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PHYSICIAN DISPENSING/PERMIT REGULATIONS

10.13.01 Dispensing of Prescription Drugs by a Licensee

10.32.12 Delegation of Acts by a License Physician to an Assistant Not Otherwise Authorized under the Health Occupations Article of the Education Article

10.32.23 Permits for the Dispensing of Prescription Drugs

EFFECTIVE: MARCH 26, 2018

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 13 DRUGS

Chapter 01 Dispensing of Prescription Drugs by a Licensee

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

.01 Scope.

This chapter defines the parameters under which a licensee may dispense prescription drugs in accordance with Health Occupations Article, §12-102, Annotated Code of Maryland.

.02 Definitions.

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

B. Terms Defined.

(1) "Board" means the Board of Dental Examiners, the Board of Physicians, or the Board of Podiatric Medical Examiners.

(2) Final Check.

(a) "Final check" means the verification of the accuracy and completeness of a filled prescription order by the permit holder before the drug is dispensed to the patient.

(b) "Final check" includes the assumption of responsibility for the filled prescription, including verifying the:

(i) Appropriateness of the dose;

(ii) Accurate expiration date;

(iii) Accuracy of the drug dispensed;

(iv) Strength of the drug dispensed;

(v) Labeling that complies with Health Occupations Article, §12-505, Annotated Code of Maryland; and

(vi) Appropriateness of the container in which the drug is dispensed, including child-proof containers where applicable.

(3) "Licensee" means the dentist, physician, or podiatrist who is licensed by the appropriate Board to practice in Maryland.

(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.

(5) "Public interest" means the dispensing of prescription drugs by a licensee to a patient when a pharmacy is not conveniently available to the patient.

.03 Application for Dispensing Permit.

A. The licensee shall complete an application on a form approved by the appropriate Board and pay a fee in accordance with the fee schedule for:

(1) Physicians at COMAR 10.32.01.12;

(2) Podiatrists at COMAR 10.40.03; or

(3) Dentists at COMAR 10.44.20.

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

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

(2) An attestation by the applicant that the applicant shall comply with the:

(a) Dispensing requirements set forth in Regulation .04 of this chapter;

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

(c) Statutes and regulations 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. Each permit issued to a licensee expires 5 years after its date of issuance and is renewable upon timely submission of a renewal application in accordance with the requirements set forth in this regulation. The fee schedule set forth in §A of this regulation applies to all renewal applications.

D. Continuing Education Requirement.

(1) 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.

(2) The continuing education credit requirement shall be implemented in accordance with Ch. 267, §2, Acts of 2012.

E. A permit issued to a licensee shall be nontransferable.

.04 Dispensing Requirements.

- A. A licensee shall submit an application to the appropriate Board on the form that the Board requires.
- B. A licensee may not dispense prescription drugs until a written permit is received from the appropriate Board, except that a written permit is not required in order to dispense starter dosages or samples provided without charge.
- C. A licensee shall personally prepare and dispense prescription drugs.
- D. Except as provided in Health Occupations Article, §12-102(c)(2)(iii), Annotated Code of Maryland, and §S of this regulation, a licensee shall dispense prescription drugs only to the patients of the licensee.
- E. A licensee shall comply with the labeling requirements set forth in Health Occupations Article, §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.
- H. A licensee shall record the dispensing of the prescription drug on the patient's chart.
- I. A licensee may not have a substantial financial interest in a pharmacy.
- J. A licensee shall, except for starter dosages or samples provided without charge, provide the patient with a written prescription.
- K. A licensee shall maintain for at least 5 years:
 - (1) A separate file for Schedule II prescriptions; and
 - (2) Another file for other prescriptions.
- L. A licensee shall maintain biennial inventories of all stocks of controlled substances.
- 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.
- N. In each patient's chart for each patient to whom prescription drugs are dispensed or in a format readily retrievable, a licensee shall maintain a single form which:
 - (1) Indicates that a pharmacy is not conveniently available to the patient;
 - (2) States that the determination that a pharmacy is not conveniently available was made solely by the patient; and
 - (3) Is signed and dated by the patient before dispensing prescription drugs to the patient for the first time.
- O. A licensee shall display prominently a sign which informs the patient that prescription drugs can be purchased from the permit holder if the patient determines that a pharmacy is not conveniently available to the patient.

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.

S. To the extent permitted by COMAR 10.32.23, a licensed physician may personally prepare and dispense 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 the drug; and

(2) A certified registered nurse practitioner who is:

(a) Authorized to practice under Health Occupations Article, Title 8, Subtitle 3, Annotated Code of Maryland; and

(b) Working with the physician in the same practice.

.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 Office of Controlled Substances Administration 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 Office of Controlled Substances Administration to enter and inspect the licensee's practice locations at all reasonable hours.

C. The Office of Controlled Substances Administration 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 Office of Controlled Substances Administration finds a deficiency at one practice location of a licensee with multiple practice locations, require the licensee to prepare, sign, and submit 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 Office of Controlled Substances Administration 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 Office of Controlled Substances Administration for inspections, as required by the appropriate Board.

F. The Office of Controlled Substances Administration:

(1) May suspend inspections of any physician who reports pursuant to Health Occupations Article, §12-102(c)(2)(ii)4L, Annotated Code of Maryland, that the physician has not personally dispensed any prescription medications during the preceding year; and

(2) To the extent otherwise required by this regulation, shall resume inspections if that physician later reports that the physician has resumed dispensing activities.

.06 Failure to Comply with Dispensing Requirements.

A licensee who fails to comply with the requirements governing dispensing of prescription drugs shall have the dispensing permit revoked and be subject to disciplinary action by the appropriate licensing board.

Effective date: September 19, 1935

Chapter, Permits for Sale of Poisons by General Merchants, repealed effective July 10, 1989(16:13 Md. R. 1421)

Chapter, Dispensing of Prescription Drugs by a Licensee, adopted effective May 11, 1992 (19:9 Md. R. 879)

Regulation .03A amended effective March 6, 2000 (27:4 Md. R. 453)

Chapter revised effective June 22, 2015 (42:12 Md. R. 762)

Regulation .02B amended effective March 26, 2018 (45:6 Md. R. 320)

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Regulation .04D, N amended effective March 26, 2018 (45:6 Md. R. 320)

Regulation .04S adopted effective March 26, 2018 (45:6 Md. R. 320)

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Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 32 BOARD OF PHYSICIANS

Chapter 12 Delegation of Acts by a Licensed Physician to an Assistant Not Otherwise Authorized under the Health Occupations Article or the Education Article

Authority: Health General Article, §§19-114 and 19-118; Health Occupations Article, §14-306; Annotated Code of Maryland

.01 Scope.

A. This chapter governs the delegation of acts by a physician to an assistant not otherwise authorized under the Health Occupations Article or the Education Article, Annotated Code of Maryland.

B. This chapter may not be construed:

- (1) As establishing the licensure, certification, or registration of assistants;
- (2) To apply to certified, registered, or licensed professionals, or health occupation students acting pursuant to Health Occupations Article, Annotated Code of Maryland; and
- (3) To mean that this chapter overrides or is to be used in lieu of more stringent regulations, policies, and procedures established by State licensure or certification requirements or Board-recognized accrediting agencies.

.02 Definitions.

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

B. Terms Defined.

(1) "Assistant" means an individual to whom only routine technical acts are delegated by a physician and who is:

(a) Trained as defined in §B(9) of this regulation and not certified, registered, or licensed by the Board or any other State health occupation board; or

(b) Certified, registered, or licensed by the Board or any other State health occupation board and is not acting under the authority of that certification, registration, or license granted by a State health occupation board.

(2) "Board" means the Board of Physicians.

(3) "CLIA" means the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. §263a) and the regulations promulgated under them, and 42 CFR Part 493, Subparts B and M.

(4) "Delegating physician" means a physician possessing an active license to practice medicine in this State who directs an assistant to perform technical acts.

(5) "Direct supervision" means oversight exercised by a delegating physician who is:

(a) Personally treating the patient; and

(b) In the presence of the assistant and the patient.

(6) "Microdermabrasion" means the use of a minimally invasive technique to gently exfoliate the dead, outermost layer of skin and is a method for improving superficial, environmental, aging, and hereditary skin changes by superficial, mechanically powered abrasion, often combined with application of topical crystals such as vitamin C.

(7) "On-site supervision" means oversight exercised by a delegating physician who is present at the site and able to be immediately available in person during the course of the performance of a delegated act.

(8) "Site" means any facility or location including those defined in Health-General Article, §§19-114 and 19-3B-01(b), Annotated Code of Maryland, used for the delivery of health services not covered in this chapter.

(9) "Technical act" means a routine medical or surgical act which does not require medical judgment and is performed with the supervision as specified within this chapter.

(10) "Trained" means possessing the knowledge, skills, and abilities, as determined by the physician, to perform delegated acts.

.03 Standards for the Delegating Physician.

A. A physician who delegates shall:

(1) Evaluate the risk to the patient and the outcome of the delegated acts;

(2) Delegate only those technical acts that are customary to the practice of the supervising physician;

(3) Delegate only those technical acts for which the assistant has been trained;

(4) Be responsible for the acts of the assistant; and

(5) Supervise the assistant.

B. The responsibility for the delegated act cannot be transferred from the delegating physician to another physician without:

(1) The expressed consent of the other physician; and

(2) Informing the assistant.

.04 Scope of Delegation.

A. A physician may not delegate to an assistant technical acts which are exclusively limited to any individual required to be licensed, certified, registered, or otherwise recognized pursuant to any provision of the Health Occupations Article and the Education Article, Annotated Code of Maryland.

B. A physician may delegate technical acts consistent with national standards in the medical community and the approved policies and procedures of the sites for the delivery of health services in the following categories:

(1) Surgical technical acts that the delegating physician directly orders while present, scrubbed, and personally performing the surgery in the same surgical field; and

(2) Nonsurgical technical acts while the assistant is under the physician's direct supervision or on-site supervision if the assistant performs the act in accordance with procedures of the site.

C. At sites included in Health-General Article, §§19-114 and 19-3B-01(b), Annotated Code of Maryland, or any unit of those sites, a physician may delegate technical acts in compliance with State regulations and the policies, procedures, and supervisory structures of those sites.

D. At sites not included in Health-General Article, §§19-114 and 19-3B-01(b), Annotated Code of Maryland, when providing the following specified levels of supervision, a physician may delegate to an assistant technical acts which include but are not limited to:

(1) Without on-site supervision:

(a) Patient preparation for physician examination;

(b) Patient history interview;

(c) Collecting and processing specimens, such as performing phlebotomy and inoculating culture media;

(d) Preparation of specimens for selected tests including:

(i) Pregnancy tests,

(ii) Dipstick and microscopic urinalysis, and

(iii) Microbiology (rapid streptococcal testing and throat cultures);

(e) Laboratory tests that the physician is satisfied the assistant is qualified to perform under State and CLIA regulations;

(f) Clinical tests such as:

(i) Application of tuberculin skin tests,

(ii) Electrocardiography,

(iii) Administering basic pulmonary function tests; and

(iv) Visual field tests;

(g) Transmitting prescriptions to a pharmacy;

(h) Providing sample packets of medication, selected by a physician who is physically present at the time of selection, to patients as directed by the delegating physician and in conformance with Health Occupations Article, §12-102(a), (d), and (f), Annotated Code of Maryland;

(i) Preparing and administering oral drugs; and

(j) Microdermabrasion;

(2) With on-site supervision:

(a) Preparing and administering injections limited to intradermal, subcutaneous, and intramuscular (deltoid, gluteal, vastus lateralis) to include small amounts of local anesthetics;

(b) Establishing a peripheral intravenous line; and

(c) Injecting fluorescein-like dyes for retinal angiography; and

(3) With direct supervision, injecting intravenous drugs or contrast materials.

E. A physician who possesses a dispensing permit may delegate the dispensing functions in accordance with the requirements of COMAR 10.32.23.

F. A physician may not delegate to an assistant acts which include but are not limited to:

(1) Conducting physical examinations;

(2) Administering any form of anesthetic agent or agent of conscious sedation other than topical anesthetics or small amounts of local anesthetics;

(3) Initiating independently any form of treatment, exclusive of cardiopulmonary resuscitation;

(4) Giving medical advice without the consult of a physician; and

(5) Providing physical therapy.

.05 Prohibited Conduct.

A. An assistant acting beyond the scope of this chapter may be:

(1) Considered to be engaged in the unlicensed practice of medicine; and

(2) Subject to all applicable penalties and fines in accordance with Health Occupations Article, §§14-602 and 14-607, Annotated Code of Maryland, and COMAR 10.32.02.

B. A delegating physician, through either act or omission, facilitation, or otherwise enabling or forcing an assistant to practice beyond the scope of this chapter, may be subject to discipline for grounds within Health Occupations Article, §14-404(a), Annotated Code of Maryland, including, but not limited to, practicing medicine with an unauthorized person or aiding an unauthorized person in the practice of medicine.

C. A delegating physician may not require an assistant to perform a delegated act.

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Regulation .02B amended effective September 2, 2002 (29:17 Md. R. 1380); March 14, 2016 (43:5 Md. R. 386)

Regulation .04 amended effective September 2, 2002 (29:17 Md. R. 1380)

Regulation .04D amended effective March 14, 2016 (43:5 Md. R. 386)

Regulation .04E, F amended effective March 26, 2018 (45:6 Md. R. 320)

Title 10 MARYLAND DEPARTMENT OF HEALTH

Subtitle 32 BOARD OF PHYSICIANS

Chapter 23 Permits for the Dispensing of Prescription Drugs

Authority: Health Occupations Article, §§12-102, 14-205, 14-306, 14-404, and 14-408; State Government Article, §§10-206 and 10-226; Annotated Code of Maryland

.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 of the dispensing process to others in accordance with Health Occupations Article, §§12-102 and 14-306, Annotated Code of Maryland.

.02 Definitions.

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

B. Terms Defined.

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

(2) "Controlled dangerous substance (CDS)" has the meaning stated in Criminal Law Article, §5-101(g), Annotated Code of Maryland.

(3) "Dispense" has the meaning stated in Health Occupations Article, §12-101, Annotated Code of Maryland.

(4) "Drug sample" has the meaning stated in 21 CFR §203.3 (i).

(5) Final Check.

(a) "Final check" means the verification of the accuracy and completeness of a filled prescription order by the permit holder before the drug is dispensed to the patient.

(b) "Final check" includes the assumption of responsibility for the filled prescription, including verifying the:

(i) Appropriateness of the dose;

(ii) Accurate expiration date;

(iii) Accuracy of the drug dispensed;

(iv) Strength of the drug dispensed;

(v) Labeling that complies with Health Occupations Article, §12-505, Annotated Code of Maryland; and

(vi) Appropriateness of the container in which the drug is dispensed, including child-proof containers where applicable.

(6) "In good standing" means that an individual:

(a) Holds a license to practice medicine in this State;

(b) Is not currently suspended by any order imposed by any medical licensing board;

(c) Is not currently on probation by any order imposed by any medical licensing board;

(d) Is not currently subject to any restrictions on practice related to the abuse, misuse, or improper prescribing of drugs;

(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), 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, or the Board dispensing permit:

(i) Revoked;

(ii) Suspended; or

(iii) Voluntarily relinquished or surrendered while under investigation or after being informed that an investigation will be commenced.

(7) "In the public interest" means that a pharmacy is not conveniently available to the patient.

(8) Mechanical Act.

(a) "Mechanical act" means an act which does not require professional judgment, medical or pharmaceutical training, or discretion.

(b) "Mechanical act" does not include:

(i) Selecting a drug;

(ii) Labeling;

(iii) Measuring or calculating dosages;

(iv) Substituting one drug for another, including substituting a generic or brand drug for the prescribed drug;

(v) Substituting one dosage form of a drug for another;

(vi) Altering the route of administration; or

(vii) Counseling patients.

(9) "OCSA" means the Office of Controlled Substances Administration of the Maryland Department of Health.

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

(11) "Readily retrievable" means maintained by any method by which the permit holder can retrieve and produce the record to OCSA during the course of an unscheduled on-site inspection.

(12) "Sample unit" has the meaning stated in 21 CFR §203.3 (aa).

(13) "Supplier" means:

(a) A wholesale distributor as defined in Health Occupations Article, §12-6C-01(v), Annotated Code of Maryland; or

(b) A pharmacy, to the extent permitted by Health Occupations Article, §12-406(b), Annotated Code of Maryland.

.03 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:

(1) A drug sample;

(2) A sample unit; or

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

.04 Qualifications for 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.

B. The applicant shall:

(1) State each location at which prescription drugs will be dispensed; and

(2) Grant permission to OCSA to inspect each location at which 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.

.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 permit within the last 5 years; and

C. Granting the application is in the public interest.

.06 Requirements for Permit Holders.

A. A permit holder shall comply with all federal and State statutes and regulations regarding prescription drugs, including all requirements for:

(1) Dispensing, including labeling;

(2) Storing and securing inventory;

(3) Allowing access only to authorized individuals;

(4) Managing inventory controls;

(5) Recordkeeping; and

(6) Submitting prescription monitoring data to the Maryland Prescription Drug Monitoring Program in accordance with Health-General Article, Title 21, Subtitle 2A, Annotated Code of Maryland.

B. A permit holder shall:

(1) Perform in person the final check of each 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 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 may not dispense medications by:

(1) Mail order; or

(2) A refill.

D. For the purposes of this regulation, "refill" means an additional allotment of the same drug initially authorized by the original, written prescription. "Refill" does not prohibit a permit holder from dispensing the same or different drug through an additional or subsequent, written prescription.

.07 Delegation of Dispensing Functions.

A. A permit holder may delegate to an unlicensed person only mechanical acts involved in dispensing a drug.

B. Delegation to a Physician Assistant.

(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 under Health Occupations Article, §15-302, Annotated Code of Maryland, 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) The permit holder shall perform the final check.

.08 Dispensing Prescription Drugs Prescribed by Physician Assistants.

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

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.

.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 Records.

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

(1) A copy of the dispensing permit issued by the Board;

(2) A record of each final check;

(3) A copy of the form, signed and dated by the patient, maintained in accordance with COMAR 10.13.01.04, indicating the patient's determination that a pharmacy is not conveniently available and demonstrating that the determination was made solely by the patient;

(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;

(5) A list of the name and license number of all physician assistants for whom the permit holder dispenses drugs at that location;

(6) A list of the name, license number, and specialty of all certified registered nurse practitioners for whom the permit holder dispenses drugs at that location;

(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;

(9) With respect to suppliers from whom the permit holder purchased prescription drugs:

(a) The name, address, and phone number of each supplier; and

(b) Documentation including:

(i) For any pharmacy supplier, the number and the expiration date of the pharmacy permit issued by the Maryland Board of Pharmacy and the number and expiration date of the CDS registration issued by OCSA; and

(ii) For each wholesale supplier, the number and the expiration date of the distribution permit issued by the Maryland Board of Pharmacy and the number and expiration date of the CDS registration issued by OCSA; and

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

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

C. A permit holder who dispenses CDS shall keep additional records available for inspection as required by COMAR 10.19.03.05.

.11 Revision of Dispensing Permit.

A permit holder may revise a permit twice during its term, without charge, to change the location at which prescriptions will be dispensed.

.12 Lapse of Dispensing Permit.

A. A permit automatically lapses if the permit holder:

(1) Dies;

(2) Fails to retain a valid and active Maryland medical license;

(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 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.

B. A lapsed permit may not be reinstated.

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

.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.

.14 Grounds for 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 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 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 outside the scope of this chapter;
- (5) Dispensing at a location not designated on the permit;
- (6) Being absent from the premises when prescription drugs are dispensed under the permit;
- (7) Failing to comply with the applicable requirements of the Prescription Drug Monitoring Program set out in Health-General Article, Title 21, Subtitle 2A, Annotated Code of Maryland;
- (8) Failing to cooperate with an investigation by the Board or an inspection by OCSA; or
- (9) Violating Regulations .06, .10, or .13 of this chapter.

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

(1) The surrender does not prevent the Board 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 has jurisdiction; and

(2) The permit holder may not apply for another permit again for a minimum of 5 years.

.15 Summary Suspension of Dispensing Permit.

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

B. Procedures for summary suspension shall be governed by COMAR 10.32.02.08.

.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.

.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.

.18 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 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.

.19 Interpretation.

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

Effective date: March 26, 2018 (45:6 Md. R. 320)

