

10.34.19.00

# **Title 10 DEPARTMENT OF HEALTH AND MENTAL HYGIENE**

## **Subtitle 34 BOARD OF PHARMACY**

### **Chapter 19 Sterile Pharmaceutical Compounding**

**Authority: Health Occupations Article, §§12-205, 12-403, 12-503, 12-505, 12-6C-01, and 12-6C-03, Annotated Code of Maryland**

10.34.19.01

#### **.01 Scope.**

This chapter applies to a licensed pharmacy in Maryland engaging in:

- A. Compounding or mixing sterile prescription solutions or suspensions to be administered parenterally or by irrigation, inhalation, or intraocular routes; and
- B. Compounding of radiopharmaceuticals, except where U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding—Sterile Preparations addresses radiopharmaceuticals, U.S. Pharmacopeia (USP) Chapter 821 Radioactivity, and U.S. Pharmacopeia (USP) Chapter 823 Radiopharmaceuticals for Positron Emission Tomography—Compounding would apply.

10.34.19.02

#### **.02 Incorporation by Reference.**

In this chapter, the following documents are incorporated by reference:

- A. U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding—Sterile Preparations (USP 797 Standards), which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).
- B. U.S. Pharmacopeia (USP) General Chapter 795 Pharmaceutical Compounding—Non-Sterile Preparations (USP 795 Standards), which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).
- C. U.S. Pharmacopeia (USP) Chapter 821 Radioactivity, which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).
- D. U.S. Pharmacopeia (USP) Chapter 823 Radiopharmaceuticals for Positron Emission Tomography—Compounding, which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).

10.34.19.03

### **.03 Definitions.**

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

B. Terms Defined.

(1) "Adverse event" means:

(a) Any adverse patient outcome related to the sterile compounding process; or

(b) Evidence of environmental contamination, including microbial contamination above the threshold set forth in USP 797 Standards.

(2) "Antineoplastic" means an agent that prevents the development, growth, or proliferation of malignant cells.

(3) "Anteroom" means the area, room, or rooms where personnel perform hand hygiene and garbing immediately adjacent to the designated clean room where the compounding of sterile preparations is performed.

(4) Batch.

(a) "Batch" means a preparation compounded in advance of receipt of a prescription, or a preparation compounded in a supply that will be used on more than one dispensing to a patient or patients or any preparation compounded in excess of the filling of an individual prescription.

(b) "Batch" includes a limited quantity of identical preparations compounded in a single, discrete process, by the same individuals, carried out during one limited time period.

(5) "Biological safety cabinet" means a containment unit:

(a) Suitable for work involving agents that pose higher risk of exposure to operators during compounding; and

(b) Used when there is a need for protection of the preparation, personnel, and environment.

(6) "Clean room" means a room with an International Standards Organization (ISO) Class 5 environment or an ISO Class 7 environment that meets USP 797 Standards, inside which compounding occurs within an ISO Class 5 engineering control device such as a laminar airflow workstation or a biological safety cabinet.

(7) "Closed system vial transfer device (CSTD)" means a closed system drug transfer device that mechanically, not by means of vents or filters, prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug aerosols or vapors into the environment.

(8) "Compounded sterile preparation" means sterile medication preparations, such as intravenous, epidural, and intraocular medications, compounded in the pharmacy using currently accepted aseptic compounding techniques under acceptable compounding conditions.

(9) "Compounding" means the preparation, mixing, assembling, packaging, or labeling of a drug:

(a) As the result of a practitioner's prescription drug order or initiative based on the practitioner/patient relationship in the course of professional practice;

(b) For the purpose of, or incidental to, research, teaching, or chemical analysis and not for the sale or dispensing of the drug or device; or

(c) In anticipation of a prescription drug order based on routine, regularly observed prescribing patterns.

(10) "Compounding aseptic isolator" means an enclosed positive or negative pressure environment especially designed for sterile preparation compounding that maintains a physical barrier between the workspace and the operator.

(11) "Controlled environment" means a designated area for compounding sterile preparations that consists of a clean room and an anteroom.

(12) "Cytotoxic" means drug entities that are damaging or debilitating to cells, tissues, or organs.

(13) "Designee" means a public agency or private entity trained in:

(a) USP 797 Standards;

(b) FDA good manufacturing practices approved by the Board to conduct inspections of nonresident pharmacies that perform sterile compounding; or

(c) Both §B(13)(a) and (b) of this regulation.

(14) "Laminar air flow workstation" means an ISO Class 5 ("Class 100") laminar airflow hood inside which sterile compounding occurs.

(15) "Media fill verification" means a process of practical examination to verify the aseptic technique of personnel or an aseptic process by manual manipulation of microbiological growth media which simulates compounding processes and techniques used in actual compounding procedures.

(16) "Parenteral" means routes of drug administration or fluid administration other than via the gastrointestinal tract.

(17) "Pharmacist" means an individual who is licensed to practice pharmacy regardless of the location where the activities of practice are performed.

(18) "Pharmacy" means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed.

(19) "Pyrogen testing" means an analysis of sterile preparations for the presence of cell material from microbiological organisms in sufficient quantity to elicit a febrile reaction.

(20) "Risk level" means a risk level of low, medium, or high as defined in USP 797 Standards.

(21) "Sterile" means free from living microorganisms or any other contaminants.

(22) "Sterile compounding" means compounding of biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797 Standards, are prepared using aseptic techniques.

(23) "Total parenteral nutrition" means providing caloric needs by the parenteral route for a patient who is unable to ingest sufficient calories.

(24) "USP 795 Standards" means standards set forth in the US Pharmacopeia (USP) General Chapter 795 Pharmaceutical Compounding—Non-Sterile Preparations.

(25) "USP 797 Standards" means standards set forth in the U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding—Sterile Preparations.

*10.34.19.04*

#### **.04 Pharmacy Environment.**

The compounding, preparation, and dispensing of compounded sterile preparations shall be accomplished in a pharmacy environment subject to State and federal laws, regulations, and standards.

*10.34.19.05*

#### **.05 General Requirements.**

A licensed pharmacist who has appropriate practical and didactic training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical application of intravenous drug therapy shall control and supervise the section of the pharmacy that prepares compounded sterile preparations and is responsible for, at a minimum, the following:

- A. Preparation of compounded sterile preparations within the pharmacy or decentralized pharmacy;
- B. Storage of materials pertinent to the preparation of compounded sterile preparations, including drugs, chemicals, and biologicals, and the establishment of specifications for procurement of the materials;
- C. Labeling of containers of compounded sterile preparations compounded within the pharmacy;
- D. Recording of transactions of the pharmacy as may be applicable to State and federal laws and regulations, as may be necessary to maintain accurate control over, and accountability for, pharmaceutical materials; and
- E. Ensuring that licensed pharmacists meeting the requirements of §A of this regulation, or registered pharmacy technicians under direct supervision of a licensed pharmacist meeting the requirements of §A of this regulation, prepare, compound, and dispense compounded sterile preparations.

*10.34.19.06*

#### **.06 Special Handling, Packaging, Labeling, and Beyond Use Dating.**

A. The pharmacy shall make available special handling and packaging materials to maintain container integrity and drug stability of the prepared prescription orders, including antineoplastic or other hazardous sterile preparations, during handling and administration to the patient including:

- (1) A reasonable effort to provide tamper-evident packaging if appropriate to setting;
- (2) Proper in-transit storage consistent with preparation labeling; and
- (3) Delivery to the patient within a reasonable time.

B. The dispensed container for any compounded sterile preparation shall include labeling according to Maryland law and regulations, in addition to the following information that is required by federal law:

- (1) The date of preparation unless otherwise readily retrievable from prescription records;
- (2) Time prepared, if applicable;
- (3) The pertinent requirements for proper storage;
- (4) The name of the prescriber, unless in an inpatient hospital setting;
- (5) The name of the patient;
- (6) Directions for use;
- (7) The name of the base solution for infusion preparations;
- (8) The name and concentration or amount of active drugs contained in the final sterile preparation;
- (9) The name or identifying initials of the pharmacist who checked or prepared the compounded sterile preparation unless otherwise readily retrievable from prescription records;
- (10) The name, address, and telephone number of the pharmacy unless in an inpatient hospital facility;
- (11) The beyond-use/expiration dating and time of the compounded sterile preparation, and if no time is stated, the time is presumed to be at 11:59 p.m. of the stated beyond use date;
- (12) Any ancillary and cautionary instructions as needed; and
- (13) A pertinent warning consistent with applicable federal and State law that cytotoxic preparations are biohazardous, when applicable.

C. A pharmacy compounding sterile infusion preparations shall provide a 24-hour telephone number to allow its patients or other health care providers who may be administering its prescriptions to contact its pharmacists.

D. Expiration or Beyond-Use Dating. In the absence of direct testing evidence, as detailed in the Stability Criteria and Beyond Use Dating section of USP 795 Standards, the pharmacist shall use "beyond-use dating" as determined by USP 797 Standards and reference materials as cited in Regulation .16 of this chapter.

*10.34.19.07*

## **.07 Record-Keeping Requirements.**

A. Patient Prescription Records.

- (1) The pharmacy shall maintain records of patient prescriptions.
- (2) Patient prescription records shall contain:
  - (a) Available medical information consistent with prevailing pharmacy standards; and

- (b) The complete record of the formulations of the solutions that were compounded.
- (3) The pharmacy shall keep completed patient prescription records in a retrievable manner for at least 5 years, either:
  - (a) At the inspection site; or
  - (b) So as to be immediately retrievable by computer or other electronic means.

B. Compounded Sterile Preparations Records.

(1) For a pharmacy preparing compounded sterile preparations, the following records shall be maintained for at least 5 years:

- (a) The training and competency evaluation of employees in sterile preparation procedures;
- (b) Refrigerator and freezer temperatures;
- (c) Certification of the sterile compounding environment, including ISO 5 workstations and the clean and anterooms;
- (d) Other facility quality control logs specific to the pharmacy's policies and procedures, for example, cleaning logs for facilities and equipment;
- (e) Records documenting inspection for expired or recalled pharmaceutical preparations or raw ingredients;
- (f) Preparation records including compounding work sheets, and records of the registered pharmacy technicians' checking/sign-off process; and
- (g) Preparation records including compounding work sheets and records of the pharmacists' checking/sign-off process.

(2) In addition to the records requirement in §B(1) of this regulation, for batch compounded sterile preparations, a pharmacy compounding sterile batch preparations for future use shall have records indicating the:

- (a) Drug and ingredient names;
- (b) Lot numbers;
- (c) Expiration dates;
- (d) Drug/diluent amounts; and
- (e) Date on which the compounded sterile batch preparations were prepared.

(3) A pharmacy shall maintain records of media fill verification results for 5 years.

10.34.19.08

### **.08 Batch Preparation.**

A. A pharmacist may prepare batched sterile preparations for future use in limited quantities supported by prior valid prescriptions or physician orders before receiving a valid written prescription or medication order.

B. Batch preparation of specific compounded sterile preparations is acceptable if the:

(1) Pharmacist can document a history of valid prescriptions or physician orders that have been generated solely within an established professional prescriber-patient-pharmacist relationship; and

(2) Pharmacy maintains the prescription on file for such preparations dispensed.

10.34.19.09

### **.09 Minimum Facility Requirements.**

A. Controlled Environment.

(1) The pharmacy shall have a controlled environment that meets USP 797 Standards.

(2) A pharmacist shall ensure that the controlled environment is:

(a) Accessible only to designated personnel; and

(b) Used only for the preparation of compounded sterile preparations, or such other tasks that require a controlled environment.

(3) The permit holder shall ensure that the controlled environment is:

(a) Structurally isolated from other areas within the pharmacy by means of restricted entry or access; and

(b) Air conditioned to maintain a temperature of the controlled environment according to USP 797 standards.

B. Controlled Environment — Clean Room. The permit holder shall ensure that the clean room in the controlled environment:

(1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for clean rooms;

(2) Contains no sinks or floor drains;

(3) Contains work surfaces constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that the work surfaces may be readily cleaned and sanitized;

(4) If cytotoxic agents are routinely used in compounding preparations, contains room or rooms equipped with special pressurization requirements consistent with USP 797 Standards and the National Institute for Occupational Safety and Health (NIOSH) standards;

(5) Has in place appropriate environmental engineering control devices capable of maintaining USP 797 air-quality standards during normal compounding activity; and

(6) Contains the following equipment:

(a) A laminar airflow workstation or other suitable International Standards Organization (ISO) Class 5 compounding environment;

(b) Waste containers that are approved by Occupational Safety and Health Administration (OSHA) for used needles and syringes, and for chemotherapy waste; and

(c) Ancillary supplies required for proper compounding.

C. Controlled Environment — Anteroom. The permit holder shall ensure that the anteroom in the controlled environment:

(1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for anterooms; and

(2) Contains the following equipment:

(a) A sink with hot and cold running water;

(b) Waste containers for personal protective equipment;

(c) An eyewash station or sink design suitable for flushing an eye injury; and

(d) A hazardous waste spill kit, if applicable.

D. The requirements specified in §§B(1) and C(1) of this regulation are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with the:

(1) Compounding aseptic isolator conditions set forth in USP 797 Standards; and

(2) Isolator vendor or manufacturer specifications.

*10.34.19.10*

## **.10 Minimum Requirements for Equipment.**

A. The permit holder shall provide at least the following equipment that is maintained in working order:

(1) Adequate refrigerator and freezer space (if applicable);

(2) A sink and wash area in the anteroom;

(3) Appropriate waste containers for:

(a) Used needles and syringes; and

(b) Cytotoxic waste including disposable apparel used in its preparation, if applicable;

(4) Laminar air flow workstation or compounding aseptic isolator that meets USP 797 Standards, dedicated for products other than antineoplastics;



(5) If applicable to types of preparations compounded, biological safety cabinet, or compounding aseptic isolator that meets USP 797 Standards, dedicated for use with antineoplastics or other hazardous sterile preparations;

(6) Appropriate filters and filtration equipment; and

(7) A device for light/dark field examination.

B. If used, the permit holder shall provide the following equipment that is maintained in working order, calibrated, or certified where appropriate:

(1) Autoclave;

(2) Automated compounding devices (for example, total parenteral nutrition compounding pumps);

(3) Electronic balance;

(4) Convection oven;

(5) Thermometers or other temperature device; and

(6) Incubator.

*10.34.19.11*

## **.11 Minimum Requirements for Supplies.**

A pharmacy engaging in compounding sterile preparations shall maintain adequate stock levels of the following supplies according to USP 797 Standards, including but not limited to:

A. Personal protective equipment:

(1) Sterile gloves;

(2) Masks;

(3) Non-shedding gowns;

(4) Shoe covers;

(5) Hair covers;

(6) Beard covers; and

(7) Other personal protective equipment;

B. Disposable syringes and needles in necessary sizes;

C. Disinfectant cleaning agents as specified in USP 797 Standards, including 70 percent sterile isopropyl alcohol;

D. Disposable lint free towels;

- E. Hand washing materials, including antimicrobial skin cleanser;
- F. Adequate equipment and materials for antineoplastic or cytotoxic agent spills;
- G. Supplies necessary for the aseptic preparation of compounded sterile preparations; and
- H. Closed system vial transfer devices (CSTD), as required for cytotoxic compounding, if applicable.

10.34.19.12

## **.12 Minimum Requirements for Policies and Procedures.**

A. The permit holder shall ensure that the pharmacist or the pharmacist's designee shall maintain a policy and procedure manual, reviewed annually, that sets forth in detail the permit holder's standard operating procedures with regard to compounding sterile preparations.

B. The permit holder shall insure that the policy and procedure manual that sets forth the standard operating procedures with regard to compounding sterile preparations is implemented and adhered to.

C. The policy and procedure manual shall include policies and procedures governing the following:

(1) A risk-management program which includes documentation of outcomes including, but not limited to:

(a) An incident reporting system;

(b) An adverse drug reaction reporting system; and

(c) A preparation contamination reporting system;

(2) Security measures ensuring that the premises where sterile compounded preparations are stored and prepared are secured, to prevent access by unauthorized personnel;

(3) Equipment including, but not limited to:

(a) Procedures for use;

(b) Documentation of appropriate certifications; and

(c) Documentation of appropriate calibration and preventive maintenance if applicable;

(4) Sanitation standards and procedures including monitoring for bacterial microorganisms to demonstrate effectiveness of cleaning activities;

(5) Reference materials as set forth in Regulation .16 of this chapter;

(6) Information concerning drug:

(a) Preparation;

(b) Storage and handling;

(c) Dispensing;

(d) Labeling;

(e) Beyond-use/expiration dating;

(f) Delivery;

*10.34.19.12*

(g) Destruction;

(h) Recalls; and

(i) Returns;

(7) Patient record keeping as set forth in Regulation .07 of this chapter;

(8) Handling, dispensing, and documentation of investigational drugs;

(9) A quality assurance program;

(10) Verification of training and competency guidelines;

(11) Compounding process media fill verification procedures;

(12) Description of appropriate garb;

(13) Conduct guidelines for personnel in the controlled areas;

(14) Personnel responsibilities;

(15) Patient education, if appropriate;

(16) Protocol and procedures to maintain the integrity of the interior work area of the laminar air flow workstations;

(17) Written procedures as applicable for handling antineoplastic agents and other hazardous substances including:

(a) Utilizing the proper equipment and supplies;

(b) A statement that compounding shall be conducted within a properly certified biological safety cabinet or negative pressure compounding aseptic isolator;

(c) Proper use of protective attire; and

(d) Proper techniques to prevent both contamination of the preparation and chemical exposure of the individual preparing the prescription;

(18) Written procedures as applicable for the disposal of infectious materials or materials containing cytotoxic residues, or hazardous waste;

(19) Written documentation of policy and procedure changes based on data gathered from quality assurance evaluations; and

(20) Written documentation of policies and procedures assuring the sterility and stability of compounded sterile preparations.

*10.34.19.13*

### **.13 Attire.**

A. When compounding sterile preparations, individuals shall comply with the following standards:

- (1) Sequencing of garbing that complies with USP 797 Standards;
- (2) Thorough hand-washing before gowning;
- (3) Wearing clean room garb inside the designated area at all times, which consists of:
  - (a) A non-shedding coverall or gown;
  - (b) Head and facial hair covers;
  - (c) A face mask; and
  - (d) Shoe covers;
- (4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area;
- (5) All jewelry shall be removed;
- (6) Sterile gloves are required; and
- (7) Make-up may not be worn in the clean room.

B. The requirements of this regulation are not applicable if a compounding aseptic isolator is used to compound sterile preparations in accordance with USP 797 Standards and isolator vendor/manufacturer specifications.

*10.34.19.14*

### **.14 Training of Staff, Patient, and Caregiver.**

A. The pharmacist shall make counseling available to the patient or primary caregiver, or both, concerning proper use of compounded sterile preparations and related supplies furnished by the pharmacy.

B. The permit holder shall ensure that pharmacy personnel engaging in compounding sterile preparations are trained and demonstrate competence in the safe handling and compounding of compounded sterile preparations and parenteral solutions, including cytotoxic agents if applicable.

C. The permit holder shall maintain records of training and demonstrated competence for individual employees for 5 years.

D. The permit holder shall ensure the continuing competence of pharmacy personnel engaged in compounding sterile preparations.

E. A pharmacy that compounds sterile preparations shall comply with the following training requirements:

(1) The pharmacy shall establish and follow a written program of training and performance evaluation designed to ensure that individuals working in the designated area have the knowledge and skills necessary to perform the assigned tasks properly and include at least the following:

(a) Aseptic technique with media fill verification at a frequency defined by risk level as described in USP 797 Standards:

(i) 12 months for low and medium risk; and

(ii) 6 months for high risk;

(b) Pharmaceutical calculations and terminology;

(c) Compounding sterile preparation documentation process;

(d) Quality assurance procedures;

(e) Aseptic preparation procedures;

(f) Proper cleansing, gowning, and gloving techniques;

(g) General conduct in the controlled area;

(h) Cleaning, sanitizing, and maintaining equipment used in the controlled area;

(i) Sterilization techniques for high risk preparations; and

(j) Container, equipment, and closure system selection.

(2) Individuals assigned to the controlled area shall successfully complete practical skills training in aseptic technique and aseptic area practices.

(3) Evaluations shall include:

(a) Written testing;

(b) Observation for adherence to aseptic technique and aseptic area policies and procedures; and

(c) Media fill verification as set forth in §E(1)(a) of this regulation.

*10.34.19.15*

## **.15 Quality Assurance.**

The permit holder shall ensure that the compounded sterile preparation retains its potency and sterility throughout the assigned "beyond use" dating period through a written quality assurance program that includes:

- A. A reasonable effort by the pharmacist to assure that compounded sterile preparations shall be kept under appropriate controlled conditions before dispensing, during transport, and at the location of use by providing adequate labeling and verbal or written instructions regarding proper storage and administration, as set forth by the product manufacturer and established standards and literature, with each compounded sterile preparation dispensed;
- B. The phases of compounded sterile preparation, distribution, storage, administration, and directions for use for each type of preparation dispensed;
- C. Environmental sampling for microbial organisms in laminar air flow workstations and clean rooms is performed according to methods and schedules specified by USP 797 Standards and if microbial contamination is suspected, for example, in the event of positive media fill verification results;
- D. Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators certified by a trained and qualified operator;
- E. Clean room and anteroom certification by a trained and qualified operator according to USP 797 Standards;
- F. The proper disposal in accordance with accepted professional standards and applicable State and federal laws of unused drugs and materials used in the preparation of compounded sterile preparations, including antineoplastic agents and hazardous materials;
- G. A formal written review process to report and evaluate compliance with this chapter; and
- H. A process that complies with applicable USP 797 Standards for performing sterility checks or pyrogen testing, or both, for applicable compounded sterile preparations.

*10.34.19.16*

### **.16 Reference Library.**

Minimum reference materials in a pharmacy shall include:

- A. U.S. Pharmaceutical, General Chapter 797, Pharmaceutical Compounding—Sterile Preparations and other applicable reference materials in order to perform sterile compounding;
- B. Reference materials containing drug stability and compatibility data; and
- C. Reference materials concerning drug interactions and incompatibility.

*10.34.19.17*

### **.17 Minimum Requirements for Inspections.**

- A. The Board shall inspect pharmacies located in Maryland at least annually.
- B. The pharmacy shall provide as part of the inspection process:
  - (1) Quality assurance testing reports;

- (2) Documentation of reporting adverse events as required in Regulation .18 of this chapter;
- (3) Microbial testing of a sampling of the sterile compounded preparations of the pharmacy if applicable according to USP 797 Standards; and
- (4) Any other information requested to ensure compliance with USP 797 Standards.

C. Within 90 days before the date of application, inspections of nonresident pharmacies may be conducted by:

- (1) A designee of the Board;
- (2) The U.S. Food and Drug Administration; or
- (3) Another appropriate state entity which indicates compliance with USP 797 Standards.

D. The Board or designee shall inspect nonresident pharmacies upon initial application and upon renewal.

E. The Board may inspect a pharmacy at any time to:

- (1) Verify compliance with permit requirements; or
- (2) Investigate a complaint.

*10.34.19.18*

## **.18 Reporting Requirements Pharmacies.**

A pharmacy shall:

A. Document and perform routine testing as required by USP 797 Standards for the appropriate risk levels of sterile compounded preparations; and

B. Report to the Board within 5 calendar days:

- (1) Adverse events that have been discovered including corrective actions taken or proposed;
- (2) Deficiencies related to the sterile compounding process;
- (3) Disciplinary actions in other states or by other state agencies;
- (4) Changes in accreditation status;
- (5) Disciplinary actions taken against a pharmacist who is an owner, operator, or employee of the pharmacy; and
- (6) Disciplinary actions taken against any other known permit, or any other authorization, held by the pharmacy permit holder.

*10.34.19.19*

## **.19 Office Use.**

Unless otherwise authorized, a person that prepares and distributes sterile compounded medications for office use into, out of, or within the State shall hold:

A. A manufacturer's permit or other permit designated by the U.S. Food and Drug Administration to ensure the safety of sterile compounded medications for office use; and

B. If applicable, a wholesale distributor's permit, issued by the Board under Health Occupations Article, Title 12, Subtitle 6C, Annotated Code of Maryland.

*10.34.19.9999*

#### Administrative History

Effective date: February 19, 1990 (17:3 Md. R. 299)

Regulation .04B amended effective July 20, 1992 (19:14 Md. R. 1284)

Regulation .05 amended effective July 20, 1992 (19:14 Md. R. 1284)

---

Regulations .01—.06 repealed and new Regulations .01—.16 adopted effective September 10, 2007 (34:18 Md. R. 1580)

Regulation .01 amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .02 amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .03B amended effective February 23, 2009 (36:4 Md. R. 354); February 1, 2016 (43:2 Md. R. 127)

Regulation .05A amended effective February 1, 2016 (43:2 Md. R. 127)

Regulation .06A amended effective February 1, 2016 (43:2 Md. R. 127)

Regulation .06A, D amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .07A amended effective February 1, 2016 (43:2 Md. R. 127)

Regulation .09 amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .09A amended effective February 1, 2016 (43:2 Md. R. 127)

Regulation .10 amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .11 amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .13 amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .14E amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .15C, E amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .16A amended effective February 23, 2009 (36:4 Md. R. 354)

Regulation .17 adopted effective February 1, 2016 (43:2 Md. R. 127)



Regulation .18 adopted effective February 1, 2016 (43:2 Md. R. 127)

Regulation .19 adopted effective February 1, 2016 (43:2 Md. R. 127)