Is There Emergency Text That Is Identical To The Proposed Text:

___ Yes  \(\times\) No

Is There An Incorporation By Reference Document Associated With This Proposal?

___ Yes  \(\times\) No

Does This Proposal Have An Impact On Environmental Hazards Affecting The Health Of Children As Defined In Health-General Article, §13-1501(c)?

___ Yes (explain)  \(\times\) No

Does This Proposal Include An Increase Or Decrease In A Fee For A License?

___ Yes, complete (1)—(8)  \(\times\) No, skip (1)—(8) and proceed to Notice of Proposed Action.

(1) Explain/justify why an increase or decrease is necessary:

(2) How much money is needed to operate effectively or to eliminate an operating fund deficit?

(3) In what year was the most recent fee increase?

(4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?

(5) Describe any measures taken to mitigate the need for increased revenue:

(6) Describe any special circumstances that have had an adverse impact on the Proposing Unit’s operating expenses.

(7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.

(8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit’s effectiveness and performance.
Notice of Proposed Action

The Secretary of Health proposes to:

1. Amend Regulation .04 under COMAR 10.13.01 Dispensing of Prescription Drugs by a Licensee;
2. Amend Regulations .02, .12, and .14 under COMAR 10.32.01 General Licensure Requirements;
3. Amend Regulations .02, .07, .08, and .09 under COMAR 10.32.03 Delegation of Duties by a Licensed Physician — Physician Assistant;
4. Amend Regulations .01 through .08 under COMAR 10.32.23 Permits for the Dispensing of Prescription Drugs;
5. Repeal Regulations .09, .16, and .17 under COMAR 10.32.23 Permits for the Dispensing of Prescription Drugs; and
6. Amend and recodify existing Regulations .10, .11, .12, .13, .14, .15, .18, and .19 to be Regulations .09, .10, .11, .12, .13, .14, .15, and .16 under COMAR 10.32.23 Permits for the Dispensing of Prescription Drugs.

This action was considered at a public meeting on:
- July 31, 2019, notice of which was given by publication on the Board’s Website at https://www.mbp.state.md.us/forms/Jul19Fullagenda.pdf from July 16 through July 31, 2019 pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland; and
- December 4, 2019, notice of which was given by publication on the Board’s Website at https://www.mbp.state.md.us/forms/Dec19Aagenda.pdf from November 15, 2019 through December 4, 2019 pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland.

Statement of Purpose

The purpose of this proposal is to update existing regulations to reflect statutory changes pursuant to the following legislation:
- Effective October 1, 2018, House Bill 591 and Senate Bill 549, “Health Occupations – Physician Assistants – Dispensing of Drugs Under a Delegation Agreement,” 2018, Chapter 442 and Chapter 443; and

Specifically, for COMAR 10.32.23, the proposal includes but is not limited to:
- An update of the authority for and scope of the chapter;
- The addition of and revision of certain definitions in Regulation .02;
- An update of instances when a dispensing permit is not required in Regulation .03;
- Requirements for a dispensing permit holder added to Regulation .06;
- Parameters set in Regulation .07 for a permit holder who is a primary supervising physician of a physician assistant to delegate dispensing authority to that physician assistant;
- Also under Regulation .07, the establishment of requirements for physician assistants who have been delegated dispensing authority; and
• Technical changes or corrections, such as substituting “disciplinary panel” for “Board,” as needed.

In addition, for COMAR 10.32.23, the proposal:
• Revises Regulation .08 to include language from Regulation .09, as Regulation .09 is to be repealed;
• Recodifies and amends existing Regulations .10 through .15 to become Regulations .09 through .14;
• In the regulation to be recodified as Regulation .09, adds record keeping provisions;
• Changes the title of the regulation to be recodified as Regulation .10 and updates language regarding change of address requirements;
• Updates various provisions regarding disciplinary matters;
• Repeals Regulation .16;
• Repeals Regulation .17 but moves and updates certain language to the regulation to be recodified as Regulation .13; and
• Amends and recodifies existing Regulations .18 and .19 to be Regulations .15 and .16.

The proposal also includes:
• Conforming changes regarding dispensing matters to COMAR 10.13.01.04, 10.32.01.12, 10.32.03.02, 10.32.03.07, and 10.32.03.08;
• A revision to COMAR 10.32.03.09 for consistency with other Board regulations; and
• Corrections to COMAR 10.32.01.02 and COMAR 10.32.01.14.

**Comparison to Federal Standards**

(Check one option)

- [x] There is no corresponding federal standard to this proposed action.

  or

- [ ] There is a corresponding federal standard to this proposed action, but the proposed action is not more restrictive or stringent.

  The corresponding federal standard is: ________________________________

  **EXPLAIN** why the proposed action is not more restrictive or stringent than the corresponding federal standard:

  or

- [ ] In compliance with Executive Order 01.01.1996.03, this proposed action is more restrictive or stringent than corresponding federal standards as follows:

  (1) Regulation citation and manner in which it is more restrictive than the applicable federal standard:

  (2) Benefit to the public health, safety or welfare, or the environment:

  (3) Analysis of additional burden or cost on the regulated person:
(4) Justification for the need for more restrictive standards:

**Impact Statements**

**Part A**

*(check one option)*

**Estimate of Economic Impact**

___ The proposed action has no economic impact.

Or

X The proposed action has an economic impact. *(IF this is checked, complete the following form in its entirety)*

I. Summary of Economic Impact. *(INSERT SHORT SUMMARY)*

Chapter 535 of 2019 established a fee of $100.00 for a new permit to be issued by the Board to a Maryland licensed physician to dispense only certain topical medications. This proposal includes the statutory fee, which was not calculated by the Board.

The Board anticipates a minimal fiscal impact. There is a small population of licensed physicians maintaining an active drug dispensing permit ($1,050.00 fee) in Maryland for the sole purpose of dispensing prepackaged topical substances who now may wish to switch to the new ($100.00 fee) dispensing permit, which would result in a savings to those licensees. Regarding other state agencies, the revised Fiscal and Policy Note for HB 1288 mentions that a switch to the lower-cost permit does not materially affect revenues for the Office of Controlled Substances Administration.

The Board is using existing resources to revise its process for handling the issuance of both types of drug dispensing permits.

II. Types of Economic Impact.  

<table>
<thead>
<tr>
<th>Revenue (R+/R-)</th>
<th>Expenditure (E+/E-)</th>
<th>Magnitude</th>
</tr>
</thead>
<tbody>
<tr>
<td>A. On issuing agency:</td>
<td></td>
<td>Minimal</td>
</tr>
<tr>
<td>B. On other State agencies:</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>C. On local governments:</td>
<td></td>
<td>None</td>
</tr>
<tr>
<td>D. On regulated industries or trade groups:</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>E. On other industries or trade groups:</td>
<td></td>
<td>Unknown</td>
</tr>
<tr>
<td>F. Direct and indirect effects on public:</td>
<td></td>
<td>Unknown</td>
</tr>
</tbody>
</table>
III. Assumptions. (Identified by Impact Letter and Number from Section II.)

**Part B**

**Economic Impact on Small Businesses**
(check one option)

X The proposed action has minimal or no economic impact on small businesses.  
 or  
___ The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

**Impact on Individuals with Disabilities**
(check one option)

X The proposed action has no impact on individuals with disabilities.  
 or  
___ The proposed action has an impact on individuals with disabilities as follows:  
(Agency to complete this assessment)

**Opportunity for Public Comment**

Comments may be sent to Sandi Van Horn, Maryland Board of Physicians, 4201 Patterson Avenue, Baltimore, MD 21215, or email to sandi.vanhorn@maryland.gov, or fax to 410-358-1298. Comments will be accepted through January 17, 2020. A public hearing has not been scheduled.

**Part C**

(For legislative use only; not for publication)

A. Fiscal Year in which regulations will become effective: FY 2020

B. Does the budget for fiscal year in which regulations become effective contain funds to implement the regulations?  
   ___ Yes ___ No  X N/A

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:  
The Board is utilizing existing resources to revise its drug dispensing permit program.

E. If these regulations have no economic impact under Part A, indicate reason briefly:  
The proposed changes to existing regulations mainly concern the delegation of dispensing authority to a licensed physician assistant.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason.  
The proposed amended regulations mainly concern certain licensed physicians and physician assistants involved in prescription drug dispensing and have no requirements to be met by small businesses.
Subtitle 13 DRUGS

10.13.01 Dispensing of Prescription Drugs by a Licensee

Authority: Health Occupations Article, §§12-102 and 12-102.1, §§12-102, 12-102.1, and 15-302.2, Annotated Code of Maryland

10.13.01.04 (September 17, 2019)

.04 Dispensing Requirements.

A.—C. (text unchanged)

D. Except as provided in Health Occupations Article, §12-102(c)(2)(iii), Annotated Code of Maryland, and §§ of this regulation, a licensee shall dispense prescription drugs only to the patients of the licensee.

E. —S. (text unchanged)

T. To the extent permitted by COMAR 10.32.03 and 10.32.23, a licensed physician may delegate to a physician assistant the dispensing of prescription drugs, including the requirements under this regulation, for a prescription written by:

(1) A physician assistant with whom the physician has a delegation agreement that:

(a) Complies with Health Occupations Article, Title 15, Subtitle 3, Annotated Code of Maryland; and

(b) Permits the physician assistant to prescribe and dispense the drug; and

(2) The licensed physician.
.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(3) (text unchanged)

(4) "Accredited training program" means a postgraduate clinical medical education program which is:

(a)—(c) (text unchanged)

(d) A program conducted in the United States of America or Canada that is the equivalent of (§B(3)(a), §B(4)(a), (b), or (c) of this regulation as determined by the Board of Physicians.)

(5)—(7) (text unchanged)

(8) "Board" means the State Board of Physicians.

(9)—(27) (text unchanged)
C. Renewal fees:

(1)—(2) (text unchanged)

[(3) Late renewal fee ... $100;]

D. (text unchanged)

E. Other fees:

(1)—(3) (text unchanged)

(4) [Permit] Five-year permit to dispense prescription drugs ... $1,050;

(5) Annual topical medication permit ... $100;

[(5)] (6)—[(7)] (8) (text unchanged)

[(8) Tapes, diskettes, and mailing labels] (9) CDs, DVDs, USB flashdrives, and soft media ... $45 plus $0.05 per record.

10.32.01.14 (November 7, 2019)

.14 Solicitation.

A. (text unchanged)

B. A physician shall also be accountable under this regulation if [he] the physician uses an agent, partnership, professional association, or health maintenance organization to implement actions prohibited by this regulation.

Subtitle 32 BOARD OF PHYSICIANS

10.32.03 Delegation of Duties by a Licensed Physician — Physician Assistant

Authority: Health Occupations Article, §§1-213, 1-606, 14-205, 15-101—15-502,

Annotated Code of Maryland
.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1)—(13) (text unchanged)

(14) “Dispense” [means to dispense starter dosages or drug samples.] has the meaning stated in Health Occupations Article, §12-101, Annotated Code of Maryland.

(15) “Dispensing authority” means the authority delegated by a primary supervising physician to a physician assistant through a Board-approved delegation agreement to dispense prescription drugs in accordance with this chapter and COMAR 10.32.23.

[(15)] (16) “Drug sample” [means a unit of a prescription drug that is intended to promote the sale of the drug and is not intended for sale.] has the meaning stated in 21 CFR §203.3 (I).

[(16)] (17)—[(23)] (24) (text unchanged)

[(24)] (25) "Prescriptive authority" means the authority delegated by a supervising physician to a physician assistant to:

(a) [Prescribe and administer:] Prescribe:

(i) Controlled dangerous substances;

(ii) Non-controlled dangerous substance [Prescription] prescription drugs; and

(iii) Medical devices; and

(b) Give verbal, written, or electronic orders for [medications; and

(c) Dispense starter dosages or drug samples.] medications.

[(25)] (26)—[(31)] (32) (text unchanged)
.07 Supervising Physicians.

A. (text unchanged)

B. A primary supervising physician who delegates dispensing authority to a physician assistant in accordance with COMAR 10.32.23 shall hold an active drug dispensing permit issued by the Board, except when:

(1) The primary supervising physician delegates to the physician assistant only the dispensing of starter doses and drug samples in accordance with Health Occupations Article, §12-102, Annotated Code of Maryland;

(2) The primary supervising physician delegates to the physician assistant only the dispensing of the devices and equipment listed in Health Occupations Article, §12-102(i), Annotated Code of Maryland; or

(3) The primary supervising physician and the physician assistant only dispense prescription drugs in the course of treating patients at the following locations:

   (i) At a medical facility or clinic that is operated on a nonprofit basis;

   (ii) At a health center that operates on a campus of an institution of higher education; or

   (iii) At a public health facility, a medical facility under contract with a state or local health department, or a facility funded with public funds.


.08 Prescriptive Authority and Dispensing [Starter Dosage or Drug Samples.] of Drugs.

A. In order for a primary supervising physician to delegate prescriptive or dispensing authority, the primary supervising physician shall ensure that the delegation agreement includes:
(1) A statement describing whether the primary supervising physician intends to delegate any of the following:

(a) Prescribing of:

(i) Controlled dangerous substances;
(ii) Non-controlled dangerous substance [Prescription] prescription drugs; or
(iii) Medical devices;

(b) Giving verbal, written, or electronic orders for medications;

(c) Dispensing starter dosages or drug samples; and

(d) Dispensing of:

(i) Controlled dangerous substances;
(ii) Non-controlled dangerous substance prescription drugs; or
(iii) Medical devices;

(2) An attestation that all prescribing or dispensing activities of the physician assistant will comply with applicable federal and State regulations;

(3) An attestation that all medical charts and records will contain a notation of any prescriptions written or dispensed by [a] the physician assistant;

(4) An attestation that all prescriptions written include the physician assistant's name and the primary supervising physician's name, business address, and business telephone number legibly written or printed;

(5) An attestation that the physician assistant has:

(a) Passed the physician assistant national certification exam administered by the National Commission on the Certification of Physician Assistants, Inc. within the previous 2 years; or

(b) Completed 8 Category I hours of pharmacology education within the previous 2 years; [and]

(6) An attestation that the physician assistant has at least one of the following:
(a) A bachelor's degree or its equivalent; or
(b) 2 years of work experience as a physician assistant; and

(7) Attestations that the physician assistant will dispense prescription drugs only at locations where the primary supervising physician permit holder is authorized to dispense prescription drugs.

[B. Dispensing of Drug Samples and Starter Dosages of Drugs by Physician Assistant.

(1) A drug sample or starter dosage shall meet the following criteria before a physician assistant may dispense the drug sample or starter dosage:

(a) Package is labeled as required by Health Occupations Article, §12-505, Annotated Code of Maryland; and

(b) No charge is made for the drug sample or starter dosage.

(2) A physician assistant shall enter an appropriate note in the patient’s medical record.

(3) A physician assistant may not delegate dispensing of drug samples or starter dosages.]

B. A physician assistant who is delegated dispensing authority in accordance with §A of this regulation:

(1) Shall comply with the requirements of:

(a) Health Occupations Article, Titles 12, 14, and 15;

(b) The permit holder’s dispensing permit, in accordance with COMAR 10.32.23;

(c) The Board-approved delegation agreement; and

(d) All federal and State statutes and regulations regarding the dispensing of prescription drugs;

(2) May only dispense prescription drugs:

(a) That both the physician assistant and the primary supervising physician permit holder have the authority to prescribe and dispense;
(b) That either the physician assistant or the primary supervising physician permit holder has prescribed; and

(c) At the locations where the permit holder is authorized to dispense prescription drugs;

(3) May not further delegate any part of the dispensing process; and

(4) Shall cease the dispensing of prescription drugs on the date:

(a) The permit holder’s medical license or dispensing permit:

(i) Expires;

(ii) Lapses; or

(iii) Is suspended, revoked, or terminated for any reason;

(b) The delegation agreement is terminated for any reason; or

(c) The physician assistant’s license:

(i) Expires; or

(ii) Is suspended, revoked, or terminated for any reason.

C. Unprofessional conduct in the practice of medicine under Health Occupations Article, §15-314(a)(3), Annotated Code of Maryland, includes the dispensing of prescription drugs by a physician assistant:

(1) Without the appropriate supervision of the permit holder;

(2) In an unauthorized location;

(3) Without a Board-approved delegation agreement that includes the authority to prescribe and dispense prescription drugs;

(4) While the permit holder’s dispensing permit is not active for any reason listed in §B(4)(a) of this regulation; and

(5) In violation of:

(i) Federal or State statutes or regulations regarding the dispensing of prescription drugs; or
(ii) Any of the attestations set out in the Board-approved delegation agreement.

10.32.03.09 (September 17, 2019)

.09 Renewal, Reinstatement, Change in Name or Address, and Continuing Education.

A. (text unchanged)

(1) The Board may not renew a license until the Comptroller of Maryland has verified that the individual has paid all undisputed taxes and unemployment insurance contributions, or arranged for [repayment, as required by COMAR 10.31.02.] repayment.

(2) (text unchanged)

B.—D. (text unchanged)

10.32.23 Permits for the Dispensing of Prescription Drugs

Authority: Health Occupations Article, §§12-102, 14-205, 14-306, 14-316, 14-404, [and] 14-408, 14-509, and 15-302.2; State Government Article, §§10-206 and 10-226;

Annotated Code of Maryland

10.32.23.01 (September 17, 2019)

.01 Scope.

This chapter defines the parameters under which a physician may obtain a permit to dispense prescription drugs to that physician’s patients, dispense prescription drugs to the patients of other prescribers under certain circumstances, and delegate parts or all of the dispensing process to others in accordance with Health Occupations Article, §§12-102, [and] 14-306, and 15.302.2, Annotated Code of Maryland.
.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) “Applicant” means a physician licensed by the Board applying for a dispensing permit.

(2) “Delegation agreement” has the meaning stated in Health Occupations Article, §15-101, Annotated Code of Maryland.

(3) “Dispensing authority” means the authority delegated by a primary supervising physician to a physician assistant through a Board-approved delegation agreement to dispense prescription drugs in accordance with this chapter and COMAR 10.32.23.

(4) “Dispensing permit” means:

(a) A permit issued by the Board to a Maryland licensed physician to dispense prescription drugs; or

(b) A topical medication permit, as that term is defined in this regulation.

(5) “Final check” means the verification of the accuracy and completeness of a filled prescription order by the permit holder or a physician assistant who has been delegated dispensing authority before the drug is dispensed to the patient.

(6) “In good standing” means that an individual:

(a)—(d) (text unchanged)
(e) Has not been within the past 5 years sanctioned by any medical licensing board for the commission of a crime of moral turpitude or for a violation of Health Occupations Article, §14-404(a)(7), (8), (9), (10), (27), or (28), Annotated Code of Maryland, or a similar statute of another state; and

(f) Has not within the past 5 years had the CDS registration issued by the OCSA or its predecessor, the registration issued by the federal Drug Enforcement Administration, or the Board dispensing permit:

(i)—(iii) (text unchanged)

[(7)] (11)—[(9)] (13) (text unchanged)

[(10) “Permit holder” means a physician licensed in this State who holds a valid dispensing permit under this chapter.]

(14) “Permit holder” means a Maryland licensed physician who holds a valid dispensing permit, as defined in this regulation.

[(11)] (15)—[(13)] (17) (text unchanged)

(18) “Topical medication permit” means a written permit issued by the Board to a Maryland licensed physician to dispense only topical medications that are approved by the federal Food and Drug Administration for the treatment of hypotichosis.

10.32.23.03 (October 9, 2019)

.03 Dispensing Permit Not Required.

A dispensing permit is not required to:

A. Dispense prescription drugs or devices at a health facility or center described in Health Occupations Article, §12-102(g)(1)—(3), Annotated Code of Maryland; [or]
B. Dispense to a patient, free of charge, in accordance with Health Occupations Article, §12-102(d) and (f), Annotated Code of Maryland:

(1) A drug sample;

(2) A sample unit; or

(3) A starter [dosage of a prescription drug, not to exceed a 72-hour supply.] dosage.

C. Dispense devices and equipment described in Health Occupations Article, §12-102(i), Annotated Code of Maryland;

D. Administer prescription drugs, in accordance with Health Occupations Article, §12-102(e), Annotated Code of Maryland;

E. Write a prescription for a patient to be filled at or by a pharmacy, as defined in Health Occupations Article, §12-101, Annotated Code of Maryland; or

F. Delegate to a physician assistant the duties described in this regulation.

10.32.23.04 (October 9, 2019)

.04 Qualifications for Dispensing Permits and Renewal of Dispensing Permits.

A. An applicant [for a dispensing permit] shall:

(1) Possess a license to practice medicine in this State;

(2) Be in good standing as that term is defined in this chapter;

(3) Be of good moral character;

(4) Demonstrate a basic knowledge of the statutes and regulations governing the practice of dispensing prescription drugs;

(5) Complete the application on a form supplied by the Board; [and]

(6) Pay the required fee as set out in COMAR [10.32.01.12.] 10.32.01.12;

[B. The applicant shall:}
(1)] (7) State each location at which prescription drugs will be dispensed; and

[(2)] (8) Grant permission to OCSA to inspect, at any reasonable hour, each location at which prescription drugs will be dispensed [at any reasonable hour].

[C. An applicant for renewal of a dispensing permit shall submit, upon request, documentation of completion of at least ten continuing education credits related to the preparing and dispensing of prescription drugs offered by the Accreditation Council for Pharmacy Education or as approved by the Secretary of the Maryland Department of Health.]

B. A permit holder applying for renewal of a dispensing permit shall:

(1) Meet the requirements in §A of this Regulation; and

(2) Submit, upon Board request, documentation of completion of:

(a) For a permit to dispense prescription drugs, at least ten continuing education credits that:

(i) Relate to the preparing and dispensing of prescription drugs offered by the Accreditation Council for Pharmacy Education or as approved by the Secretary of the Maryland Department of Health; and

(ii) Were completed within the five years prior to the expiration date of the dispensing permit; or

(b) For a topical medication permit, one hour of continuing medical education that:

(i) Relates to the dispensing of topical medications developed by a Maryland nonprofit or government entity accredited by the Accrediting Council for Continuing Medical Education; and

(ii) Were completed within the one year prior to the expiration of the topical medication permit.

10.32.23.05 (November 13, 2019)

.05 Consideration of Applications.

The Board shall grant the application for a dispensing permit if:

A. The applicant meets the requirements of Regulation .04 of this chapter;
B. The applicant has not been sanctioned by the Board for dispensing drugs without a dispensing permit within the last 5 years; and

C. Granting the application is in the public interest.

10.32.23.06 (September 17, 2019)

.06 Requirements for Permit Holders.

A. (text unchanged)

B. A permit holder shall:

(1) Perform in person the final check of each prescription drug dispensed;

(2) Sign or initial documentation in person that the final check was completed;

(3) Be present on the premises and available for consultation at the time the prescription drug is dispensed;

(4) With regard to inspections by the OCSA:

(a) Personally sign at the time of the inspection the acknowledgement of receipt of the inspection report required by Health Occupations Article, §12-102(c)(2)(ii)4D, Annotated Code of Maryland; or

(b) Assure that during all normal office hours a designee is available on the premises who will sign at the time of the inspection the acknowledgement of receipt of the inspection report;

(5) Assure that the lot number of a drug obtained from a stock bottle or other larger container:

(a) Is recorded in the office records;

(b) Can be correlated with any patient’s prescription for that drug; and

(c) Is immediately available for inspection; and
(6) Except with regard to sample units, drug samples, and starter dosages in the possession and control of an authorized prescriber, assure that physical access to all prescription drugs is denied to all individuals at all times that a permit holder is not on the premises.

(4) Only dispense a prescription drug that the permit holder is authorized to prescribe;

(5) Assure that the lot number of a prescription drug obtained from a stock bottle or other larger container:

(a) Is recorded in the office records;

(b) Can be correlated with any patient’s prescription for that drug; and

(c) Is immediately available for inspections by OCSA; and

(6) Notify any physician assistant to whom the permit holder has delegated prescriptive or dispensing authority of a lapse, expiration, surrender, or revocation of the dispensing permit.

C. With regard to inspections by the OCSA, a permit holder shall:

(1) Personally sign at the time of the inspection the acknowledgement of receipt of the inspection report required by Health Occupations Article, §12-102(c)(2)(ii)4D, Annotated Code of Maryland; or

(2) Assure that during all normal office hours a designee is available on the premises who will sign at the time of the inspection the acknowledgement of receipt of the inspection report.

[D.] E. (text unchanged)

10.32.23.07 (September 17, 2019)

.07 Delegation of Dispensing Functions.

A. (text unchanged)

B. Delegation of Dispensing Authority to a Physician Assistant.
(1) [Except as required in §B(2) of this regulation, a] A permit holder may delegate dispensing authority to a physician assistant [with whom the permit holder has a delegation agreement under Health Occupations Article, §15-302, Annotated Code of Maryland,] for the dispensing of a drug prescribed by:

(a) The permit holder to the permit holder’s patient; or

(b) [A physician assistant or certified registered nurse practitioner who meets the requirements of Regulation .08 or .09 of this chapter.] The physician assistant to the physician assistant’s patient.

(2) [The permit holder shall perform the final check.] In order for a permit holder to delegate dispensing authority, the permit holder and the physician assistant shall submit a delegation agreement on a form approved by the Board that complies with the requirements of Health Occupations Article §15-302 and 15-302.2, Annotated Code of Maryland, and COMAR 10.32.03.

(3) A permit holder may delegate the requirements in Regulation .06 to a physician assistant pursuant to a delegation agreement filed with the Board in accordance with COMAR 10.32.03, provided that:

(a) The permit holder is ultimately responsible for complying with all federal and state statutes and regulations for any dispensing that occurs under the permit; and

(b) Either the permit holder or the physician assistant:

(i) Performs in person the final check of each drug dispensed; and

(ii) Is physically present on the premises and available for consultation at the time the drug is dispensed.

(4) A permit holder may not:

(a) Require a physician assistant to:

(i) Dispense prescription drugs; or
(ii) Submit a delegation agreement that includes dispensing prescription drugs;

(b) Delegate the dispensing of prescription drugs beyond the scope of the permit holder’s authority; or

(c) Delegate the dispensing of drugs prescribed by other practitioners under Regulation .08 of this chapter.

(5) A physician assistant who has been delegated dispensing authority shall comply with all permit holder requirements.

10.32.23.08 (September 17, 2019)

.08 Permit Holder’s Dispensing of Prescription Drugs Prescribed by [Physician Assistants] Other Practitioners.

A. [Except as required in §§B and C] Subject to §§C and D of this regulation, a permit holder may dispense a drug prescribed by a physician assistant with whom the permit holder has a Board-approved delegation agreement under Health Occupations Article, §15-302, Annotated Code of Maryland, which authorizes the physician assistant to prescribe the drug.

B. Subject to §§C and D of this regulation, a permit holder may dispense a drug prescribed by a certified registered nurse practitioner who is:

(1) Authorized under Health Occupations Article, Title 8, Annotated Code of Maryland, to prescribe the drug; and

(2) Working with the permit holder in the same office setting.


E. A permit holder may not dispense prescription drugs for another physician or permit holder.
10.32.23.09 (September 17, 2019)

[.09 Dispensing Prescription Drugs Prescribed by Certified Registered Nurse Practitioners.
A. Except as required in §§B and C of this regulation, a permit holder may dispense a drug prescribed by a certified registered nurse practitioner who is:
(1) Authorized under Health Occupations Article, Title 8, Annotated Code of Maryland, to prescribe the drug; and
(2) Working with the permit holder in the same office setting.
B. The permit holder shall perform the final check.
C. The permit holder may dispense under this regulation only a drug that the permit holder is authorized to prescribe.]

10.32.23.10 (September 17, 2019)

[.10] [.09 Records.
A. A permit holder shall keep readily retrievable at each dispensing location:
(1)—(3) (text unchanged)
(4) [The delegation agreement of any physician assistant for whom the permit holder dispenses prescription drugs at that location, including the name of the primary supervising physician and any alternate supervising physician;] The Board-approved delegation agreement, including the name of the primary supervising physician and any alternate supervising physician, of any physician assistant for whom the permit holder dispenses prescription drugs or to whom the permit holder delegates dispensing of prescription drugs at that location;
(5) [A list of the name and license number of all physician assistants for whom the permit holder dispenses drugs at that location;] In regard to any physician assistant who has been delegated dispensing authority, a list of:
(a) All locations where any physician assistants are dispensing prescription drugs under the permit; and

(b) The name and license number of all physician assistants for whom the permit holder dispenses prescription drugs at that location;

(6) (text unchanged)

(7) [The permit holder’s protocols for handling drug recalls, including the arrangements for notifying patients;

(8) The permit holder’s protocols for disposal of drugs; ] The permit holder’s protocols for:

(a) Handling drug recalls, including the arrangements for notifying patients; and

(b) Disposing of drugs;

[(9)] (8) (text unchanged)

[(10)] (9) Any other purchasing, inventory, and dispensing records required by [State or] federal or State statutes or regulations.

B. In addition to meeting the requirements of Regulation [.10A.] .09A, the permit holder shall comply with any other [State or federal law or regulation] federal or State statutes or regulations relating to dispensing of prescription drugs.

C. (text unchanged)

10.32.23.11 (September 17, 2019)

[.11 Revision of Dispensing Permit.] .10 Report of Change of Address.

A. A permit holder [may revise a permit twice during its term, without charge, to change the location at which prescriptions will be dispensed.] shall notify the Board in writing of any change in address at which prescription drugs are dispensed under the dispensing permit within 60 days after the change.
B. If a permit holder fails to notify the Board within the time required under this regulation, the permit holder is subject to an administrative penalty of $100.

10.32.23.12 (September 17, 2019)

[.12] II Lapse of Dispensing Permit.

A. A dispensing permit automatically lapses if the permit holder:

(1)—(2) (text unchanged)

(3) Fails without good cause to file the annual report required by Health Occupations Article, §12-102(c)(2)(ii)4L, Annotated Code of Maryland, within 15 days of the anniversary date of the date the dispensing permit was issued; [or]

(4) Fails without good cause to notify the Board of a change of address as required by [Health Occupations Article, §14-316(f), Annotated Code of Maryland.] Regulation .10 of this chapter; or

(5) Fails to renew the dispensing permit prior to the expiration date of the dispensing permit.

B. A lapsed dispensing permit may not be reinstated.

C. The lapse of a dispensing permit is not in itself a bar to filing an application for a new dispensing permit.

10.32.23.13 (September 17, 2019)

[.13 Written Notice on Reactivation of Dispensing.

A permit holder who has reported pursuant to Health Occupations Article, §12-102(c)(2)(ii)4L, Annotated Code of Maryland, that the permit holder has not personally dispensed prescription drugs during the previous year:
A. Will not be subject to inspections by OCSA pursuant to Health Occupations Article, §12-102.1(b), Annotated Code of Maryland, unless the permit holder begins dispensing again; and
B. May not begin to dispense prescription drugs again during the term of the dispensing permit without notifying the Board in advance in writing.]

.12 Written Notice on Reactivation of Dispensing.

A. Except as provided in §B of this regulation, a permit holder who has reported pursuant to Health Occupations Article, §12-102(c)(2)(ii)4L, Annotated Code of Maryland, that the permit holder has not personally dispensed or delegated the dispensing of prescription drugs under this chapter during the previous year:

(1) Will not be subject to inspections by OCSA pursuant to Health Occupations Article, §12-102.1(b), Annotated Code of Maryland, unless the permit holder resumes dispensing prescription drugs or delegates the dispensing of prescription drugs under this chapter; and

(2) May not begin to dispense or delegate the dispensing of prescription drugs again during the term of the dispensing permit without notifying the Board in advance in writing.

B. OCSA may inspect any permit holder to determine if that permit holder is dispensing prescription drugs or delegating the dispensing of prescription drugs in violation of §A of this regulation.

10.32.23.14 (September 17, 2019)


A. Subject to the Administrative Procedure Act, in accordance with Health Occupations Article §14-405, Annotated Code of Maryland, and in addition to any sanction for violation of Health Occupations Article, §14-404(a)(28), Annotated Code of Maryland, [the Board] a disciplinary panel may revoke a dispensing permit on any of the following grounds:
(1) Violating the attestations made pursuant to COMAR 10.13.01.05C(4);
(2) Violating [State or] federal or State statutes or regulations regarding prescribing or dispensing prescription drugs;
(3) Delegating dispensing duties outside the scope of this chapter;
(4) Dispensing prescription drugs prescribed by another individual outside the scope of this chapter;
(5) Dispensing or delegating dispensing at a location not designated on the permit;
(6) Except when dispensing authority has been properly delegated to a physician assistant in accordance with Regulation .07 of this chapter, [Being] being absent from the premises when prescription drugs are dispensed under the dispensing permit;
(7) (text unchanged)
(8) Failing to cooperate with an investigation by the Board or an inspection by OCSA; [or]
(9) Violating Regulations .06, [.10, or .13] .09, or .12 of this [chapter.] chapter; or
(10) Delegating dispensing authority to a physician assistant who dispenses prescription drugs in violation of this chapter.

B. If a permit holder surrenders the dispensing permit while under investigation:

(1) The surrender does not prevent [the Board] a disciplinary panel from taking any appropriate disciplinary action under Health Occupations Article, §14-404(a)(28), Annotated Code of Maryland, or any other statute under which the [Board] disciplinary panel has jurisdiction; [and]
(2) The surrender of a dispensing permit must be accepted by a disciplinary panel;
(3) A disciplinary panel may set conditions on its agreement to accept the surrender of a dispensing permit; and
[(2)] (4) The permit holder may not apply for another dispensing permit again for a minimum of 5 years.
C. If a disciplinary panel sanctions a permit holder for violating Health Occupations Article, §14-404(a)(7), (8), (9), (10), (27), or (28), or §14-404(b)(2), Annotated Code of Maryland, the disciplinary panel, in addition to imposing any sanctions on the permit holder under COMAR 10.32.02.07 or 10.32.02.10, shall order the revocation of the dispensing permit.

D. Following revocation or surrender of a dispensing permit, the granting of a new dispensing permit is at the discretion of the Board.

E. The hearing under this regulation may be combined with any procedures under Health Occupations Article, §14-405, Annotated Code of Maryland.

10.32.23.15 (September 17, 2019)


A. [The Board] A disciplinary panel may summarily suspend a dispensing permit if [it] the disciplinary panel finds that the public safety, health, or welfare imperatively requires emergency action.

B. (text unchanged)

10.32.23.16 (September 17, 2019)

[.16 Fraud or Deception in Obtaining a Permit.

Subject to the Administrative Procedure Act, a licensee who fraudulently or deceptively obtains or attempts to obtain a permit is guilty of violating Health Occupations Article, §14-404(a)(1), Annotated Code of Maryland.]
10.32.23.17 (September 17, 2019)

[.17 Permit Holders Sanctioned for Violating the Medical Practice Act.

A. If the Board sanctions a permit holder for violating Health Occupations Article, §14-404(a)(7), (8), (9), (10), or (28), or §14-404(b), Annotated Code of Maryland, the Board shall, in addition to any sanctions imposed on the permit holder under COMAR 10.32.02.07 or 10.32.02.10, revoke the permit.

B. Subject to the requirement of §C of this regulation, reinstatement of a revoked permit is at the discretion of the Board.

C. A revoked permit may not be reinstated for a minimum of 5 years from the date of revocation.]

10.32.23.18 (September 17, 2019)

[.18] .15 Dispensing Without a Dispensing Permit.

Unless otherwise authorized by Health Occupations Article, §12-102, Annotated Code of Maryland, the dispensing of prescription drugs [by a physician] without a dispensing permit or the delegation to other individuals of dispensing prescription drugs in violation of this chapter is a violation of Health Occupations Article, §14-404(a)(28), Annotated Code of Maryland, and also may be considered unprofessional conduct in the practice of medicine in violation of Health Occupations Article, §14-404(a)(3)(ii), Annotated Code of Maryland.
10.32.23.19 (September 17, 2019)

[.19] .16 Interpretation.

Nothing in this chapter relieves any permit holder from meeting the requirements of [State or federal law or COMAR 10.13.01.] any other federal or State statutes or regulations regarding the practice of medicine or the dispensing of prescription drugs.

ROBERT R. NEALL

Secretary of Health