



MARYLAND

Department of Health

Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Dennis Schrader, Secretary

MARYLAND BOARD OF PHARMACY

4201, Patterson Avenue, Baltimore, Maryland 21215-2299

Mitra Gavvani, Board President • Deena Speights-Napata, Executive Director

September 20, 2017

Pharmacia at Mt. Washington Mill
130 Smith Avenue, Suite A
Baltimore, MD 21209
Attn: Hanaa Badr, R.Ph.

Re: Permit No. P06043, Case No. PI-16-131
Finding of Deficiencies and Imposition of Civil Monetary Penalty
By Consent

Dear Ms. Badr:

On January 6, 2016, the Board of Pharmacy (the "Board") conducted an annual inspection of Pharmacia at Mt. Washington Mill (the "Pharmacy") to ensure compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated several deficiencies regarding medication inventory and related policies and procedures. Specifically, the Pharmacy: (1) temporarily stored filled prescriptions and patient records in an unsecure manner; (2) stored food in the medication freezer; (3) lacked lot numbers on pre-packaged medications; and (4) lacked signage and policies and procedures to advise patients on the process to report medication errors. The Board's records also indicate that the Pharmacy paid a prior fine in 2015 for having an unlicensed staff person in the prescription area.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated January 6, 2016, and attached as Exhibit A.

Based upon the above deficiencies, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(c)(1), (12), (20) and COMAR 10.34.05, 10.34.14.02, 10.34.36.07.

II. CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies noted at the Pharmacy, and the subsequent mitigating factors presented by the Pharmacy, the Board hereby imposes and the Pharmacy agrees to pay a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

The civil monetary penalty is **due within thirty (30) days** of the date of this letter, in the form of a check made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Maryland Board of Pharmacy
P.O. Box 2051
Baltimore, MD 21203-2051

NOTE: Please include the case number, PI-16-131, on your check or money order to insure proper assignment to your case.

Upon your payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the Board's inspection on January 6, 2016, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the information or instructions contained in this letter, please contact Lisa S. Sanderoff, Pharmacist Investigator Supervisor, at 410-764-4686.

Sincerely,

A handwritten signature in black ink, appearing to read "Deena", written in a cursive style.

Deena Speights-Napata
Executive Director

cc: Linda M. Bethman, AAG, Board Counsel

Exhibit A

multiple deficiencies reviewed 1/16/18



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene
Lawrence J. Hogan, Jr., Governor - Boyd K. Rutherford, Lt. Governor -
Van T. Mitchell, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Mitra Gaugani, Board President - LaVerne G. Naesea, Executive Director

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name The Pharmacia at Mt. Washington Mill
Street Address 1340 Smith Ave, Suite A, Baltimore, Maryland 21209
Business Telephone Number 443-388-8710 Business Fax Number 443-869-3607
Inspection Date: 1/6/2016 Arrival Time: 9am Departure Time: 12pm
Type of Inspection: Annual Follow-up Previous Date: 1/6/2015
Name of Inspector: Shanelle Young

I. GENERAL INFORMATION

Yes No The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment.

Pharmacy Hours M-F: 8:30am-8:30pm Sat: 9am-5pm Sun: 10am-2pm

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 P06043 Expiration Date: 5/31/2016

CDS Registration Number 481553 Expiration Date: 5/31/2017

DEA Registration Number FT4211742 Expiration Date: 11/30/2016

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

Yes No The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23

Yes No The pharmacy fills original prescriptions received via the internet.

Yes No The pharmacy fills original prescriptions via e-prescribing.

Yes No The pharmacist fills mail order prescriptions.

If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07

Comments: _____
The pharmacy services 3 facilities with prescriptions and bubble packs for 1 facility per Staff Pharmacist. 1 license posted, expired & non-renewed (Mayrim Barea ST15740 Exp 10/15, not on duty).

2. PERSONNEL

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

Hanaa Hashem Badr

Pharmacist Employees	License #	Exp Date
Hanaa Hashem Badr	15473	4/2017
Asma Syed (on duty)	18133	3/2016
Trieu Bao	16045	8/2017

Registered Technicians	Registration #	Exp Date
Fortunate Mwanaka (on duty)	P100351	5/31/2017
Janet Akinduro (on duty)	P100324	5/31/2017

Unlicensed Personnel (non-registered)	Title	Duties
Tierra Ashley (on duty)	Clerk <i>Tech in training</i>	put away order, clerk, phone

3. PERSONNEL TRAINING

Yes No N/A 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 and 10.34.21.05

Yes No N/A All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B(3) and (4)

- 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 Patient safety and medication errors COMAR 10.34.26.03

Comments: _____
Pharmacist on duty could not locate personnel training at the time of inspection.

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: _____
Per Asma Syed, staff pharmacist, the pharmacy does not wholesale distribute.

4. 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. (If yes, briefly describe how access is restricted.) COMAR 10.34.05.02A (5)

Comments: _____
The prescription area closes at the same time as the rest of the establishment.

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

Yes No The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)

Comments: _____
None. _____

5. PHYSICAL REQUIREMENTS AND EQUIPMENT

- Yes No Pharmacy area is clean and orderly. HO § 12-403(b)(11)(ii)2.
- 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 10.34.07.01A
- Yes No The pharmacy has hot and cold running water.
- Yes No The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
- Yes No The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B

Temperature 42F _____

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

Temperature 69F _____

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

Temperature 5F _____

Yes No The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)

Yes No The pharmacy has online resources. HO § 12-403(b)(15)

Comments: _____
There was ice cream in the medication freezer with the Zostavax. _____

6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)

The following label requirements are met if a drug is dispensed pursuant to a prescription: HO § 12-505

- Yes No The name and address of the pharmacy; HG § 21-221(a)(1)
- Yes No The serial number of the prescription; HG § 21-221(a)(2)
- Yes No The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3)
- Yes No The name of the prescriber; HG § 21-221(a)(4)
- Yes No The name of the patient; HG § 21-221(a)(5)(i)
- Yes No The name and strength of the drug or devices; HO § 12-505(c)
- Yes No The directions for use; HO § 12-505(b)(2)(ii) and HG §21-221(a)(5)(ii)
- Yes No The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii)
- Yes No The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)
- Yes No The expiration date is indicated; HO § 12-505(b)(2)

Yes No The pharmacist and data-entry technician initials are on prescriptions. COMAR 10.34.08.01

Yes No Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

Comments:

Technician's initials can be identified in the pharmacy's computer system.

7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes No There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider. COMAR 10.34.26.02

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 roles and responsibilities of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

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

Comments:

Pharmacist on duty was unable to provide training in preventing medication errors or evidence of a QA program. There were no procedures posted conspicuously that tells patients what to do if they suspect a medication error.

8. CONFIDENTIALTY

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:

Storage of patient records are questionable. Per Asma Syed, patient records are not disclosed unless authorized by the patient or form is signed by Power of Attorney.

9. INVENTORY CONTROL PROCEDURES

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 a procedure in place for removal of all expired drugs (both prescription and OTC). COMAR 10.34.12.01

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:

Procedure for removal of expired drugs were not retrievable at the time of inspection.

10. CONTROLLED SUBSTANCES

Power of Attorney Hanaa Badr

Yes No The pharmacy has a record of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B

Inventory date: _____

Biennial Inventory completed at Opening or Closing (circle 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 There are written policies and records for return of CII, CIII-V.

Yes No Hard copy or electronic prescription files are maintained chronologically for 5 years.

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 All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)

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)

Comments:

Per Staff Pharmacist, all pharmacists order CII drugs, however there was no power of attorney paperwork for all pharmacists. CII, CIII-V prescriptions were unavailable for review per staff pharmacist.
Policies for returns were also unavailable for review.

11. AUTOMATED MEDICATION SYSTEMS Yes No (if No, go to #12)

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

Policies and procedures exist for (check all that apply): COMAR 10.34.28.04A

- | | | | |
|------------------------------|-----------------------------|---|--|
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Operation of the system |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Training of personnel using the system |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Operations during system downtime |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Control of access to the device |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | 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 safe guards. COMAR 10.34.28.06

N/A

Adequate records are maintained for at least two years addressing the following (check all that apply).
COMAR 10.34.28.11

- | | | | |
|------------------------------|-----------------------------|---|---|
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Maintenance records. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | System failure reports. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Accuracy audits. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Quality Assurance Reports. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Reports on system access and changes in access. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input checked="" type="checkbox"/> | Training records. |

Yes No N/A Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B

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:

N/A.

12. OUTSOURCING

Yes No (if No, go to #13)

Yes No N/A

The facility outsources the preparation of medication 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

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

Comments:

N/A

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)

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

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

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.

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 medication 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: COMAR 10.34.04.07 (Check all that apply)

- Yes No N/A That the prescription order was transmitted from another 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 prepared the prescription order.
- Yes No N/A The date on which the prescription order was received at the secondary pharmacy.
- Yes No N/A The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

13. Recommended Best Practices

- Yes No A perpetual inventory is maintained for Schedule II controlled substances.
- Yes No There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
- Yes No The pharmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov
- Yes No The pharmacy maintains records of all recalls. See www.recalls.gov

INSPECTOR'S COMMENTS:

Reviewed inspection form with Asma Syed, Staff Pharmacist. There were 2 discrepancies found during check of CII perpetual inventory (see attached). Checked pharmacy's inventory pulled 1 outdated item (see attached). Policies, procedures, controlled prescriptions and training were not retrievable at the time of inspection (they were locked in the manager's office). The medication freezer has food in it. Filed patient's prescriptions are stored outside the pharmacy where patients can access them. Action suggested per this inspection: 1) Have Board of Pharmacy inspection documents easily retrievable to be more prepared for on site inspections and to decrease interruptions to patient services when an inspection does occur. 2) Ensure all licenses posted are current and signed. Also ensure student pharmacist have wallet licenses posted or on their person. 3) Be sure to keep food out of the medication freezer. 4) Address audit discrepancies, fax findings with supporting documentation to the Board attention Shanelle Young by 1/13/2016. 5) Send all needed written policies and procedures and controlled documentation to the Board attention Shanelle Young by 1/13/2016.

Inspector Signature Shanelle Young

Pharmacist Name ((Print): Asma Syed Date: 1/6/2016

Signature: *Asma Syed*

Received a copy of this inspection report: *Asma Syed*
Date and Pharmacist Signature

FINAL 09/02/2014

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Clear Form

Pharmacy: The Pharmacia at Mt. Washington Mill
 Permit#: P06043
 Date: 1/6/2016
 Pharmacist Signature: *Shanelle Young*

Rx#: 21629N
 Date Filled: 1/5/2016

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY
Methadone 10mg	00406-5771-01	100	68
Morphine Sulfate 30mg	0054-0236-25	335	335
Oxycontin 10mg	59011-410-10	140	120
Oxymorphone IR 10mg	60951-795-70	80	80

COMMENTS:

Address audit discrepancies, fax findings with supporting documents to the Board attention Shanelle Young by 1/13/2016.

SCHEDULE II AUDIT

Drug N/A
 Date of last Inspection/Biennial N/A

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:
CSOS forms are in the computer system. CII invoices are signed and dated.

CIII - CV:
CIII-V invoices are signed and dated.

PRESCRIPTION REVIEW

**CII #
DATE**

COMMENTS:

Not retrievable at the time of inspection. (locked in manager's office)

**CIII - CV #
DATE**

COMMENTS:

Not retrievable at the time of inspection. (locked in manager's office)

The Pharmacia at Mt. Washington Mill

1747-A South Lakeside Baltimore MD 21209

Phone **(443) 388-8710**

RX#:21620N Dr. Meyerhoff, John

Call Date: 1/5/2016

Qty: 120 OxyCONTIN 1ER 40mg
(BRAND for OXYCODONE HCL TAB CR 40 MG) Mfg. PURDUE PHA
TAKE TWO TABLETS BY MOUTH TWICE A DAY

(Shape:round Color: F: yellow B: yellow D F: OP B: 40)

NDC: 59011-0440-10

Use By: 1 4 2017

Refills: 0 D W: 1/5 2016

IOU: 0

1ER



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene
Lawrence J. Hogan, Jr., Governor - Boyd K. Rutherford, Lt. Governor -
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cg 1/11/16 (LOT # 5)

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Mitra Gavani, Board President - LaVerne G. Naesea, Executive Director

SUPPLEMENTAL FORM FOR ASSISTED LIVING

PERMITS AND LICENSES

Corporate Pharmacy Name The Pharmacia at Mt Washington Mill

Inspection Date: 1/6/2016

Maryland Pharmacy Permit Number P06043

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 The pharmacist and technician initials are on prescriptions or patient drug profiles or computerized patient records. COMAR 10.34.08.01

Comments: _____
There were no lot numbers on blister packs at the time of inspection.

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:

Per staff pharmacist, the pharmacy does not repackage medications for another pharmacy and uses the lot number and expiration date from the manufacturer.

Inspector Signature: _____

Shamelle Young

Pharmacist Name: Asma Syed

(Print)

Received a copy of the inspection report on _____

Asma Syed
Date and Signature of the Pharmacist

