

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 47 ALCOHOL AND DRUG ABUSE ADMINISTRATION

Chapter 08 Overdose Response Program

Authority: Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland

.01 Scope.

This chapter sets forth the requirements for the Overdose Response Program administered by the Department for the purpose of providing a means of training individuals to administer naloxone to an individual experiencing, or believed to be experiencing, opioid overdose to help prevent a fatality when medical services are not immediately available.

.02 Definitions.

A. In this chapter, the following terms have the meanings indicated.

B. Terms Defined.

(1) “Department” means the Maryland Department of Health.

(2) “Education and training program” means educational instruction in opioid overdose recognition and response and the administration of naloxone.

(3) “Emergency medical services” means the Statewide comprehensive system of emergency medical care.

(4) “Health care provider” means an individual licensed or certified under Health Occupations Article, Annotated Code of Maryland, or Education Article, §13-516, Annotated Code of Maryland, to provide health care services;

(5) “Naloxone” means an opioid antagonist medication used to counter the effects of an opioid overdose.

(6) “Pharmacist” means an individual licensed to practice pharmacy in Maryland under Health Occupations Article, Title 12, Annotated Code of Maryland.

(7) “Private or Public Entity” means a health care provider, local health department, community-based organization, substance use disorder treatment organization, or other person that addresses medical or social issues related to drug addiction.

(8) “Standing order” means a written instruction for the prescribing and dispensing of naloxone in accordance with Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland.

.03 Authorization of a Private or Public Entity.

A. Application for Authorization. A private or public entity that seeks to conduct education and training programs under Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland, shall submit to the Department:

(1) A completed application form containing all identifying information for the private or public entity that is required by the Department, including:

- (a) Entity name;
- (b) Type of entity based on categories supplied by the Department;
- (c) Entity address;
- (d) Entity telephone number;
- (e) Entity email address;
- (f) Name of Entity Director;
- (g) Name of Training Program Director; and
- (h) Any additional information as requested by the Department;

(2) For a public or private entity intending to provide naloxone:

(a) A copy of a written agreement between a health care provider with prescribing authority and the private or public entity for the prescribing and dispensing of naloxone;

(b) Identifying information for the health care provider with prescribing authority including:

- (i) Name;
- (ii) Title;
- (iii) Address;
- (iv) Phone number;
- (v) Email address; and
- (vi) State license number; and

(c) If applicable, a copy of the entity's dispensing protocols for naloxone;

(3) A description of ancillary topics to be covered in addition to the core educational training curriculum provided by the Department pursuant to Regulation .04A(2) of this chapter, and copies of any training materials to be used during instruction;

(4) Any other information required by the Department; and

(5) Any fee required by the Department.

B. Approval of Applications. Upon approval of an application for authorization, the Department shall issue to the private or public entity a form that includes:

(1) The name of the private or public entity and its director;

(2) A statement that the private or public entity is authorized by the Department to conduct education and training programs;

(3) A serial number;

(4) The date of the approval of the authorization; and

(5) The date of the expiration of the authorization.

C. Term of Authorization. An authorization under this chapter shall be valid for 2 years.

D. Notification of Significant Change of Information. An authorized private or public entity shall notify the Department in writing of any significant change in the information that was submitted in the application for authorization under §A(1)—(5) of this chapter within 30 days of such change.

E. Authorization Renewal.

(1) An authorized private or public entity may apply to the Department for renewal of its authorization to conduct education and training programs.

(2) An authorized private or public entity shall submit to the Department a completed renewal application form, along with any fee required by the Department, on a schedule set by the Department.

(3) The Department may request additional information from the private or public entity as necessary to render a decision on the renewal application.

(4) If the Department finds, after review of the application for authorization renewal, that the private or public entity is in compliance with the requirements for initial authorization set forth in this chapter, the Department shall issue a renewal authorization form to the private or public entity that includes the information set forth in §B of this regulation.

(5) An authorization renewal under this chapter shall be valid for 2 years.

F. Expiration without Renewal. The Department may require a private or public entity whose authorization has expired without renewal to reapply for initial authorization as required under §A of this regulation.

G. Maintenance of Records. The Department shall maintain a record of each authorized private or public entity, including all information submitted by the private or public entity in the initial application for authorization and any additional information provided in an application for authorization renewal.

.04 Education and Training Programs.

A. A private or public entity authorized by the Department:

(1) Shall offer an education and training program on opioid overdose recognition and response; and

(2) May provide access to naloxone.

B. Education and training shall include a core curriculum provided by the Department. The core curriculum shall include:

(1) Education on recognizing the symptoms and signs of an opioid overdose;

(2) Training on responding to an opioid overdose;

(3) The proper use and administration of naloxone;

- (4) Proper rescue breathing technique;
- (5) The importance of contacting emergency medical services;
- (6) The care of an individual after the administration of naloxone; and
- (7) Any other topic required by the Department.

C. The Department may approve multiple core curricula:

- (1) For use in training specific populations;
- (2) For delivery in specific settings; or
- (3) Based on other relevant factors.

D. Education and training may include any other relevant topic at the discretion of the authorized private or public entity conducting the education and training.

E. A private or public entity authorized by the Department under this chapter may offer a training program online.

.05 Naloxone Use.

A. An individual of any age may receive from any health care provider with prescribing authority a prescription for naloxone and the necessary supplies for the administration of naloxone.

B. An individual for whom naloxone is prescribed and dispensed in accordance with this chapter may:

- (1) Possess prescribed naloxone and the necessary supplies for the administration of naloxone; and
- (2) In an emergency situation when medical services are not immediately available, administer naloxone to an individual experiencing or believed by the individual to be experiencing an opioid overdose.

C. An individual who, in accordance with [Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland](#), and this regulation, is administering naloxone to an individual experiencing, or believed by the individual to be experiencing an opioid overdose, may not be considered to be practicing:

- (1) Medicine for the purposes of [Health Occupations Article, Title 14, Annotated Code of Maryland](#); or
- (2) Registered nursing for the purposes of [Health Occupations Article, Title 8, Annotated Code of Maryland](#).

D. An individual may report information on the administration of naloxone by the individual, overdose reversals, and other program outcomes to:

- (1) The private and public entity that provided training;
- (2) The Maryland Poison Center;
- (3) The Department; or
- (4) Any other entity identified by the Department.

.06 Naloxone Prescribing and Dispensing.

A. A healthcare provider with prescribing authority may prescribe and dispense naloxone to an individual of any age who:

- (1) Is believed by the health care provider to be at risk of experiencing an opioid overdose; or
- (2) Is in a position to assist an individual at risk of experiencing an opioid overdose.

B. A health care provider with prescribing authority may prescribe and dispense naloxone by issuing a standing order if the health care provider:

- (1) Is employed by the department or a local health department; or
- (2) Has a written agreement with an authorized private or public entity under [Health-General Article, §13-3104, Annotated Code of Maryland](#).

C. A health care provider with prescribing authority who issues a standing order may delegate the dispensing of naloxone to an employee or a volunteer of an authorized private or public entity in accordance with a written agreement under [Health-General Article, §13-3104, Annotated Code of Maryland](#).

D. A health care provider who has dispensing authority also may dispense naloxone to any individual of any age in accordance with a standing order issued by a health care provider in accordance with [Health-General Article, §13-3106, Annotated Code of Maryland](#).

.07 Denial, Suspension, and Revocation of Authorization of a Private or Public Entity.

A. If the Department determines that a private or public entity has failed to comply with the requirements of this chapter, the Department may initiate one or more of the following actions against the private or public entity:

- (1) Denial of an initial application for authorization;
- (2) Denial of an application for authorization renewal;
- (3) Suspension of the authorization of the private or public entity; or
- (4) Revocation of authorization of the private or public entity.

B. Notification to Applicant or Private or Public Entity.

(1) The Department shall notify an applicant or private or public entity in writing of the denial of initial application for authorization, denial of application for authorization renewal, suspension of authorization, or revocation of authorization.

(2) The written notice shall include:

- (a) The reason for the action taken;
- (b) The effective date of the action;
- (c) The procedure for appeal of the decision to deny an initial application for, or to suspend, revoke, or not renew the authorization of, a private or public entity; and

(d) Notification that the private or public entity may file an appeal of the Department's decision and that any such appeal shall be filed within 10 days of receipt of the notice.

C. Summary Suspension.

(1) Under [State Government Article, §10-226\(c\), Annotated Code of Maryland](#), the Department may summarily suspend the authorization of a private or public entity if the Department finds that the public health, safety, or welfare imperatively requires emergency action.

(2) From the time of receipt of the notice of summary suspension, the private or public entity may not:

- (a) Conduct an education and training program; or
- (b) Provide access to naloxone.

D. Reinstatement of Authorization after Suspension. The Department may lift the suspension and reinstate authorization of a private or public entity if:

(1) The private or public entity submits in writing to the Department a request for the reinstatement that documents how the conditions leading to the suspension have been remedied or corrected; and

(2) The Department verifies that the conditions leading to the suspension have been remedied or corrected.

E. Application after Revocation. After authorization of a private or public entity has been revoked for a period of 12 months, the former authorized entity may reapply for authorization approval pursuant to the process set forth in [Regulation .03](#) of this chapter.

.08 Appeals.

A private or public entity may request a hearing on an action taken by the Department pursuant to Regulation .07 of this chapter as allowed by:

- A. [COMAR 10.01.03](#);
- B. [State Government Article, Title 10, Subtitle 2, Annotated Code of Maryland](#); and
- C. [Health-General Article, Title 2, Subtitle 2, Annotated Code of Maryland](#).

.09 Record Maintenance and Reporting.

A. The Department shall maintain the following records:

(1) Information on private or public entities authorized by the Department, including:

- (a) Names of entities and directors;
- (b) Addresses of entities;
- (c) Serial numbers of the initial authorizations;
- (d) Initial authorization dates; and
- (e) Dates of authorization renewals; and

(2) Information on private or public entities whose authorization has been suspended or revoked, including:

- (a) Names of entities and directors;
- (b) Addresses of entities;
- (c) Serial numbers of the initial authorizations;

- (d) Effective dates of suspensions or revocations;
- (e) Reasons for suspensions or revocations; and
- (f) If applicable, dates on which the approvals for authorization were reinstated.

B. If providing naloxone, a private or public entity authorized by the Department shall maintain records for each individual who has been provided naloxone, including:

- (1) Full name of individual;
- (2) Name of prescriber;
- (3) Name and address of dispenser;
- (4) Date of dispensing; and
- (5) Type and dosage of naloxone dispensed.

C. Reporting Information to the Department. A private or public entity authorized by the Department shall report to the Department:

- (1) Information on program operations, including:
 - (a) Number of individuals who have completed education and training programs;
 - (b) For private or public entities authorized by the Department that provide naloxone directly or by means of a voucher for redemption at a pharmacy:
 - (i) Form of naloxone dispensed;
 - (ii) Number of initial doses of naloxone dispensed; and
 - (iii) Number of naloxone refills dispensed; and
 - (c) Number and location of naloxone administrations and overdose reversals to the extent this information is reported to the private or public entity authorized by the Department;
- (2) Demographic information on individuals who participated in an education and training program, including aggregate number of individuals by:
 - (a) Sex;
 - (b) Ethnicity;
 - (c) Race;
 - (d) Age; and
 - (e) The specific reason to receive education and training; and
- (3) Any other information required by the Department.

D. Information under §C of this regulation shall be reported by the private or public entity authorized by the Department on a monthly basis in a format specified by the Department.

.10 General Provisions.

A. Waiver of Fees. The Department may waive any fee required under this chapter.

B. Discipline of a Health Care Provider. A health care provider who prescribes or dispenses naloxone to an individual in good faith, may not be subject to any disciplinary action under Health Occupations Article, Annotated Code of Maryland, solely for the act of prescribing or dispensing naloxone to the individual.

C. A cause of action may not arise against any health care provider with prescribing authority, or pharmacist for any act or omission when prescribing or dispensing naloxone and the necessary paraphernalia for the administration of naloxone to an individual in good faith under Health General Article, §13-3108, Annotated Code of Maryland.

D. An individual who administers naloxone to an individual who is or in good faith is believed to be experiencing an opioid overdose shall have immunity from liability under Courts and Judicial Proceedings Article, §§5-603 and 5-629, Annotated Code of Maryland.

Administrative History

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