



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

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

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED
ARTICLE #7014 2870 0000 4731 9636

August 11, 2015

Alco Pharmacy
11435 Cronhill Drive, Suite A
Owings Mills, Maryland 21117
Attn: Barbara Denrich

Re: Permit No. PW0249
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Ms. Denrich:

On June 11, 2015, the Board of Pharmacy (the "Board") conducted an annual inspection of Alco Pharmacy (the "Pharmacy") to ensure compliance of with federal and State laws governing the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was not in compliance with regulatory requirements regarding registration of pharmacy technicians. Specifically, a pharmacy technician was performing delegated pharmacy acts in the Pharmacy with a registration that expired on April 30, 2015. The Board's records indicate that the pharmacy technician subsequently renewed her registration. The Board's records also indicate that the Pharmacy had the same type of deficiency in March 2015.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy

410-764-4755 • Fax 410-384-4128 ext. 500 • Toll Free 800-542-4964

DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258

Web Site: www.dhmh.maryland.gov/pharmacy

Inspection Report dated June 11, 2015, and attached as Exhibit A.

Based upon deficiencies cited at your Pharmacy, 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) and § 12-6B-01.

II. RECOMMENDED 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 cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$2,000.00**. 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.

III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to insure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 *et seq.*, and COMAR 10.34.01. Any request for a hearing must be submitted in writing to Vanessa Thomas Gray, Compliance Investigator, Maryland Board of Pharmacy, 4201 Patterson Ave., 1st Floor, Baltimore, Maryland 21215, **no later than thirty (30) days of the date of this Notice.**

Please be advised that at the hearing you would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on your own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports, the Board may suspend or revoke the pharmacy permit, or impose civil penalties, or both. If you request a hearing but fail to appear, the Board may nevertheless hear and determine the matter in your absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty **within thirty (30) days** of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy. Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to this matter, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas Gray, Compliance Investigator, at 410-764-2493.

Sincerely,



LaVerne G. Naesea
Executive Director

cc: Linda Bethman, AAG, Board Counsel
Vanessa Thomas-Gray, Compliance Investigator



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Department of Health and Mental Hygiene
Lawrence J. Hogan, Jr., Governor · Boyd K. Rutherford, Lt. Governor
Laura Herrera Scott, MD, MPH, Acting Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue · Baltimore, Maryland · 21215-2299

Lema Israbian-Jangochian, Board President · LaVerne G. Naesea, Executive Director

Exhibit
A

COMPREHENSIVE CARE PHARMACY INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name ALCO Pharmacy 11435 Cronhill Drive • Suite A Owings Mills, MD 21117 • 443-394-7300
Pharmacy Name-Doing Business as (d/b/a) or Trade Name ALCO PHARMACY
Street Address 11435 CRONHILL DRIVE SUITE A OWINGS MILLS, MD 21117
Business Telephone Number 443 394-7300 Business Fax Number 443 394-6770
Inspection Date: 06/11/2015 Arrival Time: 10:15AM Departure Time: 1:15PM
Type of Inspection: Annual Follow-up Previous Date: 05/08/2014
Name of Inspector: NANCY RICHARD

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: 8AM - 5PM Sat: ON CALL Sun: ON CALL

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 PW0249 Expiration 05/31/2016
CDS Registration Number 442403 Expiration 03/31/2017
DEA Registration Number BA5388536 Expiration 06/30/2018

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: NO WHOLESALER/ OKAY

2. PERSONNEL

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

Pharmacist Employees	License #	Exp Date
JAMIE LEVY	11133	09/30/2015
MILES BLUMBERG	07771	07/31/2015
PAUL GOLDSTEIN	05209	11/30/2015
JULIA WEST	15817	05/31/2017
MARLA SINGER	13308	06/30/2016
JESSICA WONG	22542	09/30/2015
HOWARD GAMPEL	08173	04/30/2017
TAKIA TAYLOR-ANTHONY	16414	01/31/2016

Registered Technicians	Registration #	Exp Date
LAKIESHA TOLSON	T05503	06/30/2016
JENELLE FRANKLIN	T05534	08/31/2016
SHAKITA POLLARD	T03683	08/31/2016
LASHELLE LEE	T02202	12/31/2015
TARYN DAYE JOHNSON	T02539	08/31/2016
CATHY MALLORY	T02135	11/30/2015
EVANGELINE THRASHER	T03202	07/31/2016
LATOWYA HARRIS	T02743	12/31/2015
SHAUNAE COLEMAN	T05977 (WORKING)	04/30/2015
KATE ODAMTTEN	T01103	04/30/2016
SHAUNEE SHERROD-BROWN	T08593	08/31/2016
ASHA POLLARD	T04090	10/31/2016

Unlicensed Personnel (non-registered)	Title	Duties
DARYL HALL	DRIVER	DELIVERIES
ALL OTHER DELIVERIES ARE CONTRACTED OUT BY SDS-RX		
LINCOLN PITTS	DIRECTOR OF OPERATIONS	OVERSEE FACILITY
WILL JONES	DELIVERY SUPERVISOR	OVERSEE DELIVERIES

3. PERSONNEL TRAINING

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

- | | | | | | | |
|-----|-------------------------------------|----|--------------------------|-----|--------------------------|--|
| Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Maintaining records |
| Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Patient confidentiality |
| Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Sanitation, hygiene, infection control |
| Yes | <input checked="" type="checkbox"/> | No | <input type="checkbox"/> | N/A | <input type="checkbox"/> | Biohazard precautions |
| Yes | <input checked="" 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:

OKAY

4. POLICIES AND PROCEDURES COMAR 10.34.23.03

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

Comments:

OKAY

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)
HAS THE SAME HOURS/ LOCKED DOORS/ KEY CARD ACCESS

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:

ALSO HAS MOTION DETECTORS AND SECURITY CAMERAS FOR INSIDE AND OUT SIDE/
OKAY

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 42F AND 44F

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

Temperature 73F

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 N/A

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Sanitation
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Temperature
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Light
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Ventilation
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Segregation
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	Security

Comments: OKAY

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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The name and address of the pharmacy;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The serial number of the prescription;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The date the prescription was dispensed;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The name of the prescriber;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The name of the patient;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The name and strength of the drug or devices;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The quantity of the drug or device;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The required precautionary information regarding controlled substances;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The required cautionary statements or auxiliary labels;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The name of generic manufacturer;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	The expiration date is indicated;
Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>	(Medications in Parenteral Admixtures) The name and amount of drug(s) added;
Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>	(Medications in Parenteral Admixtures) The name of the pharmacist responsible for the admixture;
Yes <input type="checkbox"/>	No <input type="checkbox"/>	N/A <input checked="" type="checkbox"/>	(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 <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	(1) Drug name;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	(2) Drug strength;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	(3) Name of manufacturer;
Yes <input checked="" type="checkbox"/>	No <input type="checkbox"/>	N/A <input type="checkbox"/>	(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: _____
OKAY

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: _____
REPORTING MED ERRORS IS LOCATED IN THE POLICY & PROCEDURES ON THE FACILITY WEBSITE FOR ALL EMPLOYEES AND CUSTOMERS/ MEDICATION ERROR TRAINING IS THROUGH STAFF MEETINGS AND THROUGH LEARN SOMETHING/ OKAY

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: _____
USES IRON MOUNTAIN FOR ALL HIPAA TRASH/ OKAY

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

Yes No N/A The pharmacy maintains records of all recalls. See 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: _____
USES GENCO/ OKAY

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:

OKAY

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: 05/27/2014
- Yes No 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:

TRAMADOL AUDIT CONDUCTED DURING INSPECTION 6/11/15/ HYDROCODONE AUDIT WAS CONDUCTED 10/08/2014 AT CLOSING/ OKAY

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: _____
N/A

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: _____
NO AUTOMATION SYSTEMS

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:

N/A

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:

NO OUT SOURCING/ OKAY

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: _____
OKAY

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;