

MARYLAND REGISTER

**Proposed Action on Regulations**

<b>Transmittal Sheet</b>  <b>PROPOSED OR REPROPOSED</b>  <b>Actions on Regulations</b>	<b>Date Filed with AELR Committee</b>	<b>TO BE COMPLETED BY DSD</b>
	05/09/2016	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register: 6/24/2016**

**2. COMAR Codification**

**Title Subtitle Chapter Regulation**

10 47 08 02-.12

**3. Name of Promulgating Authority**

Department of Health and Mental Hygiene

**4. Name of Regulations Coordinator**

Michele Phinney

**Telephone Number**

410-767-5623

**Mailing Address**

201 W. Preston Street

**City State Zip Code**

Baltimore MD 21201

**Email**

michele.phinney@maryland.gov

**5. Name of Person to Call About this Document**

Rachael Faulkner

**Telephone No.**

410-402-8402

**Email Address**

rachael.faulkner@maryland.gov

**6. Check applicable items:**

- New Regulations

- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: October 16, 2015.

- Repeal of Existing Regulations

- Recodification

- Incorporation by Reference of Documents Requiring DSD Approval

- Reproposal of Substantively Different Text:

: Md. R

(vol.) (issue) (page nos) (date)

Under Maryland Register docket no.: --P.

**7. Is there emergency text which is identical to this proposal:**

Yes - No

**8. Incorporation by Reference**

Check if applicable: Incorporation by Reference (IBR) approval form(s) attached and 18 copies of documents proposed for incorporation submitted to DSD. (Submit 18 paper copies of IBR document to DSD and one copy to AELR.)

**9. Public Body - Open Meeting**

OPTIONAL - If promulgating authority is a public body, check to include a sentence in the Notice of Proposed Action that proposed action was considered at an open meeting held pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

OPTIONAL - If promulgating authority is a public body, check to include a paragraph that final action will be considered at an open meeting.

**10. Children's Environmental Health and Protection**

Check if the system should send a copy of the proposal to the Children's Environmental Health and Protection Advisory Council.

**11. Certificate of Authorized Officer**

I certify that the attached document is in compliance with the Administrative Procedure Act. I also certify that the attached text has been approved for legality by Linda M. Bethman, Assistant Attorney General, (telephone #410-767-6906) on April 15, 2016. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Van T. Mitchell

**Title**

Secretary

**Telephone No.**

410-767-6500

**Date**

May 9, 2016

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

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .02—.06, adopt new Regulation .07, and recodify existing Regulations .07 and .09 to be Regulations .08 and .10, respectively, and amend and recodify Regulations .08, .10 and .11 to be Regulations .09, .11 and .12, respectively under COMAR 10.47.08 Overdose Response Program.

**Statement of Purpose**

The purpose of this action is to :

- (1) Authorize advanced practice registered nurses and pharmacists to conduct overdose prevention educational training programs;
- (2) Provide for an exception to training requirements for a patient who receives a naloxone prescription under the provisions of the law;
- (3) Exempt persons who are authorized to dispense naloxone from prescription drug dispensing permit requirements;
- (4) Provide immunity from liability; and
- (5) Repeal the collection of fees that public or private entities may collect from individuals.

**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 Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 West Preston Street, Room 512, Baltimore, MD 21201, or call 410-767-6499; TTY:800-735-2258, or email to [dhmh.regs@maryland.gov](mailto:dhmh.regs@maryland.gov), or fax to 410-767-6483. Comments will be accepted through July 25, 2016. A public hearing has not been scheduled.

### **Economic Impact Statement Part C**

- A. Fiscal Year in which regulations will become effective: FY 2017
- B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?
- C. If 'yes', state whether general, special (exact name), or federal funds will be used:
- D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:
- E. If these regulations have no economic impact under Part A, indicate reason briefly: The change is procedural in nature. In addition, the repeal of fees that public and private entities may collect from individuals has no impact as there are no entities that have collected in the past, or currently collect, fees from individual participants.
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.  
See E. above.
- G. Small Business Worksheet:

Attached Document:

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

*10.47.08.02 (October 16, 2015)*

**.02 Definitions.**

- A. (text unchanged)
- B. Terms Defined.

(1) "Advanced practice registered nurse" means an individual currently licensed to practice registered nursing in Maryland under Health Occupations Article, Title 8, Annotated Code of Maryland.

[(1)] (2)—[(5)] (6) (text unchanged)

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

[(6)] (8) (text unchanged)

[(7) "Nurse practitioner" means an individual currently:

(a) Licensed to practice registered nursing in Maryland under Health Occupations Article, Title 8, Annotated Code of Maryland; and

(b) Certified as a nurse practitioner in Maryland by the State Board of Nursing.]

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

[(8) "Physician" means an individual currently licensed to practice medicine in Maryland under Health Occupations Article, Title 14, Annotated Code of Maryland.]

[(9)] (10)—[(10)] (11) (text unchanged)

(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.

10.47.08.03

### **.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) (text unchanged)

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

(a)—(e) (text unchanged)

(f) Professional credentials, including:

(i) For *licensed* physicians, State license number; [and]

(ii) For [nurse practitioners] *advanced practice registered nurses*, State [registered nurse] license number;

and

(iii) For pharmacists, a State license number.

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

(4) [If applicable, a] A description of ancillary topics to be covered in addition to the core educational training curriculum [program] provided by the Department pursuant to Regulation .04A(2) of this chapter, and copies of [associated] any 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] a copy of the entity's naloxone dispensing protocols;

(6)—(7) (text unchanged)

B.—D. (text unchanged)

E. Authorization Renewal.

(1) (text unchanged)

(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, [later than 90 days before expiration of the current authorization] on a schedule set by the Department.

(3)—(5) (text unchanged)

F.—G. (text unchanged)

10.47.08.04

### **.04 Educational Training Programs and Refresher Training Programs.**

A. Educational Training Programs.

(1) (text unchanged)

(2) An educational training program shall include a core curriculum provided by the Department [for use by all authorized private and public entities]. The core curriculum shall include training in:

(a)—(d) (text unchanged)

(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)] (f) (text unchanged)

[(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.]

(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) (text unchanged)

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

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

(a) A *licensed physician;*

(b) [A] *An advanced practice registered nurse [practitioner; or];*

(c) *A pharmacist; or*

[(c)] (d) An employee or volunteer of an authorized private or public entity [that maintains] *who is supervised in accordance with a written agreement [with] between the private or public entity and a supervisory licensed physician [or], advanced practice registered [supervisory] nurse [practitioner], or pharmacist that includes:*

(i) (text unchanged)

(ii) Information as to how the employee or volunteer providing the information will be trained and evaluated by the supervisory *licensed physician, [or] advanced practice registered nurse, [practitioner] or pharmacist;*

(iii) (text unchanged)

(iv) A description of the procedure for and frequency of contact between the employee or volunteer, or both, and the supervisory *licensed physician, [or supervisory] advanced practice registered nurse [practitioner], 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 [.05D(1) .05E of this chapter.

(2) A refresher training program shall include any information required by the Department to update any component of [the] *a core curriculum provided by the Department for the educational training program set forth in §A of this regulation.*

(3)—(4) (text unchanged)

10.47.08.05

### **.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)—(2) (text unchanged)

(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 [a completed application form] as required by §A of this regulation; *and*

(5) Has paid any fee required by the Department].

C. (text unchanged)

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

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

(1) [Submitted] *Applied* to an authorized private or public entity[,] *for renewal not later than 90 days before the date of expiration of the certificate, [a completed certificate renewal application form provided] on a form or in a manner required 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 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[, on a form provided by the Department,] the certificate holder's knowledge and skills necessary for:

(a)—(c) (text unchanged)

10.47.08.06

**.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] *advanced practice registered nurse [practitioner] with prescribing authority*, a prescription for naloxone and the necessary supplies for the administration of naloxone;

(2)—(3) (text unchanged)

B. (text unchanged)

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]:

(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. (text unchanged)

**.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.

10.47.08.08

**[.08].09 Suspension and Revocation of the Certificate of a Certificate Holder.**

A.—C. (text unchanged)

D. Summary Suspension.

(1) (text unchanged)

(2) From the time of receipt of the notice of summary suspension, the former certificate holder may not *rely on the certificate to:*

(a) Obtain a prescription for naloxone from a *licensed physician or advanced practice registered nurse [practitioner] with prescribing authority;*

(b) Present a prescription for naloxone to be dispensed by a pharmacist, *licensed physician or advanced practice registered nurse [practitioner]with prescribing authority;* or

(c) (text unchanged)

E.—G. (text unchanged)

10.47.08.10

**[.10].11 Record Maintenance and Reporting.**

A.—B. (text unchanged)

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

(1) Information on program operations, including:

- (a)—(b) (text unchanged)
- (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)—(ii) (text unchanged)
  - (iii) Number of naloxone refills dispensed [and reason given for each refill dispensed]; and
  - (d) (text unchanged)
- (2)—(3) (text unchanged)
- D. (text unchanged)

10.47.08.11

**[.11] .12 General Provisions.**

- A. (text unchanged)
- [B Prescribing and Dispensing of Naloxone. A licensed physician or nurse practitioner may prescribe and dispense naloxone to a certificate holder.]
- [C.] *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.*

**VAN T. MITCHELL**

**Secretary of Health and Mental Hygiene**