

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>
	09/30/2015	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 34 29 01-.07

**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**

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michele.phinney@maryland.gov

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

Anna Jeffers

**Telephone No.**

410-764-3833

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**6. Check applicable items:**

- New Regulations
- Amendments to Existing Regulations  
Date when existing text was downloaded from COMAR online: June 4, 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 29, 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**

September 29, 2015

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

**Subtitle 34 BOARD OF PHARMACY**

**10.34.29 Drug Therapy Management**

Authority: Health Occupations Article, §§12-6A-01, 12-6A-03—12-6A-08, and 12-6A-10, Annotated Code of Maryland

**Notice of Proposed Action**

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The Secretary of Health and Mental Hygiene proposes to amend Regulations .01—.07 under COMAR 10.34.29 Drug Therapy Management.

This action was considered by the Board of Pharmacy at a public meeting held June 17, 2015 notice of which was given by publication on the Board of Pharmacy website, <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from May 21, 2015 — June 17, 2015, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland;

and the Board of Physicians at a public meeting held July 29, 2015 notice of which was given by publication on the Board of Physician website, <http://www.mbp.state.md.us/>, from July 15, 2015 — July 29, 2015, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

**Statement of Purpose**

The purpose of this action is to add a new definition of “authorized prescriber” that includes “licensed podiatrist” and “certified advanced practice nurse with prescriptive authority.” The remainder of the other amendments throughout the proposal make multiple, but identical changes, to provide consistency with the new definition and the other health occupation boards that are now involved. The new statutory requirement under Health Occupations Article, §12-6A-06, Annotated Code of Maryland, authorizes a protocol by a licensed physician and licensed pharmacist to include initiation of drug therapy under a written, disease-state specific protocol.

**Comparison to Federal Standards**

There is no corresponding federal standard to this proposed action.

**Estimate of Economic Impact**

**I. Summary of Economic Impact.**

This proposal would have an indeterminable fiscal impact and operational impact on the Board of Pharmacy. The Board is required to promulgate regulations and has been reviewing the qualifications of pharmacists participating in Drug Therapy Management, which functions have been performed as a matter of course. The impact would be indeterminable depending on the increase in Drug Therapy Management applications.

A minor increase could be absorbed with present staffing, however; a major increase may necessitate additional resources, including personnel.

<b>II. Types of Economic Impact.</b>	Revenue (R+/R-)	Magnitude
	Expenditure (E+/E-)	
A. On issuing agency:	(R+)	Indeterminable
B. On other State agencies:	NONE	
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	Indeterminable
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	(+)	Indeterminable

**III. Assumptions.** (Identified by Impact Letter and Number from Section II.)

A. The Board of Pharmacy may receive additional revenue as more authorized prescribers and pharmacists apply.

D. A cost may incur for authorized prescribers that may decide to participate in Drug Therapy Management. The fee, if not shared with the pharmacist, has not changed and is intended for the review of the qualifications of pharmacists to participate in Drug Therapy Management.

F. The public will be positively affected by an increase in authorized prescribers and pharmacists that are available to participate in Drug Therapy Management. The revisions will have a positive impact on those patients with chronic diseases who require monitoring and modification of their medications providing those patients with more convenient access to care.

**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:
- 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 Board is not required to obtain information concerning which licensees operate small businesses, although some licensees that perform sterile pharmaceutical compounding or prepare sterile drug products may also be small businesses.
- G. Small Business Worksheet:

Attached Document:

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## **Title 10**

# **DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle 34 BOARD OF PHARMACY**

### **10.34.29 Drug Therapy Management**

Authority: Health Occupations Article, §§12-6A-01, 12-6A-03—12-6A-08, and 12-6A-10, Annotated Code of Maryland

*10.34.29.01 (June 4, 2015)*

**.01 Definitions.**

A. (text unchanged)

B. Terms Defined.

(1) "Amendment" means a change to:

(a) A protocol or [physician-pharmacist] *prescriber-pharmacist* agreement; or

(b) The parties to the [physician-pharmacist] *prescriber-pharmacist* agreement.

(2) "Applicants" means physicians [and], pharmacists, *podiatrists*, or *certified advanced practice nurses with prescriptive authority* submitting a [physician-pharmacist] *prescriber-pharmacist* agreement and protocol to their respective Boards.

(2-1) "*Authorized prescriber*" means a licensed physician, licensed podiatrist, or certified advanced practice nurse with prescriptive authority under Health Occupations Article, §8-508, Annotated Code of Maryland.

(3) "Boards" means the Board of Physicians [and], the Board of Pharmacy, *the Board of Podiatric Medical Examiners*, and *the Board of Nursing*.

(4)—(5) (text unchanged)

10.34.29.02

**.02 Content of Protocol.**

A. A protocol shall:

(1) (text unchanged)

(2) Contain the following:

(a)—(c) (text unchanged)

(d) A list of circumstances requiring contact with the [physician or physicians] *authorized prescriber or authorized prescribers* who are a party to the [physician-pharmacist] *prescriber-pharmacist* agreement;

(e) A statement prohibiting substitution of a chemically dissimilar drug product by the pharmacist for the product prescribed by the [physician] *authorized prescriber* unless permitted in the therapy management contract;

(f)—(i) (text unchanged)

B. A protocol may authorize:

(1) (text unchanged)

(2) The ordering of laboratory tests; [and]

(3) Other patient care management measures related to monitoring or improving the outcomes of drug or device therapy[.]; *and*

(4) *For protocols by a licensed physician and licensed pharmacist, the initiation of drug therapy under written, disease-state specific protocols.*

C. A protocol may not authorize acts that exceed the scope of practice of the parties to the [physician-pharmacist] *prescriber-pharmacist* agreement.

D. (text unchanged)

10.34.29.03

**.03 Content of [Physician-Pharmacist] Prescriber-Pharmacist Agreement.**

A. The [physician-pharmacist] *prescriber-pharmacist* agreement shall contain the following:

(1) The names and signatures of the physicians, *podiatrists*, or *certified advanced practice nurses with prescriptive authority* and pharmacists authorized to act under a therapy management contract;

(2) (text unchanged)

(3) The titles of the protocols to which the [physician-pharmacist] *prescriber-pharmacist* agreement pertains;

(4) The methods and timeframes by which documentation and routine communication will occur between the physicians, *podiatrists*, or *certified advanced practice nurses with prescriptive authority* and the pharmacists, including the timeframes in which the pharmacist will fully update the patient's record in writing;

(5) The name, address, and telephone number of the party to the [physician-pharmacist] *prescriber-pharmacist* agreement who is to receive correspondence from the Boards related to the [physician-pharmacist] *prescriber-pharmacist* agreement;

(6) A statement that the physicians, *podiatrists* or *certified advanced practice nurses with prescriptive authority* and pharmacists shall comply with all State and federal laws relating to patient confidentiality; and

(7) A list of devices available to the pharmacists performing under the [physician-pharmacist] *prescriber-pharmacist* agreement, which are relevant to the disease-states or conditions to be managed.

B. Technical modifications to the [physician-pharmacist] *prescriber-pharmacist* agreement shall be registered with the Board of Pharmacy within 30 days of the technical modification.

C. The party designated as the contact person to receive correspondence from the Boards shall ensure that the parties to the [physician-pharmacist] *prescriber-pharmacist* agreement are notified in a timely manner of the information received from the Boards.

D. (text unchanged)

10.34.29.04

#### **.04 Requirements for Participation in Drug Therapy Management.**

A.—C. (text unchanged)

D. [A licensed physician] *An authorized prescriber* who has entered into a [physician-pharmacist] *prescriber-pharmacist* agreement shall submit to the [Board of Physicians] *Health Occupations Board that regulates the authorized prescriber* a copy of:

- (1) The [physician-pharmacist] *prescriber-pharmacist* agreement;
- (2) Subsequent amendments made to the:
  - (a) [Physician-pharmacist] *Prescriber-pharmacist* agreement; or
  - (b) Protocols specified in the [physician-pharmacist] *prescriber-pharmacist* agreement; and
- (3) Changes to participants of the:
  - (a) [Physician-pharmacist] *Prescriber-pharmacist* agreement; or
  - (b) Protocols specified in the [physician-pharmacist] *prescriber-pharmacist* agreement.

E. The [Board of Physicians] *Health Occupations Board that regulates the authorized prescriber* shall notify the [physician] *authorized prescriber* of any additional information needed within 30 days of the receipt of the submitted information.

F. A licensed pharmacist who has entered into a [physician-pharmacist] *prescriber-pharmacist* agreement shall submit to the Board of Pharmacy a copy of:

- (1) The [physician-pharmacist] *prescriber-pharmacist* agreement;
- (2) Subsequent amendments made to the:
  - (a) [Physician-pharmacist] *Prescriber-pharmacist* agreement; or
  - (b) Protocols specified in the [physician-pharmacist] *prescriber-pharmacist* agreement; and
- (3) Changes to participants of the:
  - (a) [Physician-pharmacist] *Prescriber-pharmacist* agreement; or
  - (b) Protocols specified in the [physician-pharmacist] *prescriber-pharmacist* agreement.

G.—H. (text unchanged)

10.34.29.05

#### **.05 Guidelines for Use of Protocols.**

A. On receipt of specific instructions from the [physician] *authorized prescriber* regarding a specific patient, the pharmacist may execute the [physician's] *authorized prescriber's* specific instructions even if the instructions deviate from the protocol.

B. (text unchanged)

C. Documentation of activities performed under a protocol or the [physician's] *authorized prescriber's* specific instructions shall be maintained in such a manner that it is accessible to the:

- (1) [Physician] *Authorized prescriber*; and
- (2) (text unchanged)

D. (text unchanged)

E. Oral communications between the [physician] *authorized prescriber* and pharmacist shall be summarized in the documentation maintained by the pharmacist and forwarded to the [physician] *authorized prescriber*.

F. Unless an alternative time period is stated in the [physician-pharmacist] *prescriber-pharmacist* agreement, the pharmacist shall inform the [physician] *authorized prescriber* within 48 hours if the pharmacist:

- (1) Modifies the dose or agent under the therapy management contract; [or]
- (2) Detects an abnormal result from an assessment activity[.]; or
- (3) *For protocols by a licensed physician and pharmacist, the initiation of drug therapy under a written, disease-state specific protocol.*

10.34.29.06

#### **.06 Therapy Management Contracts.**

A. A therapy management contract shall be signed by the:

(1) [Physician or physicians] *Authorized prescriber or authorized prescribers* involved in the management of the patient under a [physician-pharmacist] *prescriber-pharmacist* agreement;

(2) Pharmacist or pharmacists involved in the management of the patient under a [physician-pharmacist] *prescriber-pharmacist* agreement; and

(3) (text unchanged)

B. A therapy management contract shall contain:

(1) (text unchanged)

(2) A statement that:

(a) (text unchanged)

(b) The pharmacist shall notify the physician under the terms of the [physician-pharmacist] *prescriber-pharmacist* agreement if the pharmacist:

(i)—(ii) (text unchanged)

(3) (text unchanged)

(4) A procedure for periodic review by the physician of the drugs modified under the [physician-pharmacist] *prescriber-pharmacist* agreement or changed with the consent of the [physician] *authorized prescriber*;

(5)—(6) (text unchanged)

[C. The therapy management contract shall terminate 1 year from the date of signing unless renewed by the parties to the therapy management contract, including the patient.]

10.34.29.07

**.07 Fees.**

A. Scope. This regulation governs [physicians] *authorized prescribers* and pharmacists participating in drug therapy management or amendment of [physicians] *authorized prescribers* and pharmacists that participate in the [physician-pharmacist] *prescriber-pharmacist* agreements relating to drug therapy management.

B. Fees. The Board of Pharmacy requires a fee for the [physician-pharmacist] *prescriber-pharmacist* agreement and protocol application (which includes review of the qualifications of the pharmacist participants) of \$100 per [physician-pharmacist] *prescriber-pharmacist* agreement.

**VAN T. MITCHELL**

**Secretary of Health and Mental Hygiene**