



# MARYLAND

## Department of Health

Wes Moore, Governor • Aruna Miller, Lt. Governor • Laura Herrera Scott, M.D., M.P.H., Secretary

### MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

Jennifer L. Hardesty, Board President • Deena Speights-Napata, Executive Director

## COMPREHENSIVE CARE PHARMACY 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 \_\_\_\_\_

Inspection Date: \_\_\_\_\_ Arrival Time: \_\_\_\_\_ Departure Time: \_\_\_\_\_

Type of Inspection:  Annual  Follow-up Previous Date: \_\_\_\_\_ Name of Inspector: \_\_\_\_\_

Yes  No  The pharmacy department provides service 24 hours. COMAR 10.34.05.

Yes  No  The pharmacy hours of operation and after hour procedures are provided to the Comprehensive Care Facility. COMAR 10.34.05.03B

Pharmacy Hours M-F: \_

Sat: \_

Sun: \_

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

Maryland Pharmacy Permit Number \_\_\_\_\_

Expiration \_\_\_\_\_

CDS Registration Number \_\_\_\_\_

Expiration \_\_\_\_\_

DEA Registration Number \_\_\_\_\_

Expiration \_\_\_\_\_

Yes  No  The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

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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### 3. PERSONNEL TRAINING

All personnel have received training in: (check all that apply) COMAR 10.34.21.03

- |     |                          |    |                          |     |                          |  |
|-----|--------------------------|----|--------------------------|-----|--------------------------|--|
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Maintaining records                                    |
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Patient confidentiality                                |
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Sanitation, hygiene, infection control                 |
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Biohazard precautions                                  |
| Yes | <input type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Patient safety and medication errors COMAR 10.34.26.03 |

Yes  No  There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03

Yes  No  N/A  All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03

Yes  No  There is a written ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03

**Comments:** \_\_\_\_\_  
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### 4. POLICIES AND PROCEDURES COMAR 10.34.23.03

- Yes  No  Personnel access to the pharmacy COMAR 10.34.23.03C
- Yes  No  Scope and method of pharmacy service COMAR 10.34.23.03B
- Yes  No  Labeling requirements and distribution methods for medications provided in a single container COMAR 10.34.23.03E (1)
- Yes  No  Procedures for interim boxes. COMAR 10.34.23.03E (2)
- Yes  No  Documentation of policy and procedure manual provided to personnel of the pharmacy and comprehensive care facility. COMAR 10.34.23.03F
- Yes  No  Reporting adverse drug reactions. COMAR 10.34.23.09K
- Yes  No  Written policies related to re-use of returned medications.
- Yes  No  Documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.

**Comments:** \_\_\_\_\_  
\_\_\_\_\_  
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**5. SECURITY COMAR 10.34.05**

Yes  No  The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the establishment is open. (Briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

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Yes  No  The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

Yes  No  The permit holder prevents individuals from being in the prescription area when a pharmacist is not immediately available on the premises to provide pharmacy service. COMAR 10.34.23.05C

**Comments:** \_\_\_\_\_  
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**6. PHYSICAL REQUIREMENTS AND EQUIPMENT COMAR 10.34.23.05**

Yes  No  Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2 and COMAR 10.34.10.01A(3).

Yes  No  The pharmacy provides a compounding service (non-sterile procedures).

Yes  No  If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02

Yes  No  The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01-1A

Yes  No  The pharmacy has hot and cold running water.

Yes  No  The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01-1B

Yes  No  The medication refrigerator(s) have a thermometer. COMAR 10.34.07.01-1B

Yes  No  The current temperature of the medication refrigerator(s) is between (36F-46F). USP

**Temperature** \_\_\_\_\_

Yes  No  The current temperature of the pharmacy department is between [59 to 86 degrees F]. COMAR 10.34.05.02A (1) (a)

**Temperature** \_\_\_\_\_

Yes  No  N/A  If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medication stored within it.

**Temperature** \_\_\_\_\_

Yes  No  The pharmacy maintains a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03

- Yes  No  The pharmacy has online resources. HO §12-403(b)(15) and COMAR 10.34.07.03
- Yes  No  The pharmacy possesses the current edition of *The Maryland Pharmacy Laws and Regulations*. HO §12-403(b) (10) (ii)
- Yes  No  Medications and supplies within the pharmacy are properly stored according to the manufacturer's specifications and State and federal laws and regulations with respect to:
- Yes  No  Sanitation
- Yes  No  Temperature
- Yes  No  Light
- Yes  No  Ventilation
- Yes  No  Segregation
- Yes  No  Security

**Comments:** \_\_\_\_\_

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**7. PRESCRIPTION LABELING, FILES, AND STORAGE**

Yes  No  N/A  Hard copy prescription files are maintained chronologically for 5 years. HO §12-403(b) (13)

The following label requirements are met if a drug is dispensed pursuant to a prescription. COMAR 10.34.23.08:

- Yes  No  N/A  The name and address of the pharmacy;
- Yes  No  N/A  The serial number of the prescription;
- Yes  No  N/A  The date the prescription was dispensed;
- Yes  No  N/A  The name of the prescriber;
- Yes  No  N/A  The name of the patient;
- Yes  No  N/A  The name and strength of the drug or devices;
- Yes  No  N/A  The quantity of the drug or device;
- Yes  No  N/A  The required precautionary information regarding controlled substances;
- Yes  No  N/A  The required cautionary statements or auxiliary labels;
- Yes  No  N/A  The name of generic manufacturer;
- Yes  No  N/A  The expiration date is indicated;
- Yes  No  N/A  (Medications in Parenteral Admixtures) The name and amount of drug(s) added;

Yes  No  N/A  (Medications in Parenteral Admixtures) The name of the pharmacist responsible for the admixture;

Yes  No  N/A  (Medications in Parenteral Admixtures) The rate of infusion; and (Medications in Parenteral Admixtures) The frequency of infusion

Yes  No  N/A  Medication provided per dosing period in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package, are labeled with at least the following:

- Yes  No  N/A  (1) Drug name;
- Yes  No  N/A  (2) Drug strength;
- Yes  No  N/A  (3) Name of manufacturer;
- Yes  No  N/A  (4) Name of the patient;

Yes  No  N/A  (5) Lot number; and  
 Yes  No  N/A  (6) Expiration date.  
 Yes  No  N/A   
 Yes  No  N/A  The pharmacist and technician initials are on prescriptions or patient drug profiles or computerized patient records. COMAR 10.34.08.01

**Comments:** \_\_\_\_\_  
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**8. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS**

Yes  No  There are written procedures to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider. COMAR 10.34.26.04  
 Yes  No  The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the role and responsibility of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

**Comments:** \_\_\_\_\_  
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**9. CONFIDENTIALITY**

Yes  No  Confidentiality is maintained in the creation, storage, access, disposal and disclosure of patient records. HO §12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations.  
 Yes  No  Any identifiable information contained in a patient’s record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG §4-301 through §4-307.COMAR 10.34.10.03B

**Comments:** \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**10. DRUG CONTROL AND ACCOUNTABILITY COMAR 10.34.23.09**

Yes  No  N/A  The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03  
 Yes  No  N/A  The pharmacy has written policies and procedures for the safe handling of drug recalls. See [www.recalls.gov](http://www.recalls.gov)  
 Yes  No  N/A  The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)  
 Yes  No  N/A  The pharmacy has a written procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01  
 Yes  No  N/A  The pharmacy has a process for discontinued medication and returned medication that accounts for proper storage and labeling. COMAR 10.34.23.09

**Comments:** \_\_\_\_\_  
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**11. EMERGENCY DRUG KIT COMAR 10.34.23.09.F**

- Yes  No  The emergency drug kit is secured with a tamper evident seal or electronic security system. COMAR 10.34.23.09.F.(1)
- Yes  No  The emergency drug kit meets the labeling requirements as set forth on COMAR 10.34.23.09.F.(2).
- Yes  No  A written policy exists regarding what medications and quantities are to be contained in interim drugs box as well as procedures for restocking medications. COMAR 10.34.23.03

**Comments:** \_\_\_\_\_  
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**12. CONTROLLED SUBSTANCES**

- Yes  No  Hard copy prescription files are maintained chronologically for 5 years. COMAR 10.34.20.03; HO §12-403(b)(13). (CDS-Federal law requires record retention for 7 years)
- Yes  No  A perpetual inventory is maintained for Schedule II controlled substances. (Recommended)
- Yes  No  Schedule II controlled substances are dispersed throughout the stock of non-controlled substances, or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)
- Yes  No  The pharmacy has a copy of the most recent required biennial inventory of Schedule II- V controlled substances. COMAR 10.19.03.05B  
Inventory date: \_\_\_\_\_ Inventory  
completed at:  Opening or  Closing (Check one)
- Yes  No  The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
- Yes  No  Records are kept of all receipts of controlled substances entered into the pharmacy inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05
- Yes  No  The prescription label for controlled drugs include the following warning: **“CAUTION Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed”**, in 6-point type or the Pharmacy utilizes an auxiliary label that contains this warning. COMAR 10.19.03.08D (1)
- Yes  No  All controlled substances prescriptions comply with COMAR 10.19.03
- Yes  No  The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)
- Yes  No  For the return of Schedule III-V drugs, the pharmacy uses a distribution system that classifies medications as pharmacy inventory until the utilization of the medication by the patient. COMAR 10.34.23.09.C

**Comments:** \_\_\_\_\_  
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**13. AUTOMATED MEDICATION SYSTEMS** Yes  No  (if No, go to #14)

Yes  No  N/A  The facility uses an automated device(s) as defined in COMAR 10.34.28.02.

Written policies and procedures exist for (check all that apply): COMAR 10.34.28.05

Yes  No  N/A  Control of access to the device.

Yes  No  N/A  Accounting for medication added and removed from the system.

Yes  No  N/A  Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safeguards.  
COMAR 10.34.28.06

Comments: \_\_\_\_\_

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Yes  No  N/A  Adequate records are maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes  No  N/A  Maintenance records.

Yes  No  N/A  System failure reports.

Yes  No  N/A  Accuracy audits.

Yes  No  N/A  Quality Assurance Reports.

Yes  No  N/A  Reports on system access and changes in access.

Yes  No  N/A  Training records.

Yes  No  N/A  The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments: \_\_\_\_\_

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\_\_\_\_\_

**14. OUTSOURCING** Yes  No  (if No, go to #13)

Yes  No  N/A  The facility outsources the preparation of medications or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02

Yes  No  N/A  The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02

Yes  No  N/A  The facility serves as a secondary pharmacy. COMAR 10.34.04.02

Yes  No  N/A  Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06

Yes  No  N/A  Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made. COMAR 10.34.04.03 and .05

Yes  No  N/A  The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.

If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number:

\_\_\_\_\_  
\_\_\_\_\_  
COMAR 10.34.04.06E

The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner (Check all that apply): COMAR 10.34.04.06

Yes  No  N/A  The prescription order was prepared by a secondary pharmacy.

Yes  No  N/A  The name of the secondary pharmacy.

Yes  No  N/A  The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.

Yes  No  N/A  The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.

Yes  No  N/A  The date on which the prescription order was transmitted to the secondary pharmacy.

Yes  No  N/A  The date on which the preparation was sent to the primary pharmacy.

Yes  No  N/A  The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F

Yes  No  N/A  The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes (check all that apply):

COMAR 10.34.04.07

Yes  No  N/A  Records of the prescription orders transmitted from another pharmacy.

Yes  No  N/A  The date on which the prescription order was transmitted from the primary pharmacy.

Yes  No  N/A  The name and information identifying the specific location of the primary pharmacy.

Yes  No  N/A  The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.

Yes  No  N/A  The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.

Yes  No  N/A  The name of the pharmacist at the secondary pharmacy who verified/performed the final check of the prescription order.

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**15. DISTRIBUTION**

Yes  No  N/A  Sales of prescription drugs other than by patient specific prescription orders exceeds 5% of the pharmacy's annual sales.

If yes, Maryland distributors license # \_\_\_\_\_ COMAR 10.34.22.01.

**Comments:** \_\_\_\_\_  
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**16. MEDICATION ORDERS (COMAR 10.34.23.09.H)**

Yes  No  Medications are dispensed from the pharmacy only in response to medication orders issued by authorized prescribers or by prescriber per institution approved protocols.

**17. MEDICATION PACKAGING (COMAR 10.34.23.07)**

Yes  No  N/A  The pharmacy prepares packaged medications. (If yes complete questions below)

**Packaged from the original manufacturer's container:**

Yes  No  N/A  The pharmacy uses a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information in a master log if kept with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container which includes the:

- Yes  No  N/A  Name of drug;
- Yes  No  N/A  Strength;
- Yes  No  N/A  Manufacturer;
- Yes  No  N/A  Lot Number assigned by the pharmacy;
- Yes  No  N/A  Lot number assigned by the distributor or manufacturer;
- Yes  No  N/A  Quantity packaged;
- Yes  No  N/A  Manufacturer's expiration date;
- Yes  No  N/A  Lot number assigned by the distributor or manufacturer;
- Yes  No  N/A  Date of packaging;
- Yes  No  N/A  Name of the pharmacy technician who performed packaging functions; and
- Yes  No  N/A  Name and initials of verifying licensed pharmacist.

**Packaged from Another Pharmacy:**

Yes  No  N/A  The licensed pharmacist packages medication received from another pharmacy licensed in Maryland or operated by the government of the United States provided that:

- Yes  No  N/A  (1) The licensed pharmacist determines that the medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the time it was dispensed by the original pharmacy and to directly send medication to the packaging pharmacy;

- Yes  No  N/A  (2) The licensed pharmacist packages and dispenses all at one time the entire quantity of the prescription medications received from another pharmacy for packaging;
- Yes  No  N/A  (3) The manufacturer's name is present on the container received from the other pharmacy; and
- Yes  No  N/A  (4) The licensed pharmacist maintains a master log that includes the following information:
- Yes  No  N/A  (a) Name of the drug;
  - Yes  No  N/A  (b) Lot number assigned by the packaging pharmacy;
  - Yes  No  N/A  (c) Strength;
  - Yes  No  N/A  (d) Manufacturer;
  - Yes  No  N/A  (e) Name, address, and telephone number of the original dispensing pharmacy;
  - Yes  No  N/A  (f) Prescription number for the original dispensing pharmacy;
  - Yes  No  N/A  (g) Quantity packaged;
  - Yes  No  N/A  (h) Expiration date as assigned by the original dispensing pharmacy;
  - Yes  No  N/A  (i) Date of packaging;
  - Yes  No  N/A  (j) Name of pharmacy technician who performed packing function;
  - Yes  No  N/A  (k) Name and initials of verifying licensed pharmacist; and
  - Yes  No  N/A  (l) Name of the patient.

**Comments:** \_\_\_\_\_  
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**18. CONSULTANT SERVICES**

Yes  No  There are written policies for and documentation of timely medication review by consulting pharmacists at all sites.

**19. DELIVERY SERVICES**

Yes  No  There are policies for and documentation of timely delivery of medications to all sites.

Yes  No  There are policies for and documentation of timely delivery of controlled dangerous substances to all sites.



# 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 \_\_\_\_\_

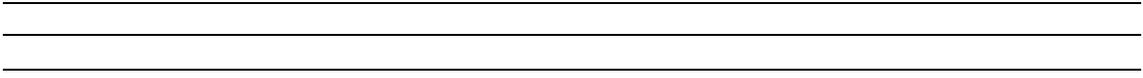
Amount at last inspection/biennial	_____	(A)
Purchased since inspection/biennial	_____	(B)
Total inventory	0	(C) = A + B
Quantity dispensed	_____	(D)
Expected inventory	0	(E) = C - D
Quantity on Hand	_____	(F)
Discrepancy	_____	(G) = (F-E) or (E-F)
		Excess Shortage

### INVOICE REVIEW

**CII:**

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**CIII - CV:**



**PRESCRIPTION REVIEW**

**CII #  
DATE**

**COMMENTS:**

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**CIII - CV #  
DATE**

**COMMENTS:**

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