



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 – Richard A. Proctor, Acting Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED
ARTICLE #7013 1090 0000 3937 6049

January 21, 2016

CVS Pharmacy # 5733
8124 Veterans Highway
Millersville, Maryland 21108
Attn: Brenton Shaffer, R.Ph.

Re: Permit No. P05461, Case #PI-16-072
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Pharmacist Shaffer:

On September 24, 2015, an annual inspection was conducted by the Board of Pharmacy (the "Board") to determine if CVS Pharmacy #5733 (the "Pharmacy") was in compliance with federal and state laws regarding the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was not clean or organized. Similar deficiencies were noted during the Pharmacy's prior inspection of October 30, 2014.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated September 24, 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 (11).

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

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 \$2,500.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Report dated September 24, 2015.

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 the Report have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has not corrected the 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 the Pharmacy would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on the Pharmacy's 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 the Pharmacy requests a hearing but fails to appear, the Board may nevertheless hear and determine the matter in the Pharmacy's 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 the Inspection Report dated September 24, 2015, 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,



Richard Proctor
Acting Executive Director

cc: Linda M. Bethman, AAG, Board Counsel

Bill Irvin, R.Ph.
Director, Regulatory Affairs
CVS Corporation
13 Commerce Avenue
Londonderry, NH 03053

Attachment



STATE OF MARYLAND

Exhibit

A

reviewed by
pending docs
housekeeping needs
(5)

Maryland Department of Health and Mental Hygiene

Lawrence J. Hogan, Jr., Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name CVS PHARMACY # 5733
Street Address 8124 VETERANS HWY., MILLERSVILLE, MD 21108
Business Telephone Number 410-987-5244 Business Fax Number 410-729-7826
Inspection Date: 09/24/2015 Arrival Time: 12PM Departure Time: 2:30PM
Type of Inspection: Annual Follow-up Previous Date: 10/30/2014
Name of Inspector: KERRI WEIGLEY

1. 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: 8AM-10PM Sat: 8AM-6PM Sun: 10AM-6PM

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 P05461 Expiration Date: 05/31/2016
CDS Registration Number 474815 Expiration Date: 02/28/2017
DEA Registration Number AR2983775 Expiration Date: 12/31/2016

- 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: _____
OKAY/VIA 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:

OKAY/TRAINING IS THROUGH LEARN NET.

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:

STAFF PHARMACIST ALEXANDER WOODY STATED THAT THEY DONT WHOLESALE DISTRIBUTE TO OTHER PHARMACIES OR DISTRIBUTORS.

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:

METAL GATES

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:

OKAY/PHARMACY ALSO HAS CAMERAS AND MOTION DETECTORS.

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 36F,38F,46F

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 medications stored within it.

Temperature OF

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:

PHARMACY WASN'T NEAT AND ORGANIZED/GENERAL HOUSEKEEPING IS SUGGESTED:
VACUUM FLOORS,DUST SHELVES,REMOVE BOXES FROM FLOOR

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 <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name and address of the pharmacy; HG § 21-221(a)(1) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The serial number of the prescription; HG § 21-221(a)(2) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The date the prescription was filled; HO § 12-505(b)(1) and HG § 21-221(a)(3) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name of the prescriber; HG § 21-221(a)(4) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name of the patient; HG § 21-221(a)(5)(i) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name and strength of the drug or devices; HO § 12-505(c) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The directions for use; HO § 12-505(b)(2)(ii) and HG § 21-221(a)(5)(ii) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2) |
| Yes <input checked="" type="checkbox"/> | No <input type="checkbox"/> | 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:

OKAY/BOTH PHARMACIST AND TECHNICIAN INITIALS ARE ON THE PRESCRIPTION.

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:

OKAY/MEDICATION ERROR SIGN IS POSTED AT DROP OFF/TRAINING IS THROUGH LEARN NET.

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:

OKAY/HIPAA DOCUMENTS ARE PLACED IN BLUE BAGS/HIPAA MEDICATION CONTAINERS ARE PLACED IN GREEN BAGS.

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:

STAFF PHARMACIST ALEXANDER WOODY STATED THAT THEY DONT WHOLESALE DISTRIBUTE TO OTHER PHARMACIES OR DISTRIBUTORS.

10. CONTROLLED SUBSTANCES

Power of Attorney ALEXANDER WOODY, AND BRENTON SHAFFER

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: 04/30/2016

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:

OKAY/REVIEWED GENCO RETURNS FOR CII-V'S.

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 No N/A
Yes No N/A
Yes No N/A
Yes No N/A
Yes No N/A

Operation of the system

Training of personnel using the system

Operations during system downtime

Control of access to the device

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 No N/A
Yes No N/A
Yes No N/A
Yes No N/A
Yes No N/A
Yes No N/A

Maintenance records.

System failure reports.

Accuracy audits.

Quality Assurance Reports.

Reports on system access and changes in access.

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:

NO AUTOMATED MEDICATION SYSTEM AS OF THIS INSPECTION.

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:

NO OUTSOURCING AS OF THIS INSPECTION.

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 ENTIRE INSPECTION REPORT WITH STAFF PHARMACIST ALEXANDER WOODY/NO
OUTDATES FOUND IN THE PHARMACY AREA/NO OUTDATES FOUND IN THE OTC AREA/ NO
DISCREPANCIES FOUND DURING THE CII AUDIT(SEE ATTACHED)/MOST DOCUMENTS WERE
EASILY RETRIEVED/MARTIA CORSEY IS A TECHNICIAN IN TRAINING, SHE WAS NOT WORKING
DURING THIS INSPECTION/POLICIES AND PROCEDURES ARE LOCATED ON THE
INTRANET/REVIEWED TRAINING DOCUMENTS/PHARMACY WASN'T NEAT AND ORGANIZED AS
OF THIS INSPECTION, AND WAS ALSO DOCUMENTED ON LAST YEAR INSPECTION/ACTIONS PER
THIS INSPECTION: 1) SEND TECHNICIAN TRAINING DOCUMENTS ON MARTIA CORSEY. 2)
GENERAL HOUSEKEEPING IS SUGGESTED: VACUUM FLOOR, DUST SHELVES, AND REMOVE
BOXES OFF OF FLOORS. 3) HAVE BRENTON SHAFFER SIGN HIS LICENSE. 4) HAVE MARIAN GORGY,
JENNIFER MACKEY, AND JEANNIE CRUM SIGN THEIR REGISTRATIONS. SEND ALL NEEDED
DOCUMENTS TO THE BOP BY 10/01/2015, ATTENTION KERRI WEIGLEY.

Inspector Signature Kerri S. Weigley

Pharmacist Name ((Print): ALEXANDER WOODY

Date: 08/24/2015

Signature: Alex Woody

Received a copy of this inspection report: Alex Woody

Date and Pharmacist Signature

FINAL 09/02/2014

