring the security of the Naloxone Hydrochloride supply at all times. These protocols must be available for review by the Department or its authorized agents upon request, and requests for copies must be provided at no expense to the Department.
3. A Community-based Agency that chooses to dispense Naloxone Hydrochloride through an Overdose Prevention Program to eligible individuals must do so without charge or compensation.
4. For any Naloxone Hydrochloride dispensed by the Overdose Prevention Program under this Section, the Program must maintain a record which shall include, at a minimum:
 - a. The name of the individual or de-identified mechanism to whom the Naloxone Hydrochloride was dispensed;
 - b. The amount of Naloxone Hydrochloride dispensed to the individual;
 - c. The date of the dispensing of the Naloxone Hydrochloride to the individual;

- d. The name of the Overdose Prevention Program staff person that dispensed the Naloxone Hydrochloride to the individual; and
- e. Attestation that the individual to whom the Naloxone Hydrochloride was dispensed is eligible to receive the medication under the Standing Order.

D. Distribution of Naloxone Hydrochloride Pursuant to Training by the Overdose Prevention Program

1. Any Community-based Agency with an Overdose Prevention Program and an active Standing Order as described in Section 4.A may distribute unit-of-use Naloxone Hydrochloride and the Medical Supplies Necessary to Administer Naloxone Hydrochloride to any individual who has successfully completed training in accordance with this Section so that the individual may possess and administer Naloxone Hydrochloride to an individual who appears to be experiencing an Opioid-related Drug Overdose.
2. Community-based Agencies that choose to distribute Naloxone Hydrochloride through an Overdose Prevention Program under this Section must offer training free of charge to any individual wishing to possess and administer Naloxone Hydrochloride, and cannot charge the individual for any Naloxone Hydrochloride or Medical Supplies Necessary to Administer Naloxone Hydrochloride distributed to the individual.
3. The Overdose Prevention Program's training curriculum is to be determined by the Community-based Agency. However, training shall be based upon the federal Substance Abuse and Mental Health Services Administration's Opioid Overdose Prevention Toolkit. Training shall include, at a minimum, the following components:
 - a. Opioid overdose prevention;
 - b. Recognition of an Opioid-related Drug Overdose;
 - c. Performance of rescue breathing and resuscitation;
 - d. Appropriate Naloxone Hydrochloride dosage and administration;
 - e. Contacting emergency medical services/calling 911; and
 - f. Caring for an individual experiencing the Opioid-related Drug Overdose following administration of Naloxone Hydrochloride.
4. The Overdose Prevention Program must maintain training records for all individuals trained to possess and administer Naloxone Hydrochloride, and must make the training records available to Department upon request.
5. An individual who has successfully completed training provided by one Community-based Agency's Overdose Prevention Program is eligible to receive Naloxone Hydrochloride from another Community-based Agency's Overdose Prevention Program so long as the individual provides documentation showing

successful completion of training that meets the minimum requirements set forth in Section 4.D.3.

6. The Overdose Prevention Program must maintain a record of all distributions of Naloxone Hydrochloride, which will include, at a minimum:
 - a. The name or de-identified mechanism of the trained individual to whom the Naloxone Hydrochloride was distributed;
 - b. The amount of Naloxone Hydrochloride and any Medical Supplies Necessary to Administer Naloxone Hydrochloride distributed to the individual;
 - c. The date of the distribution of the Naloxone Hydrochloride;
 - d. The name of the Overdose Prevention Program staff person that distributed the Naloxone Hydrochloride to the individual; and
 - e. Attestation that the individual to whom the Naloxone Hydrochloride was distributed had successfully completed training in accordance with this Section.

STATUTORY AUTHORITY: 22 M.R.S. § 2353

EFFECTIVE DATE:

May 16, 2019 (Emergency Rule Adoption)