PROPOSED REGULATION PUBLICATION FORMS

Title 10

MARYLAND DEPARTMENT OF HEALTH

REVISED DRAFT

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

Yes	<u>X</u> No		
Is There An Incorporation	on By Reference Document Associated With This Proposal?		
Yes	<u>X</u> 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)	<u>X</u> No		
Does This Proposal Ir	nclude An Increase Or Decrease In A Fee For A License?		
Yes, complete (1)—(8)	$\underline{\mathbf{X}}$ No, skip (1)—(8) and proceed to Notice of Proposed Action.		
(1) Explain/justify why an inc	rease or decrease is necessary:		
(2) How much money is need	ed 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 that administers a uniform	by the Proposing Unit or passed through to a national organization licensing exam?		
(5) Describe any measures tak	ten to mitigate the need for increased revenue:		
(6) Describe any special circu operating expenses.	mstances that have had an adverse impact on the Proposing Unit's		
(7) Describe any consideration have on the regulated prof	n given by the Proposing Unit as to the hardship a fee increase may ession.		

(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, .05, and .08 under COMAR 10.32.03 Delegation of Duties by a Licensed Physician Physician Assistant;
- (3) Amend Regulations .01, .02, .04, .06, .07, and .08 under COMAR 10.32.23 Permits for the Dispensing of Prescription Drugs;
- (4) Repeal Regulations .09, .16, and .17 under COMAR 10.32.23 Permits for the Dispensing of Prescription Drugs; and
- (5) 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:

- September 12, 2018, notice of which was given by publication on the Board's Website at https://www.mbp.state.md.us/forms/Sep18Aagenda.pdf from August 28, 2018 through September 12, 2018 pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland;
- January 30, 2019, notice of which was given by publication on the Board's Website at https://www.mbp.state.md.us/forms/Jan19Fullagenda.pdf from January 17, 2019 through January 30, 2019 pursuant to General Provisions Article, §3-302(c), Annotated Code of Maryland; and
- June 12, 2019, notice of which was given by publication on the Board's Website at https://www.mbp.state.md.us/forms/Jun19Aagenda.pdf from May 30, 2019 through June 12, 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, effective October 1, 2018, pursuant to House Bill 591 and Senate Bill 549, "Health Occupations – Physician Assistants – Dispensing of Drugs Under a Delegation Agreement," 2018, Chapter 442 and Chapter 443.

In addition, the proposal includes provisions to reflect minimum requirements for the advanced duty of dispensing prescription drugs by a physician assistant. The minimum requirements, voted on and approved by the Board on September 12, 2018, are reflected in the meeting minutes, available at https://www.mbp.state.md.us/forms/Sep18AMinutes.pdf on the Board's Website.

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;
- 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 full dispensing authority to that physician assistant;
- Also under Regulation .07, the establishment of requirements for physician assistants who have been delegated full 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;
- 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.

Also, the proposal includes conforming changes to COMAR 10.13.01.04, 10.32.03.02, 10.32.03.05, and 10.32.03.08.

Comparison to Federal Standards (Check one option)

<u>X</u>	There is no corresponding federal standard to this proposed action.
	<u>or</u>
	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:
	<u>or</u>
	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	e standards:		
	Impact Stat Part A (check one of	A		
<u>X</u>	Estimate of Eco The proposed action has no economic impact Or The proposed action has an economic impact following form in its antiacty)	ct.	elete the	
I.	following form in its entirety) Summary of Economic Impact. (INSERT SHORT SUMMARY)			
II.	Types of Economic Impact. A. On issuing agency: B. On other State agencies:	Revenue (R+/R-) Expenditure (E+/E-)	<u>Magnitude</u>	
	C. On local governments: D. On regulated industries or trade groups:	Benefit (+) Cost (-)	Magnitude	
	E. On other industries or trade groups:			
	F. Direct and indirect effects on public:			
III.	Assumptions. (Identified by Impact Letter a	nd Number from Section II.)	
<u>X</u>	Part I Economic Impact on (check one of the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action has minimal or no economic or the proposed action to the proposed action the proposed action the proposed action to the proposed action the proposed action to the proposed action the proposed action the proposed action to the proposed action the proposed action the proposed action to the proposed action	Small Businesses option)	esses.	

	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.
	The proposed action has an impact on individuals with disabilities as follows: (Agency to complete this assessment)
	Opportunity for Public Comment
Avenu	nents may be sent to Sandi Van Horn, Maryland Board of Physicians, 4201 Patterson ne, Baltimore, MD 21215, or email to sandi.vanhorn@maryland.gov, or fax to 410-358-Comments will be accepted through July 12, 2019. A public hearing has not been uled.
	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 \underline{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:
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 full dispensing authority to a 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 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,

Annotated Code of Maryland

10.13.01.04 (February 27, 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 \$S and \$T 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 10.32.23, a physician may delegate to a physician assistant the dispensing of prescription drugs for a prescription written by:

- (1) That physician assistant; and
- (2) The primary supervising physician who has delegated full dispensing authority to that physician assistant.

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

10.32.03.02 (February 27, 2019)

.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, §12-102, Annotated Code of Maryland.
- (15) "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)—(31) (text unchanged)

10.32.03.05 (February 27, 2019)

.05 Delegation Agreements — Contents.

A.—F. (text unchanged)

G. A physician assistant who has filed a delegation agreement addendum with the Board for approval to perform the advanced duty of dispensing prescription drugs shall comply with COMAR 10.32.23.07C.

10.32.03.08 (February 27, 2019)

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

A.—B. (text unchanged)

- C. A physician assistant may dispense a prescription drug or device in the course of treating a patient in the following facilities without Board approval of the advanced duty of dispensing:
- (1) At a medical facility or clinic that is operated on a nonprofit basis;
- (2) At a health center that operates on a campus of an institution of higher education; or
- (3) At a public health facility, a medical facility under contract with a state or local health department, or a facility funded with public funds.
- D. Except as provided in §§B or C of this regulation, dispensing prescription drugs is an advanced duty governed by COMAR 10.32.23.07C.

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, and 15-302.2; State Government Article, §§10-206 and 10-226;

Annotated Code of Maryland

10.32.23.01 (February 27, 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.

10.32.23.02 (February 27, 2019)

.02 Definitions.

A. (text unchanged)

B. Terms Defined.

(1) "Advanced duty" has the meaning stated in COMAR 10.32.03.01B(2).

[(1)](2)—[(2)](3) (text unchanged)

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

[(3)] (5)—[(4)] (6) (text unchanged)

[(5)] (7) Final Check.

- (a) "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 full dispensing authority* before the drug is dispensed to the patient.
- (b) (text unchanged)
- (8) "Full dispensing authority" means, with respect to a physician assistant, the authority to conduct the entire process of dispensing prescription drugs, including the final check.

 [(6)] (9) "In good standing" means that an individual:
- (a) Holds a license to practice [medicine] as a physician or a physician assistant in this State; (b)—(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), or [(28),] (27), 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 [Agency,] *Administration*, or the Board dispensing permit:
- (i)—(iii) (text unchanged)

[(7)] (10)—[(13)] (16) (text unchanged)

10.32.23.04 (February 27, 2019)

.04 Qualifications for Dispensing Permits.

- A. (text unchanged)
- B. The applicant shall:
- (1) (text unchanged)

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

C. (text unchanged)

10.32.23.06 (February 27, 2019)

.06 Requirements for Permit Holders.

A. (text unchanged)

- B. Except when full dispensing authority is delegated to a physician assistant in accordance with Regulation .07C of this chapter, [A] 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; and
- (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.]
- C. A permit holder shall 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 except when:
- (1) Sample units, drug samples, and starter dosages are in the possession and control of an authorized prescriber; or
- (2) The permit holder has delegated full dispensing authority to a physician assistant.
- D. A permit holder shall:
- (1) 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;
- (2) 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 inspection; and
- (3) 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.] E.—[D.] F. (text unchanged)

10.32.23.07 (February 27, 2019)

.07 Delegation of Dispensing Functions.

- A. (text unchanged)
- B. Delegation to a Physician Assistant of all Dispensing Functions except the Final Check.
- (1) Except as required in §B(2) of this regulation, a permit holder may delegate to a physician assistant with whom the permit holder has a delegation agreement *that includes prescriptive authority* under Health Occupations Article, §15-302, Annotated Code of Maryland, *and COMAR 10.32.03.08*, 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.
- (2) (text unchanged)
- C. Delegation to a Physician Assistant of Full Dispensing Authority By a Permit Holder Who is the Primary Supervising Physician.
- (1) A permit holder may delegate to a physician assistant full dispensing authority only after obtaining Board approval of the advanced duty of dispensing prescription drugs.
- (2) The permit holder may not:
- (a) Coerce a physician assistant to:
- (i) Dispense prescription drugs; or
- (ii) Submit a delegation agreement addendum for Board approval of the advanced duty of dispensing prescription drugs; or
- (b) Delegate the dispensing of prescription drugs beyond the scope of the permit holder's authority.

- (3) To obtain Board approval for the advanced duty of dispensing prescription drugs, a physician assistant shall:
- (a) Be of good moral character;
- (b) Be in good standing;
- (c) Submit, together with the permit holder, a delegation agreement addendum for advanced duties on a form approved by the Board that includes:
- (i) An attestation by the permit holder that the physician assistant has the appropriate education, training, and level of competence necessary to dispense prescription drugs in accordance with federal and State law;
- (ii) Attestations that the physician assistant will dispense prescription drugs only at locations where the permit holder is authorized to dispense prescription drugs;
- (iii) Attestations that all medical charts or records will contain a notation of any prescriptions written or dispensed by a physician assistant;
- (iv) Attestations that all prescriptions written or dispensed will include the physician assistant's name and the permit holder's name, business address, and business telephone number legibly written or printed; and
- (v) A training log demonstrating that the physician assistant has completed all steps in the dispensing process for a minimum of 25 prescription drugs under the in-person supervision of the permit holder; and
- (d) Have at least 1 year of experience in prescribing drugs under a Board-approved delegation agreement.
- (4) A physician assistant who has been granted full dispensing authority:

- (a) May dispense any drug that both the physician assistant and the permit holder have the authority to prescribe and dispense;
- (b) May dispense only those drugs that the physician assistant or the permit holder has prescribed;
- (c) May dispense only at the locations where the permit holder is authorized to dispense prescription drugs;
- (d) May not further delegate any part of the dispensing process; and
- (e) Shall abide by the terms of:
- (i) The Board-approved delegation agreement;
- (ii) The delegation agreement addendum for the advanced duty to dispense prescription drugs; and
- (iii) The permit holder's dispensing permit.
- (5) A physician assistant 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 or the addendum for the advanced duty to dispense prescription drugs is terminated for any reason; or
- (c) The physician assistant's license:
- (i) Expires; or
- (ii) Is suspended, revoked, or terminated for any reason.

- (6) If a physician assistant ceased the dispensing of prescription drugs for a reason listed in C(5) of this regulation, the physician assistant may not resume dispensing until the Board has approved a new delegation agreement addendum for advanced duties.
- (7) 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:
- (a) Without the appropriate supervision of the permit holder;
- (b) In an unauthorized location;
- (c) Without a Board-approved delegation agreement and addendum for the advanced duty to dispense prescription drugs;
- (d) While the permit holder's dispensing permit is not active for any reason listed in C(5)(a) of this regulation; and
- (e) 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 delegation agreement or in the delegation agreement addendum for advanced duties.

10.32.23.08 (February 27, 2019)

.08 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.

[B.] *C.*—[C.] *D.* (text unchanged)

E. A physician may not dispense prescription drugs for another physician or permit holder. 10.32.23.09 (February 27, 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 (February 27, 2019)

[.10] .09 Records.

A. A permit holder shall keep readily retrievable at each dispensing location:

(1)—(3) (text unchanged)

- (4) The *Board-approved* 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;
- (5) In regard to any physician assistant who has been delegated full dispensing authority:
- (a) The Board-approved delegation agreement addendum for advanced duties; and
- (b) A list of all locations where any physician assistants are dispensing prescription drugs;
- [(5)] (6) A list of the name and license number of all physician assistants for whom the permit holder dispenses *prescription* drugs at that location;
- [(6)] (7) A list of the name, license number, and specialty of all certified registered nurse practitioners for whom the permit holder dispenses *prescription* drugs at that location; [(7)] (8)—[(9)] (10) (text unchanged)
- [(10)] (11) 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 (February 27, 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 the permit holder's address at which prescription drugs are dispensed 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 (February 27, 2019)

[.12] .11 Lapse of Dispensing Permit.

A. A permit automatically lapses if the permit holder:

- (1)—(4) (text unchanged)
- (5) Fails to renew the dispensing permit prior to the expiration date of the dispensing permit.

B.—C. (text unchanged)

10.32.23.13 (February 27, 2019)

[.13] .12 Written Notice on Reactivation of Dispensing.

A. Except as provided in §B of this regulation, [A] 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:

[A.] (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 [begins dispensing again;] resumes dispensing prescription drugs or delegates the dispensing of prescription drugs under this chapter; and

[B.] (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 (February 27, 2019)

[.14 Grounds for] .13 Revocation of Dispensing Permit.

A. Subject to the Administrative Procedure Act, 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) (text unchanged)
- (2) Violating [State or] federal *or State* statutes or regulations regarding prescribing or dispensing prescription drugs;
- (3)—(5) (text unchanged)
- (6) Except when full 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 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. (text unchanged)
- C. If a disciplinary panel sanctions a permit holder for violating Health Occupations Article, §14-404(a)(7), (8), (9), (10), or (27), 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. A revoked permit may not be reinstated for a minimum of 5 years from the date of revocation. 10.32.23.15 (February 27, 2019)

[.15] .14 Summary Suspension of Dispensing Permit.

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 (February 27, 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 (February 27, 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 (February 27, 2019)

[.18] .15 Dispensing Without a Permit.

Unless otherwise authorized by Health Occupations Article, §12-102, Annotated Code of Maryland, the dispensing of prescription drugs [by a physician] without a permit *or the delegation to others 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 (February 27, 2019)

[.19] .16 Interpretation.

Nothing in this chapter relieves any permit holder from meeting the requirements of [State or federal law] *federal or State statutes* or COMAR 10.13.01.

ROBERT R. NEALL

Secretary of Health