

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	10/06/2015	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 10 10

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

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Baltimore MD 21201

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5. Name of Person to Call About this Document

Anna Jeffers

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6. Check applicable items:

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 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

October 6, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 34 BOARD OF PHARMACY

10.34.10 Pharmacist, Pharmacy Intern, and Pharmacy Technician Code of Conduct

Authority: Health Occupations Article, §§12-205, and 12-601, Annotated Code of Maryland

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulation .10 under COMAR 10.34.10 Pharmacist, Pharmacy Intern, and Pharmacy Technician Code of Conduct.

This action was considered by the Board of Pharmacy at a public meeting held July 15, 2015 notice of which was given by publication on the Board of Pharmacy website, <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx>, from June 18, 2015 — July 15, 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 Board of Pharmacy determination of what is “owned wholly or substantially” by an authorized prescriber or group of authorized prescribers that own or co-own a pharmacy. Although there are no provisions in the Maryland Pharmacy Act that specify a percentage that constitutes “substantial ownership,” after researching the laws and regulations in other states, the Board has interpreted “owned wholly or substantially by an authorized prescriber or group of authorized prescribers” to be 10 percent or more ownership by an authorized prescriber or group of authorized prescribers.

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, 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:

These regulations set forth the percentage that a prescriber may own of a pharmacy. It imposes no new fees and would not affect any of the Board's licensing processes. There would be a review of the owners of a pharmacy to determine if any are prescribers and what percentage the prescribers own, which is done as a matter of course.

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:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.10 Pharmacist, Pharmacy Intern, and Pharmacy Technician Code of Conduct

Authority: Health Occupations Article, §§12-205, and 12-601, Annotated Code of Maryland

.10 Whole or Substantial Ownership of a Pharmacy by an Authorized Prescriber.

A. "Owned wholly or substantially" means ownership of 10 percent or more of a pharmacy.

B. A pharmacist may not associate as a partner, coowner, or employee of a pharmacy that is owned wholly or substantially by an authorized prescriber or group of authorized prescribers.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene