Maryland Board of Pharmacy
Public Board Meeting

Agenda
March 20, 2024

Name	Title	Present	Absent
Evans, K.	Commissioner		
Fink, K.	Commissioner		
Geigher, P.	Commissioner/Treasurer		
Hardesty, J.	Commissioner		
Leikach, N.	Commissioner/President		
Morgan, K.	Commissioner		
Oliver, B.	Commissioner		
Oriaifo, A.	Commissioner		
Patel, A.	Commissioner		
Robinson, D.	Commissioner/Pharmacy Technician		
Rusinko, K.	Commissioner/Secretary		
Slagle, K.	Commissioner		
Vázquez, J.	Commissioner		
Bethman, L.	Board Counsel		
Felter, B.	Board Counsel		
Speights-Napata, D.	Executive Director		
Partin, J.	Network Specialist		
James, D.	Licensing Manager		
Leak, T.	Compliance Director		
Reed, J.	Legislative Liaison		
Chew, C.	Enforcement Compliance Auditor		

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
I. Executive Committee Report(s)	**A.) N. Leikach, Board President** **B.) K. Rusinko, Secretary**	*Members of the Board with a conflict of interest relating to any item on the agenda are advised to notify the Board at this time or when the issue is addressed in the agenda.* **1. Call to Order** **2. Sign-in Introduction and of meeting attendees** – *(Please indicate on sign-in sheet if you are requesting CE Units for attendance)* **3. Distribution of Agenda and packet materials** **4. Review and approve February 2024 Public Meeting Minutes**	
II. A. Executive Director Report	**D. Speights-Napata Executive Director**	**1. Meeting Update** **2. Staff Update**	
B. New Business	**N. Leikach, Board President**		
C. Operations	**J. Partin, Network Specialist**	**1. Procurement and Budget Updates** **a. February Financials – Paper copies distributed** **2. Management Information Systems (MIS) Unit Updates**	
D. Licensing	**K. Rusinko**	**1. Unit Updates** **2. Monthly Statistics**	

<table>
<tr><th>Subject</th><th>Responsible Party</th><th>Discussion</th><th>Action Due Date (Assigned To)</th></tr>
<tr><td></td><td></td><td>
<table>
<tr><th>License Type</th><th>New</th><th>Renewed</th><th>Reinstated</th><th>Total</th></tr>
<tr><td>Distributor</td><td>7</td><td>2</td><td>0</td><td>1,496</td></tr>
<tr><td>Pharmacy</td><td>17</td><td>0</td><td>1</td><td>2,094</td></tr>
<tr><td>Pharmacist</td><td>43</td><td>404</td><td>7</td><td>12,702</td></tr>
<tr><td>Vaccination</td><td>11</td><td>186</td><td>0</td><td>5,341</td></tr>
<tr><td>Pharmacy Intern - Graduate</td><td>3</td><td>0</td><td>0</td><td>36</td></tr>
<tr><td>Pharmacy Intern – Student</td><td>5</td><td>5</td><td>0</td><td>386</td></tr>
<tr><td>Pharmacy Technician</td><td>138</td><td>298</td><td>11</td><td>10,429</td></tr>
<tr><td>Pharmacy Technician- Student</td><td>1</td><td>0</td><td>0</td><td>38</td></tr>
<tr><td>TOTAL</td><td>225</td><td>895</td><td>19</td><td>32,522</td></tr>
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<tr><td>E. Compliance</td><td>T. Leak, Compliance Director</td><td>1. Unit Updates
2. Monthly Statistics
Complaints & Investigations:
New Complaints – 53
• Refusal to Fill - 1</td><td></td></tr>
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		● Unprofessional Conduct - 1 ● Inspection Issues- 31 ● Medication Error - 2 ● Customer Service- 6 ● Licensing Issues- 3 ● Employee Pilferage- 3 ● Out of State Disciplinary Actions - 6 Resolved - 39 Actions within Goal- 39/39 Formal (Final) Disciplinary actions taken- 1 Summary Actions Taken- 0 Average Days to Complete- N/A **Regulatory Inspections:** Total - **132** Annual Inspections - **114** ● Chain - 51 ● Independent - 18 ● Sterile Compounding - 5 ● Repository - 23 ● Comprehensive Care - 4 ● Hospital - 6 ● Supplemental Assisted Living - 3 ● Follow up - 0 ● Distributor - 3 ● Attempted- 1 Openings/Remodels/Relocations - **6** Closing Inspections - **5** Change of Ownership - **7** **Pending Opening – 1** **Pending Closing - 2**	

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F. Legislation & Regulations	**J. Reed, Legislative Liaison**	**Legislation** • HB 880 (SB 1021) – Pharmacy Benefits Administration - Maryland Medical Assistance Program and Pharmacy Benefits Managers – No position. • HB 1097 – State Board of Veterinary Medical Examiners - Veterinary Technicians and Veterinary Assistants – No position. • HB 1121 – Public Health – Opioids and Opioid Overdose Reversal Drugs – Information – No position. • HB 1132 – Drugs, Biological Products, and Devices – Off-Label Use – Promotion – No position. • HB 1201 (SB 1072) – Occupational and Professional Licensing - Military Training and Military Spouses – Letter of Information. • HB 1260 (SB 926) – State Government – Permits, Licenses, and Certificates – Reimbursement – No position. • HB 1270 (SB 1019) – Health Benefits Plans – Prescription Drugs – Rebates and Calculations of Cost Sharing – No position. • HB 1388 (SB 1182) – Labor and Employment – Noncompete and Conflict of Interest Clauses – Veterinary and Health Care Professionals – Letter of Information. • HB 1304 – Maryland Department of Health and Department of Human Services – Earned Income Tax Credit – Distribution of Information – No position. • SB 926 – State Government – Permits, Licenses, and Certificates – Reimbursement – No position. **Regulations** **Proposed COMAR 10.34.19.00** **Title 10 MARYLAND DEPARTMENT OF HEALTH** **Subtitle 34 BOARD OF PHARMACY** **Chapter 19 Sterile Pharmaceutical Compounding**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Authority: Health Occupations Article, §§12-205, 12-403, 12-503, 12-505, 12-6C-01, and 12-6C-03, Annotated Code of Maryland **.01 Scope.** This chapter applies to a **[**licensed**]** pharmacy **licensed** 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**] injections or by infusion, irrigations for internal body cavities, ophthalmic, pulmonary inhalation, baths and soaks for live organs and tissues, or implant routes and;** **B. Compounding of Hazardous Drugs, except where U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding—Sterile Preparations addresses Hazardous drugs, and U.S. Pharmacopeia (USP) Chapter 800 Hazardous Drugs—Handling in Healthcare Settings would apply.** **[**B.**] C.** 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**,] and USP Chapter 825 Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging** would apply**; and** **.02 Incorporation by Reference.** **1.** 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).**]** **B. U.S. Pharmacopeia (USP) General Chapter 800 Hazardous Drugs—Handling in Healthcare Settings (USP 800 Standards), which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).**	

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		[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).**]** **C. U.S. Pharmacopeia (USP) Chapter 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, which has been incorporated by reference in 21 U.S.C. §351(b) (as amended).** **2. The Board may reference guidance documents issued by the United States Food and Drug Administration (FDA) when inspecting and reviewing compounding practices not specifically outlined in this Chapter or a chapter of U.S. Pharmacopeia.** **.03 Definitions.** A. In this chapter, the following terms have the meanings indicated. B. Terms Defined. **(1) "Active Pharmaceutical Ingredient (API)" means any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as Bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).** **[**(1)**] (2)** "Adverse event" means: (a) Any adverse patient outcome related to the sterile compounding process; or	

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		(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.**] "Anteroom" means an ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transition room between the unclassified area of the facility and the buffer room.** (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)**] (a)** "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) "Beyond-Use Date (BUD)" means the date, or hour and the date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.** **[**(5)**] (6)** "Biological safety cabinet **(BSC)**" means a **ventilated** containment unit: (a) Suitable for work involving agents that pose higher risk of exposure to operators during compounding; and	

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		(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) “Cleanroom suite” means a classified area that consists of both an anteroom and buffer room.** **(8) “Buffer room” means an ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.** **[**(7)**] (9) [**"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.**] “Closed-system drug-transfer device (CSTD)” means drug-transfer device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of HD or vapor concentrations outside the system.** **[**(8)**] (10) [**"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.**] “Compounded sterile preparation (CSP)” means a preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, assembling or otherwise altering a drug product or bulk drug substance.** **[**(9)**] (11) [**“Compounding” means the preparation, mixing, assembling, packaging, or labeling of a drug:**] “Compounding” means the process of combining, admixing, diluting, pooling, reconstituting, repackaging, assembling or otherwise altering a drug product or bulk drug substance to create a sterile preparation:**	

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		(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)**] (12) [**"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.**] "Compounding aseptic isolator (CAI)" means a type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.** **(13) "Compounding aseptic containment isolator (CACI)" means a type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.** **[**(11)**] (14) [**"Controlled environment" means a designated area for compounding sterile preparations that consists of a clean room and an anteroom.**] "Classified Area" means an area that maintains an air quality classification based on the ISO standards required in by USP 797.** **[**(12) "Cytotoxic" means drug entities that are damaging or debilitating to cells, tissues, or organs.**]** **[**(13)**]** (**15)** "Designee" means a public agency or private entity **recognized by the Board to conduct Sterile Compounding Inspections that is** 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

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		(c) Both §B(13)(a) and (b) of this regulation. **(16) "Expiration" means the time period during which a manufactured product is expected to remain stable, or retain its identity, strength, quality, and purity, when it is properly stored according to its labeled storage conditions.** **(17) "Hazardous Drug (HD)" means a drug included on the National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs in healthcare settings, which are identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.** **(18) "ISO class" means an air-quality classification from the International Organization for Standardization.** **[**(14)**] (19) [**"Laminar air flow workstation" means an ISO Class 5 ("Class 100") laminar airflow hood inside which sterile compounding occurs.**] "Laminar airflow workbench (LAFW)" means a device that is a type of laminar airflow system that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.** **(20) "Laminar airflow system (LAFS)" means device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.** **[**(15)**] (21) [**"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.**] "Media-fill test" means a simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.**	

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		(22) "NIOSH List" means the National Institute for Occupational Safety and Health (NIOSH) maintained list of antineoplastic and other HDs used in healthcare. **[**(16)**] (23)** "Parenteral" means routes of drug administration or fluid administration other than via the gastrointestinal tract. **[**(17)**] (24)** "Pharmacist" means an individual who is licensed to practice pharmacy regardless of the location where the activities of practice are performed. **[**(18)**] (25)** "Pharmacy" means an establishment in which prescription or nonprescription drugs or devices are compounded, dispensed, or distributed. **(26) "Primary Engineering Control (PEC)" means a device or zone that provides an ISO Class 5 air quality environment for sterile compounding.** **[**(19)**] (27)** "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.**]** **(28) "Restricted-access barrier system (RABS)" means an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations.** **(29) Secondary Engineering Control (SEC)" means a space which provides a classified area where primary engineering controls are placed.** **[**(21)**] (30)** "Sterile" means free from **[**living microorganisms or any other contaminants**] viable microorganisms**.	

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		[(22)**] (31) [**"Sterile compounding" means compounding of biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals that, under USP 797 Standards, are prepared using aseptic techniques.**] "Sterile compounding" means the process of combining, admixing, diluting, pooling, reconstituting, repackaging, assembling or otherwise altering a drug product or bulk drug substance to create a preparation using aseptic techniques following UPS 797 standards.** **[**(23)**] (32)** "Total parenteral nutrition" means providing **[**caloric**] nutritional** 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)**] (33)** "USP 797 Standards" means standards set forth in the U.S. Pharmacopeia (USP) General Chapter 797 Pharmaceutical Compounding—Sterile Preparations. **(34) "USP 800 Standards" means standards set forth in USP General Chapter 800 Hazardous Drugs—Handling in Healthcare Settings.** **(35) "USP 825 Standards" means standards set forth in USP General Chapter 825 Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging.** **.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. **.05 General Requirements.** A licensed **supervising** pharmacist who has appropriate practical and didactic training in compounding sterile preparations, clean room technology, laminar flow technology, quality assurance techniques, and clinical	

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		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**] CSPs** within the pharmacy or decentralized pharmacy; B. Storage of materials pertinent to the preparation of **[**compounded sterile preparations**] CSPs**, including drugs, chemicals, and biologicals, and the establishment of specifications for procurement of the materials; C. Labeling of containers of **[**compounded sterile preparations**] CSPs** compounded within **or dispensed by** 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.**] An initial and ongoing training and competency program for all staff with duties within the cleanroom in accordance with USP 797 and Regulation .14 of this Chapter.** **F. Engineering controls and equipment utilized for compounding meet the standards of USP 797 and Regulation .09 of this Chapter.** **G. Policies and procedures, as listed in USP 797 and Regulations .12 of this Chapter, are implemented, maintained, and reviewed on an annual basis; and** **H. A quality assurance and quality control program to monitor:** **a. Adherence to policies and procedures;** **b. Prevention and detection of errors and quality issues;**	

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		c. Investigation of complaints and reported adverse events; **d. Corrective actions and recall programs.** **.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 **on CSPs [**if appropriate to setting**]**; (2) Proper in-transit storage consistent with preparation labeling; **[**and**]** **(3) For medications not distributed to a Healthcare Practitioner Intermediary, enclose information to inform the patient if the prescription is a temperature sensitive medication that is at risk for damage due to extreme hot or cold temperatures or moisture; and** **[**(3)**] (4)** Delivery to the patient within a reasonable time. B. The dispensed container for any **[**compounded sterile preparation**] CSP** 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 **the** 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;	

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		(6) Directions for use; (7) The name of the base solution for infusion preparations; (8) The **full** name and concentration or amount of active drugs contained in the final sterile preparation; (9) The name or identifying initials of the **[**pharmacist**] individual** who **[**checked or**]** prepared **[**the compounded sterile preparation**] and pharmacist who checked the CSP** 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**]** dat**[**ing**]e** and time of the **[**compounded sterile preparation**] CSP**, 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**] of the presence of hazardous drugs including instructions for safe handling and proper disposal**. 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.**]** D. **[**Expiration or Beyond-use Dating**] Beyond-use Dates. [**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	

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		"beyond-use dating" as determined by USP 797 Standards and reference materials as cited in Regulation .16 of this chapter.**]** **(1) A pharmacy shall use timeframes for BUDs as determined by USP 797 Category 1 or 2 Standards; and** **(2) BUDs greater than those set forth in USP 797 Category 1 or 2 Standards shall comply with USP 797 Category 3 Standards and appropriate reference materials cited in Regulation .16 of this Chapter.** **.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:	

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		(a) The training and competency evaluation of employees in sterile preparation procedures; (b) **[**Refrigerator and freezer temperatures**] The training and competency evaluation of non-pharmacy employees responsible for the maintenance and cleaning of the cleanroom**; **[**(b)**] (c)** Refrigerator and freezer temperatures; **(d) Incubator temperatures when in use;** **[**(c)**] (e)** Certification of the **[**sterile compounding environment**] classified area**, including ISO 5 workstations, **[**and the clean and anterooms**] cleanrooms, and other controlled rooms, for example, HD storage areas**; **[**(d)**] (f)** Other **daily** facility quality control logs specific to the pharmacy's policies and procedures, for example, cleaning logs for facilities and equipment**, cleanroom pressures, temperature and humidity**; **(g) Trending of microbiological growth and actions taken for adverse trending;** **(h) Investigations, corrective actions, and preventative measures for any adverse event;** **(i) Certificates of Analysis of API components of CSPs, and microbial growth;** **(j) Safety Data Sheets of API utilized in the process of sterile compounding and other chemicals and cleaning agents utilized in the cleanroom suite;** **[**(e)**] (k)** Records documenting inspection for expired or recalled pharmaceutical preparations**, components,** or raw ingredients; **(l) Documentation of recalls initiated by the pharmacy of compounded sterile products;** **[**(f) Preparation records including compounding work sheets, and records of the registered pharmacy technicians' checking/sign-off process; and	

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		(g) Preparation records including compounding work sheets and records of the pharmacists' checking/sign-off process.**]** **(m) Compounding and preparation records, including worksheets, processing checklists, procedure sign off forms, and final check logs.** **(o) Master formulation record (MRF) as described by USP 797 for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient; and** **(p) The results and documentation of applicable end product sterilization, testing, and validation.** (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 **of components**; (d) Drug/diluent amounts; **[**and**]** **(e) Assigned BUDs; 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.**]**	

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		.08 Batch Preparation. A. A **[**pharmacist**]** **pharmacy** 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**]** **Pharmacy [**can document a**]** **compounds limited quantities based on a documented** 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**]** each **[**preparations**]** CSP dispensed**[.];** **C. Batch preparation labeling shall be compliant with Regulation .06 of this Chapter;** **D. Record Keeping of batch preparations shall be compliant with Regulation .07 of this Chapter.** **.09 Minimum Facility Requirements.** A. **[**Controlled Environment.**]** **Classified Area.** (1) The pharmacy shall have a **[**controlled environment**]** **classified area** that meets USP 797**, 800, or 825** Standards**, as applicable**. (2) **[**A pharmacist**]** **The pharmacy** shall ensure that the **[**controlled environment**]** **classified area** is: (a) Accessible only **[**to**]** by designated personnel; and (b) Used only for the preparation of compounded sterile preparations, or such other tasks that require a **[**controlled environment**]** **classified area**.

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		(3) The **[**permit holder**] pharmacy** shall ensure that the **[**controlled environment**] classified area** 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 **and humidity** of the **[**controlled environment**] classified area** according to USP 797 standards. **(4) If compounding occurs outside of a cleanroom, the area and procedures shall meet USP 797 Standards for a segregated compounding area or for immediate use administration.** B. **[**Controlled Environment — Clean**] Buffer** Room. The **[**permit holder**] pharmacy** shall ensure that the **[**clean**] buffer** room in the **[**controlled environment**] classified area**: (1) Meets USP 797 Standards for design and USP 797 performance criteria quality standards for **[**clean**] buffer** 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**] hazardous drugs** are **[**routinely**]** used in **[**compounding**] compounded** preparations, contains room or rooms equipped with special pressurization requirements consistent with USP 797 **and 800** 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 **(dynamic conditions)**; and (6) Contains the following equipment:	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(a) **[**A laminar airflow workstation or other suitable**] Primary engineering controls validated to maintain** International Standards Organization (ISO) Class 5 compounding environment **during normal compounding activity (dynamic conditions)**; (b) Waste containers that are approved by Occupational Safety and Health Administration (OSHA) for used needles and syringes, and for **[**chemotherapy**] hazardous drug** waste; and (c) Ancillary supplies required for proper compounding. C. **[**Controlled Environment —**]** Anteroom. The **[**permit holder**] pharmacy** shall ensure that the anteroom in the **[**controlled environment**] classified area**: (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)**] (a)** Waste containers **[**for personal protective equipment**]**; **and** **[**(c)**] (b)** An eyewash station or sink design suitable for flushing an eye injury**[**;**].** **[**(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.**]** **D. A sink with hot and cold running water shall be available:**

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(1) Within the anteroom; **(2) At least a meter away from a primary engineering control within a segregated compounding area; or** **(3) If outside the cleanroom suite, the pharmacy shall have a policy and procedure on how to maintain hand hygiene while entering the cleanroom and donning protective garb.** **.10 Minimum Requirements for Equipment.** A. The **[**permit holder**] pharmacy** 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**] for hand hygiene and if applicable, cleaning equipment**; (3) Appropriate waste containers for: (a) Used needles and syringes; and (b) **[**Cytotoxic**] Hazardous drug** waste including disposable **[**apparel**] personal protective equipment (PPE)** used in its preparation, if applicable; (4) **[**Laminar air flow workstation or compounding aseptic isolator**] Primary engineering controls** that meet**[**s**]** USP 797 Standards, dedicated for products other than **[**antineoplastics**] hazardous drugs**; (5) If applicable to types of preparations compounded, biological safety cabinet, or compounding aseptic **containment** isolator that meets USP 797 Standards, dedicated for use with **[**antineoplastics or other**]** hazardous **or radiopharmaceutical** sterile preparations; (6) Appropriate filters and filtration equipment; and	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(7) A **[**device**] dedicated space or equipment** 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; (6) Incubator.**] All equipment, devices, and monitoring tools utilized in the sterile compounding process shall be maintained in working order, calibrated, or certified where appropriate.** **.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**] Garb for sterile compounding including:** (1) Sterile gloves; (2) Masks; (3) Non-shedding gowns; (4) Shoe covers;	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(5) Hair covers; (6) Beard covers; and (7) Other **garb and** personal protective equipment **(PPE) for handling hazardous drugs as required per USP 800**; B. Disposable syringes and needles in necessary sizes; C. **[**Disinfectant cleaning agents as specified in USP 797 Standards, including 70 percent sterile isopropyl alcohol;**] Cleaning agents** **(1) Disinfectant and sporicidal cleaning agents as specified in USP 797 Standards; and** **(2) If water is utilized as part of the PEC cleaning process (for example, rinsing surfaces or diluting cleaning agents), it shall be sterile, as defined by USP 797.** D. **[**Disposable lint free towels**] 70 percent sterile isopropyl or ethyl alcohol**; E. **[**Hand washing materials, including antimicrobial skin cleanser**] Disposable lint free towels**; F. **[**Adequate equipment and materials for antineoplastic or cytotoxic agent spills**] Hand washing materials, including nail picks, antimicrobial skin cleanser, and alcohol-based hand rub**; G. **[**Supplies necessary for the aseptic preparation of compounded sterile preparations; and**] A hazardous waste spill kit, if applicable;** **[**G**] H**. Supplies necessary for the aseptic preparation of compounded sterile preparations; and **[**H**] I**. Closed system vial transfer devices (CSTD), as required for **[**cytotoxic**] hazardous drug** compounding, if applicable. **.12 Minimum Requirements for Policies and Procedures.**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		A. The **[**permit holder**] pharmacy** shall ensure that **[**the**] a supervising** pharmacist **[**or the pharmacist's designee**]** shall maintain a policy and procedure manual, reviewed annually, that sets forth in detail the **[**permit holder's**] pharmacy's** standard operating procedures with regard to compounding sterile preparations. B. The **[**permit holder**] pharmacy** shall **[**insure**] ensure** 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) Environmental excursions** **[**(a) An incident reporting system;**]** (b) **[**An a**] A**dverse drug reaction**s; [**reporting system; and**]** (c) **[**A p**] P**reparation contamination **[**reporting system**]**; **and** **(d) Recalls of CSPs prepared by the Pharmacy.** (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	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(c) Documentation of appropriate **[**calibration and**]** preventive maintenance **and calibration,** if applicable; (4) Sanitation **and cleaning** standards and procedures **[**including monitoring for bacterial microorganisms to demonstrate effectiveness of cleaning activities**]**; (5) **Maintenance and availability of [**R**]**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**]** Beyond-use Dating; (f) **Release testing and verification;** **[**(f)**] (g)** Delivery; **[**(g)**] (h)** Destruction; **[**(h)**] (j)** Recalls; and **[**(i)**] (j)** Returns; (7) Patient record keeping as set forth in Regulation .07 of this chapter;	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(8) **Facility and equipment control monitoring as set forth in Regulation .07 of this Chapter;** (9) **Facility and certification and viable testing program, as described by USP 797;** **[**(8)**] (10)** Handling, dispensing, and documentation of investigational drugs; **[**(9)**] (11)** A quality assurance program; **[**(10)**] (12) [**Verification of training and competency guidelines] **Training verification procedures, including:** **(a) Gloved thumb and fingertip sampling;** **(b) Visual observation for adherence to aseptic technique; and** **(c) Media-fill testing with post gloved fingertip and thumb, and surface sampling;** **[**(11) Compounding process media fill, verification procedures;**]** **[**(12)**] (13)** Description of appropriate garb **donning and doffing processes**; **[**(13)**] (14)** Conduct guidelines for personnel in the controlled areas; **[**(14)**] (15)** Personnel responsibilities**, including pharmacists who are not physically involved in the compounding process, compounding staff, and cleaning and maintenance staff who have access to the cleanroom**; **[**(15)**] (16)** Patient education, **[**if appropriate**] unless in an inpatient setting**; **[**(16)**] (17)** Protocol**s** and procedures to maintain the integrity of the **[**interior work area of the laminar air flow workstations**] of the cleanroom suite and the PECs**;

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		[(17)**] (18) [**Written procedures as applicable for **[**h**] H**andling **[**antineoplastic agents and other**] of** hazardous **[**substances including**] drugs as per USP 800, if applicable,** 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 **containment** isolator; (c) Proper use of **personal** protective **[**attire**] equipment**; and (d) Proper techniques to prevent both contamination of the preparation and chemical exposure of the individual preparing the **[**prescription**] medication**; (19) **Segregation of biological and hazardous material from other compounding activities to prevent cross-contamination, if applicable;** **[**(18)**] (20) [**Written procedures as applicable for the**] The** disposal of infectious materials or materials containing **[**cytotoxic residues,**]** hazardous **drugs or** waste**, as per USP 800 Standards, if applicable**; **[**(19)**] (21)** Written documentation of policy and procedure changes based on data gathered from quality assurance evaluations; and **[**(20)**] (22) [**Written documentation of policy and procedures assuring**] Assurance of** the sterility and stability of compounded sterile preparations**, including end-product testing and sterilization, if applicable**. **.13 [Attire] Cleanroom Garbing.** A. When compounding sterile preparations, individuals shall comply with the following standards: (1) Sequencing of garbing that complies with USP 797 **and 800** Standards**, as applicable**; (2) Thorough hand-washing before gowning;	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(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; **and** **(e) Other personal protective equipment required for the handling and preparation of hazardous drugs, as per USP 800.** (4) Clean room garb, with the exception of sterile gloves, shall be donned and removed outside the designated clean room area; (a) **Personal protective equipment and garb required for the handling and preparation of hazardous drugs shall be removed, as per USP 800;** (5) **[**All jewelry shall be removed**] All jewelry that can be physically removed, shall be removed**; (6) Sterile **powder free** gloves are required; **[**and**]** (7) Make-up**, cosmetic lotions creams or ointments, false nails, and other cosmetic accessories** may not be worn in the clean room**; and** **(8) Nails shall be natural and short, not extending past the nail bed;** **[**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.**]**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		.14 Training of Staff, Patient, and Caregiver. A. The **[**pharmacist**] pharmacy** 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**]:** **(1) Proper use of compounded sterile preparations and related supplies dispensed by the pharmacy;** **(2) Signs of contamination or other issues seen in compounded sterile preparations; and** **(3) Proper disposal of excess medications, biohazards, sharps, and hazardous drug waste.** B. The **[**permit holder**] pharmacy** 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**] hazardous drugs,** if applicable. C. The **[**permit holder**] pharmacy** shall maintain records of training and demonstrated competence for individual employees for 5 years. D. The **[**permit holder**] pharmacy** 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 **annual** 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:**] Aseptic technique with gloved fingertip and thumb sampling, and media-fill testing with post gloved thumb and fingertip and surface sampling at a minimum frequency defined by USP 797 Standards;**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		[(i) 12 months for low and medium risk; and (ii) 6 months for high risk;**]** (b) Pharmaceutical calculations and terminology; (c) **[**Compounding sterile preparation**] Sterile compounding** documentation process; (d) Quality assurance procedures; (e) Aseptic preparation procedures**, including principals of unidirectional airflow**; (f) Proper **hand** cleansing, gowning, and gloving techniques; (g) General conduct **[**in**] within** the controlled area; (h) Cleaning, sanitizing, and maintaining equipment used in the controlled area; (i) **Cleaning, sanitizing, and maintaining the cleanroom suite;** **[**(i)**] (j)** Sterilization techniques **[**for high risk preparations; and**], if applicable;** **[**(j)**] (k)** Container **[**, equipment,**]** and closure system selection**[**.**];** **(l) Identifying and reporting of problems, failures, and errors to designated persons.** (2) Individuals assigned to the **[**controlled**] classified** area shall successfully complete practical skills training in aseptic technique and aseptic area practices **prior to compounding medication for patients**. (3) Evaluations shall include: (a) Written testing;	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		(b) Observation for adherence to aseptic technique and aseptic area policies and procedures; and (c) Media-fill **[**verification**]** **testing with gloved fingertip and thumb sampling, and surface sampling** as set forth in §E(1)(a) of this regulation. **(4) A pharmacy with only one pharmacist performing compounding shall establish and maintain training and competencies through a third party who is competent in standards set forth in this Chapter and USP 797:** **(5) Individuals who enter the cleanroom for cleaning, maintenance, or any other reason shall, at a minimum, have demonstrated competence and understanding of appropriate garbing, hand hygiene, conduct, and duties within the cleanroom:** **(6) Individuals responsible for handling, storing, packing, and transporting of CSPs shall be trained in duties associated with their position:** **(7) Upon initial hire staff shall complete evaluations, as set forth in §E(1) of this Regulation, including three passing consecutive gloved fingertip and thumb samplings.** **.15 Quality Assurance.** The **[**permit holder**]** **pharmacy** shall ensure that the **[**compounded sterile preparation**]** **CSP** retains its potency and sterility throughout the assigned **[**"beyond use" dating period**]** **BUD** through a written quality assurance program that includes: A. A reasonable effort by the pharmacist to assure that **[**compounded sterile preparations**]** **CSPs** 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**]** **CSP** dispensed;

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		B. The **[**phases of compounded sterile preparation**]** **sterile compounding process**, 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.**] C. [**Laminar air flow workstations, biological safety cabinets, and compounding aseptic isolators**]** **Primary engineering controls [**certified**]** **certification** by a trained and qualified operator**, according to USP 797 Standards**; **[**E.**] D. [**Clean room and anteroom**]** **Secondary engineering control** certification by a trained and qualified operator according to USP 797 Standards; **E. Environmental sampling microbial organisms is performed according to methods and schedules specified by USP 797 Standards;** **F. Trending of microbial growth observed during viable testing;** **G. A formal written process for reviewing and investigating environmental excursions occurring, both with personnel and within the cleanroom, including suspected sources of contamination, corrective and preventative actions, follow-up actions, associated recalls, and reporting to State and Federal Agencies, as required by law;** **[**F.**] H.** 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 **drugs, radiopharmaceutical waste, and any potentially contaminated** materials; **[**G.**] I.** A **[**formal**]** written review process to **document,** report**,** and evaluate compliance with this **[**chapter**]** **Chapter**; and

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		[H.**]** **J.** A process that complies with applicable USP **[**797**]** Standards for performing sterility**, [**checks or**]** **potency,** pyrogen **and endotoxin** testing, **[**or both**]** **or other quality attributes**, for applicable **[**compounded sterile preparations**]** **CSPs**. **.16 Reference Library.** Minimum reference materials in a pharmacy shall include: A. **[**U.S. Pharmaceutical**]** **United States Pharmacopeia**, General Chapter 797, Pharmaceutical Compounding—Sterile Preparations**, United States Pharmacopeia, General Chapter 800, United States Pharmacopeia, General Chapter 825,** 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**[.]; and** **D. Reference materials containing drug dosing for veterinary patients, if applicable.** **.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**]**	

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		(1) Documents, reports, and information required under this Chapter; and **[**(4)**] (2)** 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. **.18 Reporting Requirements Pharmacies.** A pharmacy shall: A. Document and perform routine testing as required by USP 797 Standards for the appropriate **[**risk levels**] categories** 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;	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
III. Committee Reports	**A. Practice Committee K. Evans, Chair**	(3) Disciplinary actions in other states or by other state agencies; (4) Changes in accreditation status; (5) Disciplinary actions taken against a pharmacist **or pharmacy technician** 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. **.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**] registration as** 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. **Drug Therapy Management** Pharmacy: University of Maryland (St. Joseph Medical Center) Pharmacists: Erica Wilson and Angela Stranko Protocol: Heart Failure Pharmacy: Johns Hopkins Pharmacists: Joshua Chou, Jessica Merey, and Maika Patino Protocols: Hypertension, Diabetes, Smoking Cessation, Cardiovascular Risk Reduction, and Management of Acid Suppressing Pharmacotherapy **Commissioners Rusinko and Vázquez Recused**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		Practice of Pharmacy Questions **QUESTION ONE; Ngan Pham, MedStar** **Commissioner Evans Recused** I'm reaching out to inquire about a hospital bedside discharge medication delivery process. There is a proposal for social work to pick up medications from outpatient pharmacies (i.e., CVS) to deliver them to patients prior to discharge. The intention is to improve access for patients with barriers to medication adherence. The proposed process would involve social work picking up medications and delivering them to the nurses, the nurses would lock away the medications on the unit, and then the nurse would hand the medications to patients at discharge. I would like to know from the Board of Pharmacy perspective: ● Is the proposed process allowed? ● Is the inpatient pharmacy responsible for any part of this process? If so, what are the responsibilities that pharmacy should take into consideration? **PROPOSED RESPONSE ONE** The policies and procedures of a hospital must address distribution and storage methods, and security. COMAR 10.34.03.04. Provided a patient designates a social worker as their agent, the process described is not prohibited. COMAR 10.34.25.03. **QUESTION TWO; Inspection staff** Does the Board consider batching (pre-packaging of a non-patient specific medication, e.g. bingo cards) to be a delegated pharmacy act requiring registration? **PROPOSED RESPONSE TWO** As pre-packaging and repackaging of a medication (e.g., batching) is performed in anticipation of a prescription, this constitutes a delegated pharmacy act which must be performed by a registered pharmacy technician, or registered pharmacy intern. Unlicensed personnel are restricted to operational support roles such	

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		as a cashier, administrative/billing clerk, delivery driver, custodian, or inventory control clerk. COMAR 10.34.21.02B(2). **QUESTION THREE; B. Hilker, Meritus Health** MHA is asking hospitals to weigh in on allowing patients to bring their medical marijuana to the hospital for inpatient use. What is the Board's stance on this or how does the law currently read? **PROPOSED RESPONSE THREE** The policies and procedures which hospital facilities follow are not within the scope of the Board of Pharmacy. As the Office of Health Care Quality monitors the quality of care in Maryland's healthcare facilities, you may contact the Office of Health Care Quality at 410-402-8015. **QUESTION FOUR; B. Sawyer** I am a Virginia-licensed pharmacist who is considering a remote, non-dispensing clinical pharmacist position that involves chronic disease state management and patient counseling with various physician offices across Virginia, Maryland, Pennsylvania, and Georgia. The pharmacy services will be billed "incident to" the license of a supervising physician; therefore, the employer requires licensure in the pharmacist's state of residence only. Does the Board have guidance on working as an independent contractor in this type of work? Are there any laws pertaining to the provision of counseling by a pharmacist located in Virginia to a patient located in Maryland? **PROPOSED RESPONSE FOUR** A pharmacist who provides remote chronic disease state management and counseling to patients located in Maryland must obtain a license to practice pharmacy issued by the Maryland Board of Pharmacy. Md. Code Ann., Health Occ. § 1-1005.	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
B. Licensing Committee	**K. Rusinko, Chair**	**1. Review of Pharmacist Applications: None** **2. Review of Pharmacist Renewal Applications: None** **3. Review of Pharmacist Reinstatement Applications:** **a.** **G.T.-** The applicant is requesting to be refunded his reciprocity application fee. **Committee Recommendation:** *Approve,refund for submitting wrong application.* *b.* **J.E.-** The applicant paid for renewal which had not been processed since he made a mistake **Committee Recommendation:** *Approve, renew application.* **c.** **S.O.-** The applicant is requesting to be reimbursed for a portion of the reinstatement fee. **Committee Recommendation:** *Deny* **4. Review of Technician Applications: None** **5. Review of Technician Reinstatement Applications: None** **6. Review of Intern New Applications: None** **7. Review of Pharmacy Applications: None** **8. Review of Continuing Education Program Request: None** **9. Review of Pharmacy Technicians Training Programs: None** **10. New Business:**	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
		a. Rishika Kabra- Wants to be approved as an CPR/First Aid Training Provider. Provided evidence to show the various modes of CPR training. They provide two ways to attend CPR training via instructor-led through Zoom conference or in-person with a live instructor. They also provide a skill evaluation checklist for instructors to follow. **Committee Recommendation:** *Deny, it's the same certificate unless you can show that it's a different certificate for Zoom versus in-person. Unless you can provide a list of locations for the in-person with a live instructor?*	

Subject	Responsible Party	Discussion	Action Due Date (Assigned To)
C. Public Relations Committee	**J. Vázquez, Chair**	**Public Relations Committee Update:**	
D. Disciplinary	**K. Fink, Chair**	**Disciplinary Committee Update**	
E. Emergency Preparedness Task Force	**N. Leikach, Chair**	**Emergency Preparedness Task Force Update**	
IV. Other Business & FYI	**N. Leikach, President**		
V. Adjournment	**N. Leikach, President**	**A. The Public Meeting was adjourned** **B. I would like to ask for a motion to close the public meeting and open a closed public session for the purpose of engaging in medical review committee deliberations of confidential matters contained in licensure applications in accordance with General Provisions Article Section 3-305(b)(13).** **C. Immediately thereafter, N. Leikach, convened an Administrative Session for purposes of discussing confidential disciplinary cases.** **D. With the exception of cases requiring recusals, the Board members present at the Public Meeting continued to participate in the Administrative Session.**	