**PROPOSAL**

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**Title 10
MARYLAND DEPARTMENT OF HEALTH**

**Subtitle 47 ALCOHOL AND DRUG ABUSE ADMINISTRATION**

**10.47.08 Overdose Response Program**

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

**Notice of Proposed Action**

[19-015-P]

The Secretary of Health proposes to amend Regulations **.01—.04**, repeal Regulations **.05** and **.09**, and amend and recodify existing Regulations **.06—.08** and **.10—.12** to be Regulations **.05—.07** and **.08—.10**, respectively, under **COMAR 10.47.08 Overdose Response Program**.

**Statement of Purpose**

The purpose of this action is to:

(1) Clarify the role of the Overdose Response Program;

(2) Repeal certification requirements within the Overdose Response Program;

(3) Update requirements for a private or public entity to conduct education and training on opioid overdose recognition and response; and

(4) Update record and reporting requirements.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

The proposed action has no economic impact.

**Economic Impact on Small Businesses**

The proposed action has minimal or no economic impact on small businesses.

**Impact on Individuals with Disabilities**

The proposed action has no impact on individuals with disabilities.

**Opportunity for Public Comment**

Comments may be sent to Jake Whitaker, Acting Director, Office of Regulation and Policy Coordination, Maryland Department of Health, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499 (TTY 800-735-2258), or email to mdh.regs@maryland.gov, or fax to 410-767-6483. Comments will be accepted through February 19, 2019. A public hearing has not been scheduled.

**.01 Scope.**

This chapter sets forth the requirements for **[**an**]** *the*Overdose Response Program **[**overseen**]** *administered*by the Department for the purpose of providing a means of **[**authorizing certain**]** *training*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. (text unchanged)

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)**]** *(1)*(text unchanged)

**[**(5)**]***(2)* “**[**Educational**]***Education and* training program” means **[**initial**]** educational instruction in *opioid*overdose recognition and response and the administration of naloxone.

**[**(6)**]***(3)* (text unchanged)

*(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;*

**[**(7) “Licensed physician” means an individual licensed to practice medicine in Maryland under Health Occupations Article, Title 14, Annotated Code of Maryland.**]**

**[**(8)**]***(5)—***[**(10)**]***(7)*(text unchanged)

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

**[**(12)**]***(8)* “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**]***education and*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)—(e) (text unchanged)

(f) Name of Entity Director;**[** and**]**

(g) **[**If applicable, name**]** *Name* of Training Program Director;*and*

*(h) Any additional information as requested by the Department;*

**[**(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)**]** *(2)* **[**If applicable, a**]** *For a public or private entity intending to provide naloxone:*

*(a)**A* copy of **[**any**]** *a*written agreement between a **[**supervisory licensed physician, advanced practice registered nurse, or pharmacist**]** *health care provider with prescribing authority*and the private or public entity **[**required under Regulation .04A(6)(d) of this chapter**]***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;*

**[**(4)**]** *(3)* (text unchanged)

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

**[**(6)**]** *(4)—***[**(7)**]** *(5)* (text unchanged)

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) (text unchanged)

(2) A statement that the private or public entity is authorized by the Department to conduct **[**educational**]** *education and* training**[**and refresher training**]** programs **[**and to issue and renew certificates**]**;

(3)—(5) (text unchanged)

C. (text unchanged)

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)**]** *§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 **[**educational**]** *education and* training **[**and refresher training**]**programs **[**and to issue and renew certificates**]**.

(2)—(5) (text unchanged)

F.—G. (text unchanged)

**.04 [Educational] *Education and*Training Programs [and Refresher Training Programs].**

**[**A. Educational Training Programs.**]**

**[**(1)**]** *A.*A private or public entity authorized by the Department **[**shall**]***:*

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

*(2) May provide access to naloxone*.

**[**(2)**]** *B.***[**An educational**]** *Education and*training **[**program**]** shall include a core curriculum provided by the Department. The core curriculum shall include **[**training in**]**:

**[**(a)**]** *(1)***[**Recognition of**]** *Education on recognizing*the symptoms and signs of an opioid overdose;

**[**(b)**]** *(2)***[**Protocols for the proper use and administration of naloxone**]***Training on responding to an opioid overdose*;

*(3) The proper use and administration of naloxone;*

**[**(c)**]***(4)*Proper rescue breathing technique;

**[**(d)**]***(5)*—**[**(f)**]***(7)*(text unchanged)

**[**(3)**]** *C.* (text unchanged)

**[**(4)**]** *D.***[**An educational**]** *Education and* training **[**program**]** may include any other relevant topic at the discretion of the authorized private or public entity conducting the **[**educational**]***education and*training **[**program**]**.

**[**(5)**]** *E.*(text unchanged)

**[**(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.**]**

**[.06] *.05* [Certificate Holders] *Naloxone Use.***

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

(1) On presentment of a valid certificate,**]** *An individual of any age may*receive from any **[**licensed physician or advanced practice registered nurse**]***health care provider* 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.**]**

*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. **[**A certificate holder**]***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 **[**certificate holder**]** *individual*to be experiencing an opioid overdose, may not be considered to be practicing:

(1)—(2) (text unchanged)

D. **[**A certificate holder**]***An individual* may report information on the administration of naloxone by the **[**certificate holder**]***individual*, overdose reversals, and other program outcomes to:

(1) The private and public entity that **[**issued the certificate**]***provided training*;

(2)—(4) (text unchanged)

**[.07] *.06* Naloxone Prescribing and Dispensing.**

A. A **[**licensed physician or an advanced practice registered nurse**]***healthcare provider* with prescribing authority may prescribe and dispense naloxone to **[**a certificate holder.**]***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 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.**]** *B.* A **[**licensed physician or an advanced practice registered nurse**]***health care provider* 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**]***health care provider*:

(1) (text unchanged)

(2) **[**Supervises or conducts an educational training program**]***Has a written agreement with an authorized private or public entity*under Health-General Article, §13-3104**[**(d)(2)**]**, Annotated Code of Maryland**[**, and Regulation .04 of this chapter**]**.

**[**D.**]***C.* A **[**licensed physician or an advanced practice registered nurse**]** *health care provider* with prescribing authority who issues a standing order may delegate **[**to the following individuals the authority for**]** *the* dispensing *of*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**]** *an*employee or a volunteer of **[**a**]** *an authorized*private or public entity **[**who is authorized to conduct an educational training program**]** in accordance with **[**Regulation .04 of this chapter**]***a written agreement under Health-General Article, §13-3104, Annotated Code of Maryland*.

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

**[.08] *.07* Denial, Suspension, and Revocation of Authorization of a Private or Public Entity.**

A. (text unchanged)

**[**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.**]***B.* (text unchanged)

**[**D.**]** *C.* Summary Suspension.

(1) (text unchanged)

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

(a) Conduct an **[**educational**]** *education and* training program **[**or refresher training program;

(b) Issue certificates**]**; or

**[**(c)**]** *(b)* **[**Dispense**]***Provide access to* naloxone.

**[**E.**]** *D.*—**[**F.**]** *E.*(text unchanged)

**[.10] *.08*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.—C. (text unchanged)

**[.11] *.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)—(d) (text unchanged)

(e) Dates of authorization renewals; *and*

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

(a)—(e) (text unchanged)

(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**]** *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) 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.**]**

*(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 **[**educational**]** *education and* training **[**and refresher training**]** programs;

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

**[**(c)**]***(b)* For private or public entities authorized by the Department that **[**dispense**]***provide* naloxone **[**to certificate holders**]** directly or by means of a voucher for redemption at a pharmacy:

(i)— (iii) (text unchanged)

**[**(d)**]***(c)* 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**]** *individuals who participated in an education and training program, including aggregate number of individuals*by:

(a)—(d) (text unchanged)

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

(3) (text unchanged)

D. (text unchanged)

**[.12] *.10* General Provisions.**

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

B. Discipline of a **[**Physician**]** *Health Care Provider*. A **[**licensed physician**]** *health care provider* who prescribes or dispenses naloxone to **[**a certificate holder in a manner consistent with the protocol established by the authorized private or public entity**]** *an individual in good faith,*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**]** *individual*.

**[**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.**]***C.* A cause of action may not arise against any **[**licensed physician, advanced practice registered nurse**]** *health care provider* 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**]** *prescribing or dispensing* naloxone and the necessary paraphernalia for the administration of naloxone to **[**a certificate holder or patient**]** *an individual in good faith* under Health General Article, §13-3108, Annotated Code of Maryland.

**[**E.**]** *D.*(text unchanged)

ROBERT R. NEALL
Secretary of Health