

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	11/09/2015	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 12/28/2015

2. COMAR Codification

Title Subtitle Chapter Regulation

10 34 39 01-.05

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator

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5. Name of Person to Call About this Document

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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 November 6, 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

November 9, 2015

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.39 Pharmacist Administration of Self-Administered Drugs

Authority: Health Occupations Article, §§12-101, 12-102(b), and 12-509, Annotated
Code of Maryland

Notice of Proposed Action

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The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01 — .05 under a new chapter, COMAR 10.34.39 Pharmacist Administration of Self-Administered Drugs.

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

Statement of Purpose

The purpose of this action is to require a pharmacist, that administers self-administered drugs to a patient that have been prescribed by an authorized prescriber, to have an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction. The proposal also requires that the pharmacist attest that the pharmacist has the appropriate training in administration of self-administered drugs that consists of the administration of ear drops; eye drops; inhalation therapies; intramuscular injections; intranasal therapies; subcutaneous injections; and topical therapies. The pharmacist will be further required to document administration of a self-administered drug in the patient record which shall include the name of the drug; dosage administered; site of administration; date and time of administration; and any instructions provided to the patient.

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 January 27, 2016. 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:

This new chapter does not impose any new fees. The training requirements would most likely be met during pharmaceutical training or when qualifying to administer immunizations so the number of pharmacists who would need to take a course on administration would be minimal. The course that is required may also be applied to the pharmacist's continuing education credits.

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 administer self-administered drugs may also be small businesses.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 34 BOARD OF PHARMACY

10.34.39 Pharmacist Administration of Self-Administered Drugs

Authority: Health Occupations Article, §§12-101, 12-102(b), and 12-509, Annotated Code of Maryland

.01 Scope.

This chapter does not limit or affect the right of an individual to practice a health occupation that the individual is authorized to practice.

.02 Definitions.

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

B. Terms Defined.

(1) "Board" means the State Board of Pharmacy.

(2) "Pharmacist" means an individual who practices pharmacy regardless of the location where the activities of practice are performed.

(3) "Pharmacy" means an establishment holding a permit under Health Occupations Article, §12-401, Annotated Code of Maryland.

(4) "Pharmacy Experiential Program" means a program under the American Council on Pharmacy Education.

(5) Practice Pharmacy.

(a) "Practice pharmacy" means to engage in any of the following activities:

(i) Providing pharmaceutical care;

(ii) Compounding, dispensing, or distributing prescription drugs or devices;

(iii) Compounding or dispensing nonprescription drugs or devices;

(iv) Monitoring prescriptions and nonprescription drugs or devices;

(v) Providing information, explanation, or recommendations to patients and health care practitioners about the safe and effective use of prescription or nonprescription drugs or devices;

(vi) Identifying and appraising problems concerning the use or monitoring of therapy with drugs or devices;

(vii) Acting within the parameters of a therapy management contract, as provided under Health Occupations Article, Subtitle 6A, Annotated Code of Maryland; or

(viii) Administering vaccinations in accordance with Health Occupations Article, §12-508, Annotated Code of Maryland or self-administered drugs in accordance with Health Occupations Article, §12-509, Annotated Code of Maryland.

(ix) Delegating a pharmacy act to a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program;

(x) Supervising a delegated pharmacy act performed by a registered pharmacy technician, pharmacy student, or an individual engaged in a Board approved pharmacy technician training program; or

(xi) Providing drug therapy management in accordance with Health-General Article, §19-713.6, Annotated Code of Maryland.

(b) "Practice pharmacy" does not include the operations of a person who holds a permit issued under Health Occupations Article, §12-602, Annotated Code of Maryland.

(6) "Registered pharmacy intern" means an individual who is registered with the Board to practice pharmacy under the direct supervision of a pharmacist.

(7) Self-Administered Drug.

(a) "Self-administered drug" means a drug that is regularly administered by the patient for whom the drug is prescribed or by an individual who is not otherwise authorized to administer drugs under Health Occupations Article, 12-509, Annotated Code of Maryland.

(b) "Self-administered drug" includes:

(i) Eye drops;

(ii) A drug that is administered by an intramuscular injection or a subcutaneous injection;

(iii) Ear drops;

(iv) Inhalation therapies;

(v) Intranasal therapies; and

(vi) Topical therapies.

.03 Requirements to Administer Self-Administered Drugs.

A. A licensed pharmacist shall attest that the pharmacist has the appropriate training in administration of self-administered drugs that consists of instruction on:

- (1) Ear drops;
- (2) Eye drops;
- (3) Inhalation therapies;
- (4) Intramuscular injections;
- (5) Intranasal therapies;
- (6) Subcutaneous injections; and
- (7) Topical therapies.

B. A licensed pharmacist shall possess an active certification in basic cardiopulmonary resuscitation obtained through in-person classroom instruction.

C. A licensed pharmacist, certified under Health Occupations Article, §12-508, Annotated Code of Maryland, is deemed to have satisfied the training requirements in this chapter.

D. A licensed pharmacist may administer a self-administered drug in accordance with a prescription.

E. A pharmacy student in a Pharmacy Experiential Program or a registered pharmacy intern, may administer a self-administered drug under direct supervision of a licensed pharmacist who meets the requirements in §A or B of this regulation.

.05 Record Keeping.

A. The pharmacist shall document in the patient record the administration of a self-administered drug that includes the following information:

- (1) Name of the drug;
- (2) Dosage administered;
- (3) Site of administration;
- (4) Date and time of administration; and
- (5) Any instructions provided to the patient.

B. The patient record shall be maintained for 5 years, unless otherwise required by law, and be:

- (1) Readily retrievable; and
- (2) Made available on the request of the Board.

VAN T. MITCHELL

Secretary of Health and Mental Hygiene