



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

HOSPITAL INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name _____

Pharmacy Name-Doing Business As (DBA) 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: _____

Inspection Date: _____ Arrival Time: _____ Departure Time: _____

Type of Inspection: Annual Follow-up Previous Date: _____

Name of Inspector: _____

- | | | |
|-----|----|--|
| Yes | No | If the pharmacy is not open 24 hours, policies and procedures are in place for emergency access to the Pharmacy when locked. |
| Yes | No | The pharmacy orders, stocks, or dispenses controlled drugs. |
| Yes | No | The Pharmacy performs Sterile Compounding.
(If yes, will need to complete Sterile Compounding Inspection Form) |
| 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: _____

3. SECURITY (COMAR 10.19.03.12) (COMAR 10.34.03.06) (COMAR 10.34.05)

Yes No The Pharmacy maintains policies and procedures for limiting access to the Pharmacy. (If yes, provide a brief description of how access is restricted)

Comments: _____

4. PHYSICAL REQUIREMENTS AND EQUIPMENT (COMAR 10.34.03.07) (COMAR 10.34.07.01) (HO 12-403.(11))

Yes No The Pharmacy has written (or e-format) Policies and Procedures.
(If yes, date of last review/update.) _____

Yes No The Pharmacy is of sufficient size with adequate lighting, ventilation and moisture control for the safe storage of drugs and Practice of Pharmacy.

Yes No N/A The Pharmacy compounds medications (non-sterile products).

Yes No The Pharmacy has a Class A balance or better.

Yes No The Pharmacy has hot and cold running water.

Yes No The refrigerator(s) temperature is checked daily.
(Temperature) _____

Yes No The references available for the safe and proper dispensing of medications are:

On-line access

Written references (List main references used and year of publication)

Comments: _____

5. DRUG SAMPLES HO §12-102

Yes	No	N/A	There are written policies and procedures on how drug samples are dispensed. There
Yes	No	N/A	are recording systems for the acquisition and dispensing of drug samples.
Yes	No	N/A	There is a note/order written in the patient's chart/record when a sample is dispensed.

Comments: _____

6. EMERGENCY ROOM (ER) DISPENSING (HO 12-1-2.(f))

Yes	No	The institution's ER dispenses medication directly to the patient.
Yes	No	The patient is given "starter doses" for 72 hours or less.
Yes	No	The labeling of the "starter doses" complies with HO 12-505.

Comments: _____

7. LABELING OF MEDICATION FOR USE OUTSIDE THE INSTITUTION (COMAR 10.34.03.10)

Yes	No	The labeling on all medications dispensed for use outside the institution (clinics, ambulatory patients, discharged patients) meets the requirements of HO 12-505 as well as any federal or state laws (check all that apply). Name of patient Name and strength of drug Name of Pharmacy and address Directions and any cautionary statements Expiration dates Any special handling or storage requirements
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Comments: _____

8. UNLICENSED PERSONNEL (COMAR 10.34.21.01 to .05)

- Yes No N/A** There are policies and procedures to specify duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist.
- Yes No N/A** The unlicensed personnel who perform tasks in the Pharmacy have received documented training for the tasks they will perform.
- The unlicensed personnel received training in (check all that apply):
- Yes No N/A** Maintaining records
- Yes No N/A** Patient confidentiality
- Yes No N/A** Sanitation, hygiene, infection control
- Yes No N/A** Biohazard precautions
- Yes No N/A** There are ongoing quality assurance programs that document the competency and accuracy of then licensed personnel performance of assigned tasks.
- Yes No N/A** All unlicensed personnel have been given a written job description.

Comments: _____

9. CONFIDENTIALITY (HG 4-301 to 307)

- Yes No** Confidentiality is maintained in the creating, storing, accessing and disclosing of patient's records.
- Yes No** 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- 4-307.

Comments: _____

10. MEDICATION ORDERS (COMAR 10.34.03.12)

Prescribers authorized to write medication orders:

- Yes No** _____ **MD**
- Yes No** _____ **NP**
- Yes No** _____ **PA**
- Yes No** _____ **Other (Explain):** _____

- Yes No** Medications are dispensed from the pharmacy only in response to medication orders issued by authorized prescribers or by clinicians per institution approved protocols.
- Yes No** Pertinent patient information necessary for drug monitoring including the patient's sex, age, height, weight, diagnosis, drug interactions, and allergies are readily available to the pharmacist.
- Yes No** The institution has specific guidelines for writing medication orders under approved medication protocols and therapeutic interchanges.
- Yes No** The pharmacist notes the mode of transmission of a medication order on the prescription when it does not contain the original prescriber's signature. (COMAR10.34.20.03)
- Yes No** The institution has a policy and procedure in place for receiving and transcribing verbal medication orders.
- Yes No** The Pharmacy and Therapeutics Services Committee or its equivalent has developed automatic stop order policies on medications that are not specifically limited to duration or number of doses.

Comments: _____

14. STORAGE (COMAR 10.34.04.08, 10.07.02.15)

- Yes** **No** The Pharmacy controls storage of all drugs and investigational medications throughout the institution.
- Yes** **No** All poisons and external preparations are sequestered from oral and injectable drugs.
- Yes** **No** All flammables and alcohol preparations are maintained in areas that meet basic local building code requirements for storage of volatiles and such other laws, ordinances, or regulations.
- Yes** **No** The Pharmacy developed and implemented policies and procedures to ensure that discontinued and outdated drugs and drug containers with worn, illegible, or missing labels are returned to the Pharmacy for proper disposition.

Comments: _____

15. 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: _____

16. INVESTIGATIONAL DRUGS (COMAR 10.34.03.08.R)

- Yes** **No** **N/A** The Pharmacy participate in the development of policies and procedures for identification and handling of investigational drugs.
- Yes** **No** **N/A** The Pharmacy provides information on pharmaceutical and toxicological effects of investigational drugs to medical and nursing staff.
- Yes** **No** **N/A** The Pharmacy and Therapeutics Committee develops policies for protection of patients enrolled in hospital-sponsored research.

Comments: _____

17. CONTROLLED SUBSTANCES (COMAR 10.34.03.13)

Yes **No** Records are kept regarding use and accountability of Schedule II substances containing at least the following:

- Yes** **No** **N/A** Name and strength of drug
- Yes** **No** **N/A** Dose
- Yes** **No** **N/A** Dosage form
- Yes** **No** **N/A** Prescriber
- Yes** **No** **N/A** Patient
- Yes** **No** **N/A** Date and time of administration
- Yes** **No** **N/A** Individual who administered drug
- Yes** **No** The Pharmacy performs biennial scheduled drug inventories.
- Yes** **No** Records (including signatures) are kept of all receipts of controlled substances into the Pharmacy.
- Yes** **No** Records are kept of all deliveries made by the Pharmacy with signatures of personnel delivering and receiving

Yes	No	Records are kept of partially administered Schedule II drugs whether returned to the Pharmacy or disposed of immediately with verification by a witness.
Yes	No	Access to all controlled substances outside the Pharmacy is restricted to licensed personnel approved by institutional policy.
Yes	No	Controlled substances stored outside the Pharmacy are accounted for at least at the change of shift by a licensed person authorized by the institution, unless an on-demand report of perpetual inventory is available with an automated dispensing system.
Yes	No	A pharmacist or a person designated by the director performs a physical count of each Schedule II substance in the Pharmacy at least monthly to identify any discrepancies.
Yes	No	The Director or a pharmacist designee investigates all discrepancies, report losses as required by law and takes appropriate action.
Yes	No	A procedure is in place for any Schedule II substances that have been dispensed and are no longer needed and must be returned to the Pharmacy.

Comments: _____

18. AUTOMATED MEDICATION SYSTEMS (COMAR 10.34.28)

Yes	No	N/A	The facility uses automated devices as defined in 10.34.28.02.
Yes	No	N/A	The pharmacy uses the following (check all that apply): Centralized automated medication system. Decentralized automated medication system. Remote automated medication system.
Yes	No	N/A	Policies and procedures exist for (check all that apply): Control of access to the device. Review of orders by a licensed pharmacist prior to removal of the medication. Control of starter doses. Accounting for medication added and removed from the system.
Yes	No	N/A	Sufficient safe guards are in place to ensure accurate replenishment of the automated medication system.
Yes	No	N/A	Adequate records are maintained for at least two years addressing the following (check all that apply): Maintenance records. System failure reports. Accuracy audits. Quality assurance reports. Reports on system access and changes in access. Training records.
Yes	No	N/A	Transaction records for medications dispensed are maintained for five years.
Yes	No	N/A	Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, forms and drug entities, and minimizes the potential for misidentification of medications, dosages, and dosage forms.
Yes	No	N/A	The Pharmacy maintains records, documents, or other evidence of a multidisciplinary committee, that includes a licensed pharmacist, that is charged with oversight of the remote or decentralized automated medication system, which has: Established criteria and a process for determining which drugs may be stored in a remote or decentralized automated medication system; Reviews the decisions, referred to in regulations, on a regular basis; Develops policies and procedures regarding the remote or decentralized automated medication system; and Ensures that the system complies with the appropriate sections of the law.

Yes	No	N/A	The Pharmacy maintains records, documents, or other evidence of a quality Assurance program regarding the automated medication system in accordance with the requirements of CHAPTER 28, §.10.
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Comments: _____

19. OUTSOURCING

Yes No

Yes	No	N/A	The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
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Yes	No	N/A	The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
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Yes	No	N/A	The facility serves as a secondary pharmacy. COMAR 10.34.04.02
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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
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Comments: _____

Yes	No	N/A	The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)
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If the pharmacy outsources a prescription order:

Yes	No	N/A	The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
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Yes	No	N/A	Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
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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
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The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner: COMAR 10.34.04.06 (Check all that apply)

Yes	No	N/A	That the prescription order was prepared by a secondary pharmacy.
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Yes	No	N/A	The name of the secondary pharmacy.
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Yes	No	N/A	The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
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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.
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Yes	No	N/A	The date on which the prescription order was transmitted to the secondary pharmacy.
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Yes	No	N/A	The date on which the medication was sent to the primary pharmacy.
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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
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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
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- Yes** **No** The Pharmacy maintains 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.
- Yes** **No** The Pharmacy maintains records, proceedings, files, and any other documents showing an ongoing Quality Assurance Program that clearly and concisely sets forth policies and procedures to identify, investigate, and promote the prevention of medication errors; and protocols and procedures to minimize the potential for medication errors.
- Yes** **No** The Pharmacy records contain evidence of a periodic review every three (3) months of the quality assurance program and specifically detail:
 - Yes** **No** The system's weaknesses found during the periodic review.
 - Yes** **No** The actions taken to remedy any weaknesses identified in the medication system.
- Yes** **No** The records contain an analysis of a pharmacy's medication delivery system to identify high-alert medications required under the law and specifically (a) list high-alert medications present in the prescription area of the pharmacy; (b) state the date that a high-alert medication was added to or removed from the list of high-alert medications; (c) state the dates that the list was reviewed by the Pharmacy permit holder; and (d) detail actions taken based on the review of the list of high-alert medications and any medication errors relating to the high-alert medications.

Comments: _____

21. QUALITY ASSURANCE – GENERAL

- Yes** **No** The permit holder maintains policies and procedures for the participation of the Pharmacy in the institutional quality assurance and improvement program.
- Yes** **No** The Pharmacy conducts an on-going plan for a quality management program that reviews and evaluates pharmaceutical services and recommend improvements thereof.

Comments: _____

22. NURSING UNITS

- Yes** **No** The Pharmacy maintains policies and procedures for the evaluation of all drug storage areas throughout the institution on a monthly basis and maintain written records of these reviews.
- Yes** **No** Inspections of all drug storage areas throughout the institution are conducted monthly and writtenevaluations are recorded and maintained.

Comments: _____

23. NON-DISPENSING FUNCTIONS OF PHARMACISTS (COMAR 10.34.03.07)

- Yes No** The institution maintains policies and procedures for medication protocols.
If yes:
- Yes No** Approved medication protocols authorize the modification, continuation, and discontinuation of therapy.
- Yes No** The medication protocols authorize the ordering of laboratory tests and other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.
- Yes No** Medication protocols do not authorize the substitution of chemically dissimilar drugs unless permitted in the protocol.
- Yes No** A pharmacist therapeutically interchanges medications only if given prior approval by the authorized prescriber, or if the institution has established guidelines and procedures for the therapeutic interchange of medications.
- Yes No** Guidelines and procedures have been established regarding the therapeutic interchange of medications.

If yes, where are these policies maintained.

Comments: _____

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

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	_____	(C) = A + B
Quantity dispensed	_____	(D)
Expected inventory	_____	(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:

**CIII - CV #
DATE**

COMMENTS:
