

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>
	10/09/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

**1. Desired date of publication in Maryland Register: 11/13/2015**

**2. COMAR Codification**

**Title Subtitle Chapter Regulation**

10 47 07 05

**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

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michele.phinney@maryland.gov

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

Lisa Fassett

**Telephone No.**

410-402-8449

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lisa.fassett1@maryland.gov

**6. Check applicable items:**

New Regulations

Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: September 8, 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 State Government Article, §10-506(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 September 28, 2015. 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**

October 8, 2015

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

**Subtitle 47 ALCOHOL AND DRUG ABUSE ADMINISTRATION**

**10.47.07 Prescription Drug Monitoring Program**

Authority: Health-General Article, Title 21, Subtitle 2A, Annotated Code of Maryland

**Notice of Proposed Action**

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The Secretary of Health and Mental Hygiene proposes to amend Regulation .05 under COMAR 10.47.07 Prescription Drug Monitoring Program.

**Statement of Purpose**

The purpose of this action is to include additional entities and requirements for requesting prescription drug monitoring data as required by Health-General Article, §21-2A-06, Annotated Code of Maryland.

**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 December 14, 2015. A public hearing has not been scheduled.

**Economic Impact Statement Part C**

A. Fiscal Year in which regulations will become effective: FY 2016

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 proposal includes additional entities that may request prescription drug monitoring data. The Prescription Drug Monitoring Program anticipates meeting additional requests through existing resources.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

The regulations do not include small businesses as an entity that may request prescription drug monitoring data.

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**

### **10.47.07 Prescription Drug Monitoring Program**

Authority: Health-General Article, Title 21, Subtitle 2A. Annotated Code of Maryland

*10.47.07.05 (September 8, 2015)*

#### **.05 Disclosure of Prescription Monitoring Data.**

A.—B. (text unchanged)

C. Disclosure of Prescription Monitoring Data to a Federal, State, or Local Law Enforcement Agency. The Program shall disclose prescription monitoring data to a federal, State, or local law enforcement agency, for the purpose of furthering an existing bona fide individual investigation, on receipt of a subpoena that:

(1)—(4) (text unchanged)

(5) Bears the name, title, and [original] signature of the official under whose authority the subpoena is issued.

D. Disclosure of Prescription Monitoring Data to a Licensing Entity.

(1) The Program shall disclose prescription monitoring data to [a]:

(a) A licensing entity *other than the State Board of Physicians* upon receipt of an administrative subpoena [that:] *voted on by a quorum of the board; or*

(b) *The State Board of Physicians upon receipt of an administrative subpoena voted on by a quorum of a disciplinary panel, as defined in Health-General Article, §14-101, Annotated Code of Maryland.*

(2) *The Program shall disclose prescription monitoring data that:*

[(1)] (3)—[(5)] (7) (text unchanged)

E.—G. (text unchanged)

H. *Disclosure of Prescription Monitoring Data to Units of the Department.* Upon request, the Program may disclose prescription monitoring data to the Office of the Chief Medical Examiner, the Maryland Medical Assistance Program, the Office of the Inspector General of the Department, the Office of Health Care Quality, and the Division of Drug Control provided that the request:

(1) Includes information sufficient to identify the unique [prescriber, dispenser, licensed health care practitioner, or patient] *individual* about whom prescription monitoring data is requested;

(2)—(4) (text unchanged)

I. *Disclosure of Prescription Monitoring Data to Case Review Entities.*

(1) *Upon request, the Program may disclose prescription monitoring data to the following case review entities for the purposes of furthering an existing bona fide individual case review:*

(a) *The State Child Fatality Review Team or a local child fatality review team as defined in Health-General Article, §5-701, Annotated Code of Maryland, upon request from the chair of the State or local team;*

(b) *A local drug overdose fatality review team as described in Health-General Article, §5-902 and 5-902, Annotated Code of Maryland, upon request from the chair of the local team;*

(c) *The Maternal Mortality Review Program, as defined in Health-General Article, §13-1203, Annotated Code of Maryland, on request from the Program; and*

(d) *A medical review committee described in Health Occupations Article, §1-403(b)(3), Annotated Code of Maryland, upon request from the committee.*

(2) *The request shall:*

(a) *Include information sufficient to identify the unique individual about whom prescription monitoring data is requested;*

(b) *Specify the time frame for which prescription monitoring data is requested, including the day, month and year the report is to begin and end;*

(c) *Include a case number or other identifier sufficient to identify an existing bona fide individual case review;*  
and

(d) *Be approved by the Secretary.*

[I.] J. *Disclosure of Prescription Monitoring Data for Research, Analysis, Education, and Public Reporting.*

(1) (text unchanged)

(2) The Secretary may waive the requirement of [§I(1)(b)] §J(1)(b) of this [section] *regulation* for requests from units of the Department.

[J.] K. *Technical Advisory Committee Review.*

(1) (text unchanged)

(2) Notwithstanding [§J(1)] §K(1) of this regulation, the Program may disclose prescription monitoring data to the authorized administrator of another state's prescription drug monitoring program for disclosure to a prescriber, a dispenser, a licensed health care practitioner authorized by a prescriber or a dispenser, or a patient in a manner consistent with §§B(1)—(4) and F of this regulation.

(3) (text unchanged)

(4) If the Technical Advisory Committee has not provided clinical guidance and interpretation in accordance with [§J(1) or (3)] §K(1) or (3) of this regulation within 10 business days of submission of the request or data to the Technical Advisory Committee for review, the Department may:

(a)—(b) (text unchanged)

(5)—(6) (text unchanged)

**VAN T. MITCHELL**

**Secretary of Health and Mental Hygiene**