

MARYLAND REGISTER

Proposed Action on Regulations

Transmittal Sheet PROPOSED OR REPROPOSED Actions on Regulations	Date Filed with AELR Committee	TO BE COMPLETED BY DSD
	04/22/2014	Date Filed with Division of State Documents
		Document Number
		Date of Publication in MD Register

1. Desired date of publication in Maryland Register: 5/30/2014

2. COMAR Codification

Title Subtitle Chapter Regulation

10 13 01 02-.06

3. Name of Promulgating Authority

Department of Health and Mental Hygiene

4. Name of Regulations Coordinator Telephone Number
Michele Phinney 410-767-5623

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Anna Jeffers 410-764-3833

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6. Check applicable items:
 X- New Regulations

X- Amendments to Existing Regulations

Date when existing text was downloaded from COMAR online: April 19, 2013.

Repeal of Existing Regulations

X- 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:

X- Yes No

If yes, corresponding proposed text published in:

same issue

X- future issue

previous issue; it appeared in

: Md. R

(vol.) (issue) (page no's) (date)

Under Maryland Register docket no.: --E.

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

X- 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 Bethman, Assistant Attorney General, (telephone #410-767-6906) on January 2, 2014. A written copy of the approval is on file at this agency.

Name of Authorized Officer

Joshua M. Sharfstein, M.D.

Title
Secretary
Date
April 22, 2014

Telephone No.
410-767-6500

Title 10
DEPARTMENT OF HEALTH AND MENTAL HYGIENE
Subtitle 13 DRUGS

10.13.01 Dispensing of Prescription Drugs by a Licensee

Authority: Health Occupations Article, §§12-102 and 12-102.1, Annotated Code of Maryland

Notice of Proposed Action

[]

The Secretary of Health and Mental Hygiene proposes to amend Regulations .02—.04, adopt new Regulation .05, and amend and recodify Regulation .05 to be Regulation .06 under COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee.

This action was considered by the Board of Pharmacy at a public meeting held March 19, 2014, notice of which was given by publication on the Board of Pharmacy web site <http://dhmh.maryland.gov/pharmacy/SitePages/Home.aspx> from February 20 - March 19, 2014, pursuant to the State Government Article, §10-506(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to revise the current regulations to address patient safety and to clarify that licensees are required to comply with dispensing and labeling requirements of State and federal law. The proposal clarifies that each permit issued to a licensee be non-transferable. It requires a permit holder to complete 10 continuing education credits over a 5-year period relating to preparing and dispensing or prescription drugs as a condition of permit renewal. Additionally, the revisions require the Division of Drug Control (DDC) to inspect a licensee's office within 6 months of the licensee receiving a permit from their respective licensing board and one more time within the 5 year permit period. DDC is required to enter and inspect the office of a licensee who holds a renewal dispensing permit at least 2 times during the duration of the permit.

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 will have an economic impact on the Division of Drug Control (DDC). The DDC will be required to perform two inspections within 5 years of every dispensing practitioner. In FY 2014, \$220,700 was allocated to the DDC. This allocation included funding to support the three additional PINs and associated vehicles and office supplies for the increase in inspections.

This proposal may have an economic impact on regulated trade groups (dispensing practitioners). Physicians, dentists and podiatrists may be subject to an increase in cost for dispensing permits fees. Per Chapter 267 of 2012 (Health Occupations Article, §12-102.2, Annotated Code of Maryland), the dispensing permits shall be increased in an amount that approximates the cost for DDC to perform the inspections; fees will then be reverted to the State General Fund.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	(E+)	\$316,000
B. On other State agencies:		
State General Fund	(R+)	\$316,000
C. On local governments:	NONE	
	Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	\$316,000
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 Division of Drug Control (DDC) will be required to perform two inspections in 5 years of every prescriber. This will result in the need to hire additional inspectors. The costs will be covered by an increase in fees by the respective licensing boards that license dispensing licensees and will be revenue for the State General Fund.

Year 1 implementation of Chapter 267 of 2012 has required more than the resources appropriated (\$220,700) to accomplish the requirements of this law. Laboratories Administration Deputy Director of Administrative and Support Services, Division of Drug Control Division Chief, Deputy Chief and Pharmacist Inspectors have devoted a significant amount of effort to accomplish the requirements of implementing this mandate. Fee has been raised by \$1,000 in year 1 to approximate the cost of the expense

to operate this program. The estimated revenue has therefore been determined by multiplying the total number of dispensing practitioners (1,580) by the cost per dispensing permit (\$1,000). Consequently, $1,580 \times \$1,000 = \$1,580,000 \div 5 \text{ years} = \$316,000$. The fee increase will be proposed in the fee regulations for the respective boards.

B. Reversion back to the State General Fund of fees collected from Dispensing Practitioners (see A. above)

D. See A. above.

F. There will be a positive impact on the public as these regulations will ensure that all prescriptions in Maryland, regardless of the dispensing site, are dispensed in compliance with all federal and State laws and regulations developed to assure patient safety.

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 A. Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. 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 June 30, 2014. A public hearing has not been scheduled.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2014

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 dispense prescriptions drugs may also be small

businesses.

G. Small Business Worksheet:

Attached Document:

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle 13 DRUGS

10.13.01 Dispensing of Prescription Drugs by a Licensee

Authority: Health Occupations Article, §§12-102 and 12-102.1, Annotated Code of Maryland

10.13.01.02 (April 19, 2013)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) "Board" means the Board of Dental Examiners, the Board of [Physician Quality Assurance] *Physicians*, or the Board of Podiatric Medical Examiners.

(2) *Final Check*.

(a) "*Final check*" means the verification by the licensee that the prescription is correct before the prescription is dispensed to the patient.

(b) "*Final check*" includes the assumption of responsibility for the filled prescription, including, but not limited to:

(i) *Appropriateness of the dose;*

(ii) *Correct expiration date;*

(iii) *Accuracy of drug, strength, and labeling;*

(iv) *Verification of ingredients; and*

(v) *Proper container.*

[(2)] (3) (text unchanged)

(4) "*Personally preparing and dispensing*" means the licensed dentist, physician, or podiatrist:

(a) *Is physically present on the premises where the prescription is filled; and*

(b) *Performs a final check of the prescription before it is dispensed to the patient.*

[(3)] (5) (text unchanged)

10.13.01.03 (April 19, 2013)

.03 Application for Dispensing Permit.

A. (text unchanged)

B. The application shall require the following information to indicate that the [licensee] *applicant* is [prescribing] *personally preparing and dispensing prescription drugs* in the public interest:

(1) The name, address, and license number of the applicant;

(2) [A certificate] *An attestation* by the applicant that the applicant *shall comply with the:*

(a) [Shall comply with the dispensing] *Dispensing* requirements set forth in Regulation .04 of this chapter;

[and]

(b) *Inspection requirements set forth in Regulation .05 of this chapter; and*

[(b) Is thoroughly familiar with the statute] (c) *Statutes* and regulations [which govern] *governing* dispensing of prescription drugs set forth in Health Occupations Article, Title 12, Annotated Code of Maryland, *COMAR 10.19.03*, and *COMAR 10.34; and*

(3) *The address of each practice location where the applicant dispenses prescription drugs.*

C. (text unchanged)

D. A permit holder shall complete 10 continuing education credits over a 5-year period relating to the preparing and dispensing of prescription drugs as a condition of permit renewal.

E. A permit issued to a licensee shall be non-transferable.

10.13.01.04 (April 19, 2013)

.04 Dispensing Requirements.

A.—B. (text unchanged)

C. A licensee shall personally prepare and dispense prescription drugs.

[C.] *D.* (text unchanged)

[D.] *E.* A licensee shall comply with the labeling requirements [of] *set forth in Health Occupations Article, [§12-509] §12-505, Annotated Code of Maryland.*

F. A licensee shall comply with the child resistant packaging requirements set forth in Health-General Article, Title 22, Subtitle 3, Annotated Code of Maryland.

G. A licensee shall comply with drug recalls.

[E.] *H.—[F.] I.* (text unchanged)

[G. A licensee shall allow the Division of Drug Control to enter and inspect the licensee's office at all reasonable hours.]

[H.] *J.* (text unchanged)

[I.] *K.* A licensee shall maintain [a] *for at least 5 years:*

(1) *A separate file for Schedule II prescriptions[. All]; and*

(2) *Another file for other prescriptions. [shall be kept:*

(1) *In another file; and*

(2) *For 5 years.]*

L. A licensee shall maintain biennial inventories of all stocks of controlled substances.

[J.] *M.* A licensee shall dispense prescription drugs to a patient only when *the patient determines that a pharmacy is not conveniently available to the patient. [The decision whether a pharmacy is conveniently available shall be made by the patient based upon factors to be determined solely in the discretion of the patient.]*

[K. A licensee shall maintain a single form in each patient's chart for each patient to whom prescription drugs are dispensed. At a minimum, the form shall:] *N. In each patient's chart for each patient to whom prescription drugs are dispensed, a licensee shall maintain a single form which:*

(1) [Indicate] *Indicates that a pharmacy is not conveniently available to the patient;*

(2) [State] *States that the determination that a pharmacy is not conveniently available was made solely by the*

patient; and

(3) [Be] *Is signed and dated by the patient before dispensing prescription drugs to the patient for the first time.*

[L.] *O.* (text unchanged)

P. A licensee may not make any agreement that denies a patient a free choice of pharmacist or pharmacy services

Q. A licensee shall post a sign conspicuously positioned and readable regarding the process for resolving incorrectly filled prescriptions or includes written information regarding the process with each prescription dispensed.

R. A licensee shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary to prepare and dispense prescriptions properly.

.05 Inspection Requirements.

A. The Board of Dental Examiners, the Board of Physicians, and the Board of Podiatric Medical Examiners shall report annually to the Division of Drug Control the names and addresses of its licensees who:

(1) *Are authorized to personally prepare and dispense prescription drugs; and*

(2) *Have reported to the appropriate Board that they have personally prepared and dispensed prescription drugs within the previous year.*

B. A licensee shall allow the Division of Drug Control to enter and inspect the licensee's practice locations at all reasonable hours.

C. The Division of Drug Control shall:

(1) *Enter and inspect the practice locations of a licensee who holds an initial dispensing permit:*

(a) *Within 6 months after receiving the annual report set forth in §A(1) of this regulation; and*

(b) *At least one more time during the duration of the permit;*

(2) *If a licensee who holds an initial dispensing permit has more than one practice location:*

(a) *Enter and inspect a practice location of the licensee within 6 months after receiving the annual report set forth in §A(1) of this regulation; and*

(b) *Enter and inspect a different practice location at least one time during the duration of the permit;*

(3) *If a licensee who holds a dispensing permit is seeking renewal:*

(a) *Enter and inspect a practice location of a licensee at least two times during the duration of the permit; and*

(b) *If licensee has more than one practice location, enter and inspect two different practice locations during the duration of the permit;*

(4) If the Division of Drug Control finds a deficiency at one practice location of a licensee with multiple practice locations, licensee is required to sign an affidavit attesting that all practice locations are in or will be in compliance as a result of the inspection;

(5) Report to the Board of Pharmacy a wholesale distributor not licensed in Maryland; and

(6) Report the results of the inspections required under §C(1) and (2) of this regulation to the respective board of licensure.

D. A licensee shall sign and date an inspection form provided by the Division of Drug Control relating to the requirements set forth in Health Occupations Article, §12-102, Annotated Code of Maryland.

E. A licensee shall pay a fee in an amount that will produce funds to approximate, but not exceed, the documented costs to the Division of Drug Control for inspections, as required by the appropriate Board.

10.13.01.05 (April 19, 2013)

[.05].06 Failure to Comply with Dispensing Requirements.

A licensee who fails to comply with the requirements governing dispensing of prescription drugs [may be subject to disciplinary action pursuant to Health Occupations Article, §4-315(a), 14-404, or 16-312, Annotated Code of Maryland] *shall have the dispensing permit revoked and be subject to disciplinary action by the appropriate licensing board.*

JOSHUA M. SHARFSTEIN, M.D.

Secretary of Health and Mental Hygiene