

# **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle**

### **Chapter XX Overdose Response Program**

**Authority: Health-General Article, xxxxxx, 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) "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.
- (2) "Certificate holder" means an individual who possesses a valid certificate.
- (3) "Department" means the Department of Health and Mental Hygiene.
- (4) "Educational training program" means initial educational instruction in overdose identification and response and the administration of naloxone.
- (5) "Emergency medical services" means the statewide comprehensive system of emergency medical care.
- (6) "Naloxone" means an opioid antagonist medication used to counter the effects of an opioid overdose.
- (7) "Nurse practitioner" means an individual currently licensed to practice registered nursing in Maryland under Health Occupations Article, Title 8, Annotated Code of Maryland, and currently certified as a nurse practitioner in Maryland by the State Board of Nursing.
- (8) "Physician" means an individual currently licensed to practice medicine in Maryland under Health Occupations Article, Title 14, Annotated Code of Maryland.
- (9) "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.
- (10) "Refresher training program" means continuing educational instruction in overdose identification and response and the administration of naloxone.

### **.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 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; and

(f) Name of Director;

(2) Identifying information for any physician or nurse practitioner 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 physicians, State license number; and

(ii) For nurse practitioners, State registered nurse license number and State nurse practitioner certificate number;

(3) If applicable, a copy of any written agreement between a supervisory physician or nurse practitioner and the private or public entity required under section .04A(5)(c) of this regulation;

(4) If applicable, a description of ancillary topics to be covered in addition to the core educational training program provided by the Department pursuant to section .04A(2), and copies of associated training materials to be used during instruction;

(5) For a private or public entity intending to dispense naloxone to certificate holders who present a valid prescription, information on 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 must notify the Department of any significant change in information required in an application for authorization under section .03A(1)-(6) within 30 days of such change.

E. Authorization Renewal. 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.

- (1) An authorized private or public entity shall submit to the Department a completed renewal application form, along with any fee required by the Department, no later than 90 days before expiration of the current authorization.
- (2) The Department may request additional information from the private or public entity as necessary to render a decision.
- (3) If the Department finds 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 section .03B.
- (4) 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 resubmit the application information and materials as required under section .03(A).

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 contain a core curriculum provided by the Department for use by all authorized private and public entities that includes 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;
  - (f) How to obtain a prescription for naloxone and have that prescription filled; and
  - (g) Any other topic required by the Department.
- (3) An educational training program shall provide notification of the reasons why a certificate may be suspended or revoked and information on the process for appealing a suspension or revocation.
- (4) An educational training program may contain any other relevant topic at the discretion of the authorized private or public entity conducting the educational training program.
- (5) An educational training program shall be conducted by:
- (a) A physician;
  - (b) A nurse practitioner; or
  - (c) An employee or volunteer of an authorized private or public entity that maintains a written agreement with a supervisory physician or nurse practitioner 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; and
    - (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(s) or volunteer(s) and supervisory physician or nurse practitioner.

**B. Refresher Training Programs.**

- (1) A private or public entity authorized by the Department may offer a refresher training program as a requirement for renewal of a certificate under section .05D(2).
- (2) A refresher training program shall include any information required by the Department to update any component of the core curriculum provided by the Department for the educational training program set forth in section .04A.
- (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 may offer a refresher training program online.

**.05 Certificates.**

**A. Application for a Certificate.** 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.

**B. Certificate Issuance.** A private or public entity authorized by the Department 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, family, or social status, 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;
- (4) Has submitted to the authorized private or public entity a completed application form as required by .05A of this chapter; and
- (5) Has paid any fee required by the Department.

B. 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; and
- (7) Any other information required by the Department.

C. Certificate Term. A certificate issued pursuant to this regulation shall be valid for 2 years from the date of issuance.

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

- (1) Submitted to the authorized private or public entity no later than 90 days before the date of expiration of the certificate a completed certificate renewal application form provided by the Department, along with any fee 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 section .04B of this regulation; or
- (3) Demonstrated proficiency to the authorized private or public entity issuing the certificate, by means of an assessment that documents, on a form provided by the Department, the certificate holder's knowledge and skills necessary for:
  - (a) Identifying an opioid overdose;
  - (b) Appropriately administering naloxone; and
  - (c) Ensuring proper follow-up care.

E. 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, and may charge a reasonable fee for the replacement certificate.

(2) A replacement certificate issued under .05E(1) shall have the same format and contain the same information 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 licensed nurse practitioner 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 medicine for the purposes of Title 14 of the Health Occupations Article.

D. A certificate holder may report information on the administration of naloxone by the certificate holder, overdose reversals, and other program outcomes to the private and public entity that issued the certificate, the Maryland Poison Center, the Department, or any other entity identified by the Department.

## **.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 regulation, 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 section .04 of this regulation.

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 must file an appeal of the Department's decision 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 section .03 of this regulation.

## **.08 Suspension and Revocation of the Certificate of a Certificate Holder.**

A. The Department may suspend or revoke the certificate of a certificate holder for failure to follow the protocols for use and administration of naloxone established by the authorized private or public entity that issued the certificate.

B. The Department may suspend or revoke certificates issued by a private or public entity if:

- (1) The certificates were not issued pursuant to this regulation; or
- (2) The Department determines that the private or public entity has failed to satisfy the requirements for educational training programs or refresher training programs as set forth in section .04 of this regulation following the Department's suspension or revocation of the private or public entity's authorization pursuant to section .07 of this regulation.

C. Notification of Certificate Holder. The Department shall notify the affected certificate holder in writing of the certificate suspension or revocation.

(1) 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 suspend or revoke the certificate;
- (d) Notification that the certificate holder must file an appeal of the Department's decision within 10 days of receipt of the notice; and
- (e) If the suspension or revocation of a certificate is due solely to the failure of the private or public entity that issued the certificate to satisfy the requirements for educational training programs or refresher training programs as set forth in .08B(02) above, the Department shall provide the former certificate holder with a list of alternative private or public entities currently authorized by the Department to which the former certificate holder can apply to obtain a valid certificate.

D. Summary Suspension.

- (1) Under State Government Article, §10-226(c), Annotated Code of Maryland, the Department may summarily suspend the certificate of a certificate holder 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 former certificate holder may not:
  - (1) Obtain a prescription for naloxone from a physician or nurse practitioner;
  - (2) Present a prescription for naloxone to be dispensed by a pharmacist, physician or nurse practitioner; or
  - (3) Administer naloxone.

E. Surrender of Certificate. Within 5 business days of receipt of notice of revocation of a certificate, the former certificate holder shall surrender the certificate to the Department.

F. Reinstatement of Certificate after Suspension. The Department may lift the suspension and reinstate the certificate of a certificate holder if:

- (1) The certificate holder 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.

G. Application after Revocation. If the certificate revocation is due solely to the suspension or revocation of the authorization of the private or public entity that issued the certificate, the former certificate holder may apply to obtain a valid certificate immediately upon satisfying the requirements of section .05 of this regulation at an alternative private or public entity authorized by the Department.

## **.09 Appeals.**

A private or public entity or certificate holder may make an administrative appeal of an action taken by the Department pursuant to section .07 or .08 of this regulation 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.

## **.10 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.
- (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 the following records:

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

- (a) Name;
- (b) Address;
- (c) Date of Birth;
- (d) Demographic information, including:
  - (i) Gender; and
  - (ii) Race;
- (e) The specific status determination for eligibility to receive a certificate under section .05B(2);
- (f) Certificate serial number;
- (g) Date of issuance of the certificate; and
- (e) Date of expiration of the certificate.

C. Reporting Information to the Department.

(1) A private or public entity authorized by the Department shall report to the Department:

- (a) Information on program operations, including:
  - (i) Number of individuals who have completed educational training and refresher training programs;
  - (ii) Number of individuals who have been issued certificates;
  - (iii) For private or public entities dispensing naloxone to certificate holders:
    - a. Form of naloxone dispensed;
    - b. Number of initial doses of naloxone dispensed; and
    - c. Number of naloxone refills dispensed and reason given for each refill dispensed; and
  - (iv) Number and location of naloxone administrations and overdose reversals to the extent this information is reported by certificate holders to the authorized private or public entity;
- (b) Information on certificate holders, including the total number of certificate holders by:
  - (i) Race;

(ii) Gender; and

(iii) Age; and

(c) Any other information required by the Department.

(2) A private or public entity authorized by the Department shall annually report to the Department the information required under section .09C(1).

## **.11 General Provisions.**

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

B. Prescribing and Dispensing of Naloxone. A licensed physician or nurse practitioner may prescribe and dispense naloxone to a certificate holder.

C. Discipline of a Physician. A 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 Title 14 of the Health Occupations Article *solely* for the act of prescribing or dispensing naloxone to the certificate holder.

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