MARYLAND
Department of Health
Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Robert R. Neall, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Mitra Gavgani, Board President • Deena Speights-Napata, Executive Director

SUPPLEMENTAL STERILE PROCESSING INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business As (d/b/a) or Trade Name _____
Street Address _____
Business Telephone Number _____ **Business Fax Number** _____
Maryland Pharmacy Permit Number _____ **Expiration** _____
CDS Registration Number _____ **Expiration** _____
DEA Registration Number _____ **Expiration** _____
Pharmacy Hours M-F:_____ **Sat:**_____ **Sun:**_____
Inspection Date: _____ **Arrival Time:** _____ **Departure Time:** _____
Type of Inspection: ◯ **Opening** ◯ **Annual** ◯ **Follow-up** **Previous Date:** _____
Name of Inspector: _____

Yes ☐ **No** ☐ The pharmacy department provides service 24 hours a day. COMAR 10.34.05.

Yes ☐ **No** ☐ **N/A** ☐ The pharmacy hours of operation are prominently displayed. COMAR 10.34.05.03B

Yes ☐ **No** ☐ All permits, licenses, and registrations are posted conspicuously. HO §12-311, HO §12-408(b) and HO §12-6B-08

Yes ☐ **No** ☐ The pharmacy fills original prescriptions received via the internet.
If yes, how do pharmacists verify that a relationship exists between the patient and the prescriber?

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HG §21-220; COMAR 10.19.03.02 and .07

Yes ☐ **No** ☐ The pharmacy wholesale distributes to another pharmacy. COMAR 10.34.37

Yes ☐ **No** ☐ The pharmacy wholesale distributes to a wholesale distributor. COMAR 10.34.37

Yes ☐ **No** ☐ **N/A** ☐ The wholesale distribution business exceeds 5% of the pharmacy annual sales. COMAR 10.34.37

Comments: _____
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2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws

_____

Pharmacist Employees	License #	Exp Date

Registered Technicians	Registration #	Exp Date

Unlicensed Personnel (non-registered)	Title	Duties

3. FACILITY AND EQUIPMENT STANDARDS FOR COMPOUNDING STERILE PREPARATIONS

Documentation shows:

Yes ☐ **No** ☐ Certification that each LAFW (Laminar Air Flow Workbench), BSC (Biological Safety Cabinet), and CAI (Compounding Aseptic Isolator) is functioning properly and meets the air quality requirement of ISO Class 5, and is performed by a qualified operator(s) using current, state-of-the-art electronic air sampling at least every six months and whenever the LAFW, BSC, or CAI is relocated. COMAR 10.34.19.03B(5) & (10); COMAR 10.34.19.15D

Yes ☐ **No** ☐ The air quality of the clean room and anteroom area is evaluated by a qualified operator(s) for conformance to ISO Class 7 and ISO Class 8 requirements, as appropriate, at least every six months and when renovations occur. COMAR 10.34.19.03B(5); COMAR 10.34.19.15E

Yes ☐ **No** ☐ Records of clean room testing are maintained and reviewed by the supervising pharmacist. COMAR 10.34.19.07B(1)

Yes ☐ **No** ☐ Evidence of daily calibration and routine maintenance on the following equipment, if applicable, for use:

- **Yes** ☐ **No** ☐ **N/A** ☐ Autoclave
- **Yes** ☐ **No** ☐ **N/A** ☐ Electronic Balance
- **Yes** ☐ **No** ☐ **N/A** ☐ Convection Oven
- **Yes** ☐ **No** ☐ **N/A** ☐ Incubator
- **Yes** ☐ **No** ☐ **N/A** ☐ Automated Compounding Devices (pumps) COMAR 10.34.19.10B

Yes ☐ **No** ☐ A refrigerator and freezer, if applicable, with sufficient capacity to meet the storage requirements for all material requiring refrigeration/freezing must be available in the facility. Evidence of maintenance of acceptable temperature ranges must be available. COMAR 10.34.19.10A

Yes ☐ **No** ☐ The facility must contain appropriate waste containers to isolate sharps, hazardous waste, biological, and chemotherapy waste. COMAR 10.34.19.09B(6) & .15F; COMAR 10.34.19.10A(3)

Access to designated areas and clean rooms is limited to those individuals who are properly attired. COMAR 10.34.19.09A

Yes ☐ **No** ☐ All equipment used in the designated area or clean room must be made of a material that can be easily cleaned and disinfected. COMAR 10.34.19.09B(3)

Yes ☐ **No** ☐ **N/A** ☐ Closed system vial transfer devices (CSTD) are employed when handling cytotoxic drugs. COMAR 10.34.19.12(17)

Comments: _____

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4. COMPOUNDING AREA COMAR 10.34.19.09

Yes ☐ **No** ☐ Clean room walls, ceilings, counters, lighting fixtures and floors are made of non-porous, non-shedding, cleanable surfaces. COMAR 10.34.19.09B(3)

Yes ☐ **No** ☐ Supplies are stored in a manner that maintains integrity of an aseptic environment.

The anteroom contains a sink with hot and cold running water. COMAR 10.34.19.09C(2)(a)

Comments: _____

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5. POLICIES AND PROCEDURES *MUST ADDRESS:* COMAR 10.34.19.12

Policies and procedures address at least the following:

Yes ☐	No ☐		The compounding, filling, and labeling of sterile compounds. COMAR 10.34.19.12C(6)(a), (c) and (d)
Yes ☐	No ☐		Proper labeling of the compounded sterile preparation including the intended route of administration and recommended rate of administration. COMAR 10.34.19.12C(6)(d)
Yes ☐	No ☐		Availability of equipment and supplies. COMAR 10.34.19.12C(3); COMAR 10.34.19.12C(17)(a)
Yes ☐	No ☐		The training of staff in the preparation of compounded sterile preparations. COMAR 10.34.19.12C(10); COMAR 10.34.19.14B
Yes ☐	No ☐		Staff competency evaluations. COMAR 10.34.19.14E
Yes ☐	No ☐		Quality Assurance Program. COMAR 10.34.19.12C(9); 10.34.19.15
Yes ☐	No ☐		All record keeping requirements COMAR 10.34.19.12C(7)
Yes ☐	No ☐		A written process, verified by a pharmacist, describing ingredients and the process for each preparation. COMAR 10.34.19.05B(4); COMAR 10.34.19.07B(1) and (2)
Yes ☐	No ☐		Documentation demonstrating that all personnel involved have read the policies procedures before compounding sterile preparations. COMAR 10.34.19.12B
Yes ☐	No ☐		Documentation of communication of policy and procedure for additions and deletions
Yes ☐	No ☐		The storage and handling of products and supplies. COMAR 10.34.19.12C(6)(b)
Yes ☐	No ☐		The storage and delivery of final preparation. COMAR 10.34.19.12(6)(b) and (f)
Yes ☐	No ☐		Media fill process verification testing. COMAR 10.34.19.12C(11)
Yes ☐	No ☐		The criteria for Beyond Use Dating (BUD). COMAR 10.34.19.12C(6)(e)
Yes ☐	No ☐		Personnel access and movement of materials into and near the compounding area. COMAR 10.34.19.12C(2)
Yes ☐	No ☐		The use and maintenance of environmental control devices used to create the critical area for manipulation of sterile preparations (e.g. laminar air flow workstations, biological safety cabinet, ISO Class 7 clean room, and/or CAIs. COMAR 10.34.19.12C(3)
Yes ☐	No ☐		A regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to an institutional infection control policy may follow that policy).
Yes ☐	No ☐		The method used to monitor the environment for bacterial microorganisms. COMAR 10.34.19.12C(4)
Yes ☐	No ☐		The disposal of packaging materials, used syringes, containers, and needles to avoid accumulation and maintain sanitation in the controlled area. COMAR 10.34.19.12C(18); COMAR 10.34.19.15F
Yes ☐	No ☐		Written policies and procedures for the use of established master formulas and worksheets for sterile batch compounding, if applicable
Yes ☐	No ☐	N/A ☐	Established sterilization procedures including documentation of results, if applicable. COMAR 10.34.19.12C(4)
Yes ☐	No ☐	N/A ☐	End-product evaluation and testing, if applicable. COMAR 10.34.19.12C(11); COMAR 10.34.19.15H

Comments: _____

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6. LABELING REQUIREMENTS COMAR 10.34.19.06

All labeling must include the following:

Yes ☐ No ☐ The name and concentration or amount of each ingredient contained in the preparation. COMAR 10.34.19.06B(7) and (8)

Yes ☐ No ☐ Instructions for storage and handling. COMAR 10.34.19.06B(12)

Yes ☐ No ☐ N/A ☐ Cytotoxic agents include a special label which states "Chemotherapy-Dispose of Properly." COMAR 10.34.19.06B(13)

Yes ☐ No ☐ Beyond Use Dating. COMAR 10.34.19.06B(11)

Yes ☐ No ☐ For short dated preparations, labeling must include:

- Yes ☐ No ☐ N/A ☐ Time
- Yes ☐ No ☐ N/A ☐ Date
- Yes ☐ No ☐ N/A ☐ Caution label/start-up time

Comments: _____

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7. RECORD KEEPING REQUIREMENTS COMAR 10.34.19.07

The following records must be maintained:

Yes ☐ No ☐ A readily retrievable medication profile for each patient. COMAR 10.34.19.07A

Yes ☐ No ☐ N/A ☐ Compounding worksheets for preparations for future use, indicating the drug name and amount/dose, ingredient lot numbers, quantity prepared, preparation date and BUD. COMAR 10.34.19.07B(2)

Yes ☐ No ☐ Documentation for 3 years to include: COMAR 10.34.19.07B – 5 years

- Yes ☐ No ☐ Training and competency evaluation of employees in sterile preparation procedures. COMAR 10.34.19.07B(1)(a)
- Yes ☐ No ☐ Refrigerator and freezer temperatures. COMAR 10.34.19.07B(1)(b)
- Yes ☐ No ☐ Certification of the testing of the sterile compounding environment.COMAR **10.34.19.07B(1)(c)**
- Yes ☐ No ☐ N/A ☐ Other facility quality control logs specific to the pharmacy's policies and procedures (e.g. cleaning logs for facilities and equipment). COMAR 10.34.19.07B(1)(d)
- Yes ☐ No ☐ N/A ☐ Preparation records including the master work sheet, the preparation work sheet and records of end-product evaluation, if applicable. COMAR 10.34.19.07B(1)(f)
- Yes ☐ No ☐ N/A ☐ Daily, weekly and monthly records of disinfection of workbench surface, walls, floors, ceilings, shelving, tables and stools, and after any unanticipated event which increases the risk of contamination. COMAR 10.34.19.07B(1)(d)

Comments: _____

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8. INVENTORY CONTROL PROCEDURES

Yes ☐ No ☐ N/A ☐ The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03

Yes ☐ No ☐ N/A ☐ The pharmacy maintains records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to other pharmacies. COMAR 10.34.37.03

Comments: _____

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9. ATTIRE 10.34.19.13

Yes ☐ No ☐ Clean room garb consists of a non-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times. COMAR 10.34.19.13A(3)

Yes ☐ No ☐ Clean room garb must be donned and removed outside the designated area. COMAR 10.34.19.13A(4) Hand,

Yes ☐ No ☐ finger, and wrist jewelry must be removed. COMAR 10.34.19.13A(5)

Yes ☐ No ☐ Head and facial hair must be covered. COMAR 10.34.19.13A(3)(b)

Yes ☐ No ☐ Makeup must not be worn in clean room. COMAR 10.34.19.13A(7)

Yes ☐ No ☐ Protective gloves made of non-shedding materials are required. COMAR 10.34.19.11A

Yes ☐ No ☐ N/A ☐ When preparing cytotoxic agents, appropriate personal protective equipment including gowns and gloves are worn. COMAR 10.34.19.12C(17); COMAR 10.34.19.14B

Requirements may not apply if a barrier isolator is used to compound sterile preparations.

10. TRAINING OF STAFF, PATIENT, AND CAREGIVER COMAR 10.34.19.14

Yes ☐ No ☐ N/A ☐ In non-hospital environments: Consultation shall be available to the patient and/or primary caregiver concerning proper use of compounded sterile preparations and related supplies furnished by the pharmacy. COMAR 10.34.19.14A

Yes ☐ No ☐ N/A ☐ The supervising pharmacist shall ensure all personnel engaging in compounding sterile drug preparations shall have training and demonstrate on-going competence in the safe handling and compounding of sterile drug preparations including cytotoxic agents if applicable. COMAR 10.34.19.14B

Yes ☐ No ☐ N/A ☐ Pharmacies must establish and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly. COMAR 10.34.19.14E(1)

Yes ☐ No ☐ N/A ☐ The program of training and evaluation addresses the following:

- Yes ☐ No ☐ N/A ☐ Aseptic technique
- Yes ☐ No ☐ N/A ☐ Pharmaceutical calculations/terminology
- Yes ☐ No ☐ N/A ☐ Sterile preparations compounding documentation
- Yes ☐ No ☐ N/A ☐ Quality assurance procedures
- Yes ☐ No ☐ N/A ☐ Aseptic preparation procedures
- Yes ☐ No ☐ N/A ☐ Proper cleansing and garbing techniques
- Yes ☐ No ☐ N/A ☐ General conduct in the controlled area
- Yes ☐ No ☐ N/A ☐ Cleaning/sanitizing and maintaining equipment used in the controlled area
- Yes ☐ No ☐ N/A ☐ Sterilization techniques if applicable See COMAR 10.34.19.14E(1)(a) – (i) for above
- Yes ☐ No ☐ N/A ☐ Handling, storage, and delivery of sterile compounded preparations
- Yes ☐ No ☐ N/A ☐ Equipment training COMAR 10.34.19.14E(1)(j)
- Yes ☐ No ☐ N/A ☐ Competency assessment COMAR 10.34.19.14B
- Yes ☐ No ☐ N/A ☐ Equipment and closure system selection COMAR 10.34.19.14E(1)(j)

Yes ☐ No ☐ N/A ☐ Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices. COMAR 10.34.19.14E(2)

Yes ☐ No ☐ N/A ☐ Evaluations must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures. COMAR 10.34.19.14E(3)

Yes ☐ No ☐ N/A ☐ Each person's proficiency and continuing training needs must be reassessed every 12 months (every 6 months for high-risk compounding). COMAR 10.34.19.14E(1)(a)

Yes ☐ No ☐ N/A ☐ Records of training and demonstrated competence shall be available for each individual and shall be retained for three (3) years beyond the period of employment. 5 years for employees. COMAR 10.34.19.14C

Comments: _____

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11. DISPOSAL OF WASTE MATERIAL

Yes ☐ No ☐ Pharmacies compounding sterile preparations shall have written policies and procedures for disposal of infectious materials and/or materials containing cytotoxic residue or hazardous waste. COMAR 10.34.19.12C(18)

Yes ☐ No ☐ Procedures must include cleanup of spills and shall be in conformance with local health jurisdictions. COMAR 10.34.19.12C(4)

Comments: _____

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12. QUALITY ASSURANCE AND PROCESS VERIFICATION COMAR 10.34.19.15

Yes ☐ No ☐ N/A ☐ Each pharmacy shall have a documented, ongoing quality assurance program that monitors personnel performance, equipment and facilities. COMAR 10.34.19.12C; COMAR 10.34.19.15

Yes ☐ No ☐ N/A ☐ The Quality Assurance Program shall include documentation of monitoring to assure successful:

- Yes ☐ No ☐ N/A ☐ Cleaning and sanitization of the parenteral medication preparation area. COMAR 10.34.19.15E
- Yes ☐ No ☐ N/A ☐ The storage of compounded parenteral preparations in the pharmacy and periodic documentation of refrigeration/freezer temperature. COMAR 10.34.19.15B
- Yes ☐ No ☐ N/A ☐ Steps taken in the event of a drug recall. COMAR 10.34.19.12C(6)(h)
- Yes ☐ No ☐ N/A ☐ Written justification including literature references of the chosen beyond use dates for compounded sterile preparations.
- Yes ☐ No ☐ N/A ☐ Written policies and procedures for implementing the immediate use exemption for admixtures.
- Yes ☐ No ☐ N/A ☐ Each individual involved in the preparation of compounded sterile preparations must successfully complete a verification process before being allowed to prepare sterile preparations. COMAR 10.34.19.14B

Yes ☐ No ☐ N/A ☐ The verification process shall be carried out using the same personnel, procedures, equipment, and materials as normal production, except that an appropriate microbiological growth medium is used in the compounding process to verify the sterility of the final preparation. COMAR 10.34.19.12C(11); COMAR 10.34.19.15C

Yes ☐ No ☐ N/A ☐ Completed media samples must be incubated according to currently accepted standards. COMAR 10.34.19.15C

Yes ☐ No ☐ N/A ☐ If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the verification process repeated.

Yes ☐ No ☐ N/A ☐ Personnel competency must be re-verified at least every 12 months (every 6 months for high-risk), whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic technique is observed.

Yes ☐ **No** ☐ **N/A** ☐ The verification and re-verification process must be documented. COMAR 10.34.19.07B(3)

Yes ☐ **No** ☐ **N/A** ☐ Other personnel monitoring requirements as required by current standards must be performed, such as fingertip touch testing.

Yes ☐ **No** ☐ **N/A** ☐ There must be current and appropriate reference materials regarding the compounding of sterile preparations located in or immediately available to the pharmacy. COMAR 10.34.19.16

Yes ☐ **No** ☐ **N/A** ☐ Written documentation that the end product has been tested on a periodic sampling basis for microbial contamination and steps taken in the event that testing for contamination proves positive, if applicable. COMAR 10.34.19.15C

Comments: _____

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Inspectors Comments:

Inspector Signature_____

Pharmacist Name: _____ **Date:** _____
(Print)

Received a copy of the inspection report on _____ _____
Date and Signature of the Pharmacist

FINAL 9/03/2014

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CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Clear Form

Pharmacy: _____
Permit#: _____
Date: _____
Pharmacist Signature: _____

Rx#:_____
Date Filled:_____

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY

COMMENTS:
_____
_____
_____
_____

SCHEDULE II AUDIT

Drug _____
Date of last Inspection/Biennial _____

Amount at last inspection/biennial	_____	(A)
Purchased since inspection/biennial	_____	(B)
Total inventory	0	(C) = A + B
Quantity dispensed	_____	(D)
Expected inventory	0	(E) = C - D
Quantity on Hand	_____	(F)
Discrepancy	0	(G) = (F-E) or (E-F)

Excess Shortage

INVOICE REVIEW

CII:
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_____

CIII - CV:
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PRESCRIPTION REVIEW

CII #
DATE

COMMENTS:

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CIII - CV #
DATE

COMMENTS:

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