MARYLAND REGISTER

# Proposed Action on Regulations

| Transmittal Sheet<br><br>**PROPOSED OR REPROPOSED**<br><br>**Actions on Regulations** | **Date Filed with AELR Committee**<br>05/03/2018 | **TO BE COMPLETED BY DSD**<br>Date Filed with Division of State Documents<br>Document Number<br>Date of Publication in MD Register |
|---|---|---|

**1. Desired date of publication in Maryland Register: 6/8/2018**

**2. COMAR Codification**

| Title | Subtitle | Chapter | Regulation |
|---|---|---|---|
| 10 | 13 | 03 | 01-.04 |

**3. Name of Promulgating Authority**

Department
of Health
and Mental
Hygiene

**4. Name of Regulations Coordinator** **Telephone Number**
Michele Phinney 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** **Telephone No.**
Lisa Burgess 410-767-6492

**Email Address**
lisaa.burgess@maryland.gov

**6. Check applicable items:**

**X-** New Regulations

_ Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: .

_ 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 **X-** 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 Kathleen A. Ellis, Assistant Attorney General, (telephone #410-767-1867) on April 2, 2018. A written copy of the approval is on file at this agency.

**Name of Authorized Officer**

Robert R. Neall

| **Title** | **Telephone No.** |
|---|---|
| Secretary of Health | 410-767-6500 |

**Date**

May 3, 2018

# Title 10
# DEPARTMENT OF HEALTH AND MENTAL HYGIENE
## Subtitle 13 DRUGS
## 10.13.03 Guidelines for Co-Prescribing Opioid Overdose Reversal Drugs

Authority: Health-General Article, §§2-104(b), 13-3501, and 13-3502, Annotated Code of Maryland

### Notice of Proposed Action

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The Secretary of Health proposes to adopt new Regulations .01—.04 under a new chapter COMAR 10.13.03 Guidelines for Co-Prescribing Opioid Overdose Reversal Drugs.

### Statement of Purpose

The purpose of this action is to provide guidance to healthcare practitioners, who are prescribing opioids to treat a patient's pain or an opioid use disorder, in determining the appropriate circumstances in which to consider prescribing an opioid overdose reversal drug. These guidelines are being promulgated in accordance with House Bill 1329 / Senate Bill 967 Heroin and Opioid Prevention Effort (HOPE) and Treatment Act of 2017 (Chapters 571 and 572, Acts of 2017).

### 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, 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 July 9, 2018. A public hearing has not been scheduled.

**Economic Impact Statement Part C**

A. Fiscal Year in which regulations will become effective: FY 2018
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:
These regulations are a reflection of existing guidelines in the prescriber community. Medicaid already pays for an opioid overdose reversal drug.
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

# MARYLAND DEPARTMENT OF HEALTH

## Subtitle 13 DRUGS

### *10.13.03 Guidelines for Co-Prescribing Opioid Overdose Reversal Drugs*

Authority: *Health-General Article, §§2-104(b), 13-3501, and 13-3502, Annotated Code of Maryland*

***.01 Scope.***

*This chapter applies to all licensed health care practitioners who may prescribe an opioid overdose reversal drug to an individual who:*

*A. May be at an elevated risk of experiencing an opioid overdose including, but not limited to, an individual who:*
*(1) Is receiving an opioid for chronic pain;*
*(2) Is receiving an opioid and a prescription for a benzodiazepine; or*
*(3) Has an opioid use disorder; or*

*B. Resides or spends time with an individual who:*
*(1) Is prescribed opioids;*
*(2) Misuses opioids; or*
*(3) Has an opioid use disorder.*

***.02 Definitions.***

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

*B. Terms Defined.*

*(1) "Co–prescribing" means, with respect to an opioid overdose reversal drug, the practice of prescribing the drug in conjunction with an opioid prescription for a patient at an elevated risk of overdose.*

*(2) "Department" means the Maryland Department of Health.*

*(3) "Monitored prescription drug" means a prescription drug that contains a Schedule II, Schedule III, Schedule IV, or Schedule V controlled dangerous substance designated under Title 5, Subtitle 4 of the Criminal Law Article.*

*(4) "Opioid overdose reversal drug" means a drug that:*

*(a) Rapidly reverses the respiratory depressant effects of an opioid medication; and*

*(b) Is approved by the federal Food and Drug Administration for the treatment of a known or suspected opioid overdose.*

*(5) "Prescribing licensed health care provider" means an individual who is authorized by law to prescribe a monitored prescription drug as defined in Health-General Article, §21–2A–01, Annotated Code of Maryland.*

*(6) "Risk factor" means a characteristic, condition, behavior or any variable that increases the likelihood of developing a disease or injury.*

*(7) "Secretary" means the Secretary of the Maryland Department of Health.*

*(8) Targeted Patient Population.*

*(a) "Targeted patient population" means an individual likely to experience or witness an opioid overdose.*

*(b) "Targeted patient population" includes, but is not limited to, an individual who:*

*(i) Is being prescribed opioids for acute, if appropriate, or chronic pain;*

*(ii) Is being treated for an opioid use disorder;*

*(iii) Is receiving a prescription for an opioid and a benzodiazepine; or*

*(iv) Resides or spends time with an individual who is prescribed opioids, misuses opioids, or has an opioid use disorder.*

***.03 General Provisions.***

*A. When determined appropriate by the prescribing licensed health care provider, targeted patient populations may be co-prescribed an opioid overdose reversal drug, if the individual has at least one opioid overdose risk factor.*

*B. Responsibilities of the Prescribing Licensed Health Care Provider.*

*(1) Risk Monitoring.*

*(a) It is suggested that the licensed health care provider routinely assess patients for their risk of being likely to experience or witness an opioid overdose.*

*(b) The prescriber may utilize additional sources of information for determining a patient's opioid overdose risk including, but not limited to:*

*(i) Checking the Maryland Prescription Drug Monitoring Program;*

*(ii) Reviewing medical records; and*

*(iii) Soliciting family input, if appropriate.*

*(2) Education. If a patient is assessed to be at risk of an opioid overdose, the prescriber may educate the patient, including but not limited to, the following areas:*

*(a) The risks of an opioid overdose; and*

*(b) How to identify and respond to an opioid overdose.*

*(3) Documentation. Licensed health care providers should document education and clinical services related to the provision of an opioid overdose reversal drug in their patients' medical records in accordance with the standard of care.*

***.04 Additional Guidelines.***

*The Secretary may make the following additional clinical guidance available on the Department's website:*

*A. Any available opioid overdose reversal drug formulations, corresponding prescribing templates, and any standing order for these drugs; and*

*B. Any other applicable information deemed necessary by the Secretary.*

**ROBERT R. NEALL**

**Secretary of Health**