

Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE

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 an Overdose Response Program overseen by the Department for the purpose of providing a means of authorizing certain individuals to obtain and 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) “Advanced practice nurse” has the meaning stated in Health Occupations Article, §8–101, Annotated Code of Maryland.
- (2) “Certificate” means a form, issued to an individual by a private or public entity authorized by the Department, which allows the individual to obtain a prescription for, possess, and administer naloxone.
- (3) “Certificate holder” means an individual who possesses a valid certificate.
- (4) “Department” means the Department of Health and Mental Hygiene.
- (5) “Educational training program” means initial educational instruction in overdose recognition and response and the administration of naloxone.
- (6) “Emergency medical services” means the Statewide comprehensive system of emergency medical care.
- (7) “Licensed physician” means an individual licensed to practice medicine in Maryland under Health Occupations Article, Title 14, Annotated Code of Maryland.
- (8) “Naloxone” means an opioid antagonist medication used to counter the effects of an opioid overdose.
- (9) “Pharmacist” means an individual licensed to practice pharmacy in Maryland under Health Occupations Article, Title 12, Annotated Code of Maryland.

(10) “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.

(11) “Refresher training program” means continuing educational instruction in overdose recognition and response and the administration of naloxone.

(12) “Standing order” means a written instruction for the prescribing and dispensing of naloxone to a certificate holder 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 educational training and refresher training programs and to issue and renew certificates 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; and
- (g) If applicable, name of Training Program Director;

(2) Identifying information for any licensed physician, advanced practice registered nurse, and pharmacist who will directly conduct, or who will supervise any individual who will conduct, the educational training and refresher training programs, including:

- (a) Name;
- (b) Title;
- (c) Address;
- (d) Phone number;
- (e) Email address; and
- (f) Professional credentials, including:
 - (i) For licensed physicians, State license number;

(ii) For advanced practice registered nurses, a State license number; and

(iii) For pharmacists, a State license number.

(3) If applicable, a copy of any written agreement between a supervisory licensed physician, advanced practice registered nurse, or pharmacist and the private or public entity required under Regulation .04A(6)(d) of this chapter;

(4) 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;

(5) For a private or public entity intending to dispense naloxone to certificate holders, a copy of the entity's naloxone dispensing protocols;

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

(7) 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 educational training and refresher training programs and to issue and renew certificates;

(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)—(6) 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 educational training and refresher training programs and to issue and renew certificates.

(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 Educational Training Programs and Refresher Training Programs.

A. Educational Training Programs.

(1) A private or public entity authorized by the Department shall offer an educational training program.

(2) An educational training program shall include a core curriculum provided by the Department. The core curriculum shall include training in:

- (a) Recognition of the symptoms and signs of an opioid overdose;
- (b) Protocols for the proper use and administration of naloxone;
- (c) Proper rescue breathing technique;
- (d) The importance of contacting emergency medical services;
- (e) The care of an individual after the administration of naloxone; and
- (f) Any other topic required by the Department.

(3) The Department may approve multiple core curricula:

- (a) For use in training specific populations;
- (b) For delivery in specific settings; or
- (c) Based on other relevant factors.

(4) An educational training program may include any other relevant topic at the discretion of the authorized private or public entity conducting the educational training program.

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

(6) An educational training program shall be conducted by:

- (a) A licensed physician;

- (b) An advanced practice registered nurse;
- (c) A pharmacist; or
- (d) An employee or volunteer of an authorized private or public entity who is supervised in accordance with a written agreement between the private or public entity and a supervisory licensed physician, advanced practice registered nurse, or pharmacist that includes:
 - (i) Procedures for providing patient overdose information;
 - (ii) Information as to how the employee or volunteer providing the information will be trained and evaluated by the supervisory licensed physician, advanced practice registered nurse, or pharmacist;
 - (iii) Standards for documenting the provision of patient overdose information to patients; and
 - (iv) A description of the procedure for and frequency of contact between the employee or volunteer, or both, and the supervisory licensed physician, advanced practice registered nurse, or pharmacist.

B. Refresher Training Programs.

- (1) A private or public entity authorized by the Department under this chapter may offer a refresher training program as a requirement for renewal of a certificate under Regulation .05E of this chapter.
- (2) A refresher training program shall include any information required by the Department to update any component of a core curriculum provided by the Department for the educational training program set forth in §A of this regulation.
- (3) A refresher training program may include any other relevant topic at the discretion of the authorized private or public entity conducting the refresher training program.
- (4) A private or public entity authorized by the Department under this chapter may offer a refresher training program online.

.05 Certificates.

A. Application for a Certificate.

- (1) An individual who seeks to receive a certificate shall submit an application on a form provided by the Department to a private or public entity authorized by the Department.
- (2) Notwithstanding §A(1) of this regulation, a private or public entity may accept an oral application from an individual who seeks to receive a certificate, provided that the private or public entity:
 - (a) Receives from the individual all of the information required to be entered on the application form provided by the Department, and
 - (b) Records, in hard copy or electronic format, all of the required information, including the individual's written or electronic signature, in a manner that may be reproduced and inspected by the Department.

B. Certificate Issuance. A private or public entity authorized by the Department under this chapter shall issue a certificate to an individual who:

- (1) Is at least 18 years old;
- (2) Has, or reasonably expects to have, as a result of the individual's occupation or volunteer work, or family or social experience, the ability to assist an individual who is experiencing an opioid overdose;
- (3) Has successfully completed an educational training program offered by the authorized private or public entity; and
- (4) Has submitted information to the authorized private or public entity as required by §A of this regulation.

C. Certificate Format. The authorized private or public entity shall issue a certificate in a format provided by the Department that shall include:

- (1) The name, address, and telephone number of the private or public entity certifying the individual;
- (2) The full name of the certificate holder;
- (3) A statement that the certificate holder is authorized to obtain a prescription for naloxone in the certificate holder's name, and possess and administer naloxone in accordance with Health-General Article, Title 13, Subtitle 31, Annotated Code of Maryland;
- (4) A serial number;
- (5) The date of issuance;
- (6) The date of expiration;
- (7) The telephone number for the Maryland Poison Center; and
- (8) Any other information required by the Department.

D. Certificate Term. A certificate issued pursuant to this regulation shall be valid for 2 years.

E. Certificate Renewal. An authorized private or public entity shall issue a renewal certificate to a certificate holder who has:

- (1) Applied to an authorized private or public entity for renewal not later than 90 days before the date of expiration of the certificate, on a form or in a manner required by the Department; and
- (2) Successfully completed a refresher training program conducted by an authorized private or public entity that meets the requirements of Regulation .04B of this chapter, or demonstrated proficiency to the authorized private or public entity issuing the certificate, by means of an assessment that documents the certificate holder's knowledge and skills necessary for:
 - (a) Recognizing an opioid overdose;
 - (b) Appropriately administering naloxone; and

(c) Ensuring proper follow-up care.

F. Certificate Replacement.

(1) An authorized private or public entity may issue a replacement certificate to replace a lost, destroyed, or mutilated certificate originally issued by the authorized private or public entity.

(2) A replacement certificate issued under §F(1) of this regulation shall have the same format and contain the same information as that set forth in the original certificate.

.06 Certificate Holders.

A. Authority of a Certificate Holder. A certificate holder may:

(1) On presentment of a valid certificate, receive from any licensed physician or advanced practice registered nurse with prescribing authority, a prescription for naloxone and the necessary supplies for the administration of naloxone;

(2) Possess prescribed naloxone and the necessary supplies for the administration of naloxone; and

(3) In an emergency situation when medical services are not immediately available, administer naloxone to an individual experiencing or believed by the certificate holder to be experiencing an opioid overdose.

B. Responsibilities of a Certificate Holder. A certificate holder shall:

(1) Follow the protocols for the use and administration of naloxone established by the authorized private or public entity that issued the certificate; and

(2) Make a good faith effort to obtain immediate medical attention for an individual experiencing, or believed by the certificate holder to be experiencing, an opioid overdose.

C. A certificate holder 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 certificate holder 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. A certificate holder may report information on the administration of naloxone by the certificate holder, overdose reversals, and other program outcomes to:

(1) The private and public entity that issued the certificate;

(2) The Maryland Poison Center;

(3) The Department; or

(4) Any other entity identified by the Department.

.07 Naloxone Prescribing and Dispensing.

A. A licensed physician or an advanced practice registered nurse with prescribing authority may prescribe and dispense naloxone to a certificate holder.

B. A registered nurse may dispense naloxone to a certificate holder in a local health department if the registered nurse complies with:

(1) The formulary developed and approved under Health-General Article, §3-403(b), Annotated Code of Maryland; and

(2) The requirements established under of the Health Occupations Article, §8-512, Annotated Code of Maryland.

C. A licensed physician or an advanced practice registered nurse with prescribing authority may prescribe and dispense naloxone to a certificate holder by issuing a standing order if the licensed physician or advanced practice registered nurse:

(1) Is employed by the department or a local health department; or

(2) Supervises or conducts an educational training program under Health-General Article, §13-3104(d)(2), Annotated Code of Maryland, and Regulation .04 of this chapter.

D. A licensed physician or an advanced practice registered nurse with prescribing authority who issues a standing order may delegate to the following individuals the authority for dispensing naloxone to a certificate holder:

(1) A licensed registered nurse who:

(a) Is employed by a local health department; and

(b) Completes a training program approved by the Department; and

(2) An employee or a volunteer of a private or public entity who is authorized to conduct an educational training program in accordance with Regulation .04 of this chapter.

E. A licensed health care provider who has dispensing authority also may dispense naloxone to a certificate holder in accordance with a standing order issued by a licensed physician.

.08 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. Effect on Certificates Issued by a Private or Public Entity. The Department may suspend or revoke the certificates issued by a private or public entity if:

- (1) The private or public entity's authorization has been suspended or revoked; and
- (2) The Department determines that the private or public entity failed to satisfy the requirements for educational training programs or refresher training programs as set forth in Regulation .04 of this chapter.

C. 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.

D. 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 educational training program or refresher training program;
- (b) Issue certificates; or
- (c) Dispense naloxone.

E. 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.

F. 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.

.10 Appeals.

A private or public entity or certificate holder may request a hearing on an action taken by the Department pursuant to Regulation .07 or .08 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.

.11 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;
- (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; and
- (3) A list of individuals whose certificates have been suspended or revoked, including:
 - (a) Names;
 - (b) Addresses;
 - (c) Serial numbers of the suspended or revoked certificates;
 - (d) Effective dates of suspensions or revocations;

(e) Reasons for suspensions or revocations; and

(f) If applicable, dates on which the certificates were reinstated.

B. A private or public entity authorized by the Department shall maintain records, including:

(1) Information for each certificate holder who has been issued a certificate by the private or public entity authorized by the Department, including:

(a) Full name;

(b) Address;

(c) Date of birth;

(d) Demographic information, including:

(i) Ethnicity;

(ii) Race; and

(iii) Sex; and

(e) The specific status determination for eligibility to receive a certificate under Regulation .05B(2) of this chapter; and

(2) Information about each certificate issued by the private or public entity authorized by the Department, including:

(a) Full name of the individual to whom the certificate was issued;

(b) Certificate serial number;

(c) Date of issuance of the certificate; and

(d) Date of expiration of the certificate.

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 educational training and refresher training programs;

(b) Number of individuals who have been issued certificates; and

(c) For private or public entities authorized by the Department that dispense naloxone to certificate holders 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

(d) Number and location of naloxone administrations and overdose reversals to the extent this information is reported by certificate holders to the private or public entity authorized by the Department;

(2) Demographic information on certificate holders, including the aggregate number of certificate holders by:

(a) Sex;

(b) Ethnicity;

(c) Race;

(d) Age; and

(e) The specific status determination for eligibility to receive a certificate under Regulation .05B(2) of this chapter; 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.

.12 General Provisions.

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

B. Discipline of a Physician. A licensed physician who prescribes or dispenses naloxone to a certificate holder in a manner consistent with the protocol established by the authorized private or public entity may not be subject to any disciplinary action under of the Health Occupations Article, Title 14, Annotated Code of Maryland, solely for the act of prescribing or dispensing naloxone to the certificate holder.

C. An advanced practice registered nurse with prescribing authority, who prescribes or dispenses naloxone to a certificate holder in a manner consistent with the protocol established by the authorized private or public entity, may not be subject to any disciplinary action under Health Occupations Article, Title 8, Annotated Code of Maryland, solely for the act of prescribing or dispensing naloxone to the certificate holder.

D. A cause of action may not arise against any licensed physician, advanced practice registered nurse with prescribing authority, or pharmacist for any act or omission when the physician, advanced practice registered nurse with prescribing authority, or pharmacist in good faith prescribes or dispenses naloxone and the necessary paraphernalia for the administration of naloxone to a certificate holder or patient under Health General Article, §13-3108, Annotated Code of Maryland.

E. 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

Effective date: March 3, 2014 (41:4 Md. R. 301)

Regulation .02B amended effective April 13, 2015 (42:7 Md. R. 570)

Regulation .03A, D amended effective April 13, 2015 (42:7 Md. R. 570)

Regulation .04A amended effective April 13, 2015 (42:7 Md. R. 570)

Regulation .05 amended effective April 13, 2015 (42:7 Md. R. 570)

Regulation .08C amended effective April 13, 2015 (42:7 Md. R. 570)

Regulation .10B, C amended effective April 13, 2015 (42:7 Md. R. 570)

Regulation .10D adopted effective April 13, 2015 (42:7 Md. R. 570)

Chapter revised effective September 12, 2016 (43:18 Md. R. 1017)