



STATE OF MARYLAND

Department of Health and Mental Hygiene Martin O'Malles, Governor Anthony G. Brown, 12. Gavernor Joshaa M. Sharfstein, M.D.

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue Baltimore, Maryland 21215-2299 Michael N. Souranis, Board President - Le Verne G. Nacsec, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED ARTICLE #7011 3500 0000 7160 2470

February 27, 2013

CVS Pharmacy #4418 8501 Fort Smallwood Road Pasadena, Maryland 21122 Attn: Lawrence Kotey, P.D.

> Re: Permit No. P05464

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Mr. Kotev:

On June 13, 2012, an inspection was conducted by the Board of Pharmacy (the "Board") to determine if CVS Pharmacy #4418 (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 in substantial compliance with regulatory requirements regarding registration of pharmacy technicians. Specifically, the Pharmacy employed a pharmacy technician who was not registered with the Board despite having already completed a technician training program. The Board's records indicate that, to date, the pharmacy technician is still not registered.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated June 13, 2012, 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(b)(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 \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Report dated June 13, 2012.

In determining the recommended civil monetary penalty, the Board took into consideration the following factors:

- 1. History of previous violations;
- 2. Whether the violation was self-reported;
- 3. Admission of misconduct and cooperation during Board inspection;
- 4. Remedial measures implemented;
- 5. Timely good faith effort to rectify consequences of misconduct;
- 6. Potential harm to the public or adverse impact;
- 7. Whether incident was isolated and unlikely to recur;
- 8. Whether misconduct was motivated by financial gain.

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 a follow-up inspection indicate that the Pharmacy is not in substantial compliance, 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 recommended 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 by submitted in writing to Vanessa Thomas Gray, 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 the Inspection Report dated June 13, 2012, 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, Investigator, at 410-764-2493.

Sincerely,

LaVerne G. Naesea Executive Director

Attachment

cc: CVS, Director of Regulatory Compliance

Linda M. Bethman, Assistant Attorney General, Board Counsel

Vanessa Thomas-Gray, Compliance Investigator



STATE OF MARYLAND

Ed, Tech Training ,

Department of Health and Mental Hypiene

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4201 Patterson Avenue® Baltimory, Maryland 21215-2299 Michael Somans, Buard President - Lal erne G. Aaesen, Livernive Director

COMMUNITY PHARMACY INSPECTION REPORT Pe mit: P05464 Inspection I esult Inspect on Date Type of Inspection 6/13/2012 FIRST STREET STORY OF STREET Previous Insp. Dale: 5/31/2011 Phainmacy Name CVS PHARMACY #4418 Inspector Ychan Corporate Name MARYLAND CVS PHARMACY LLC 8501 FORT SMALLWOOD RD Address i elephone 4104371149 City PASADENA Permit Exp. Date State 2013 Zp 21122 Fax 4104393043 Arrival time 2:00PM . GENERAL INFORMATION Departure Time 4 30PM Yes Yes

The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment

All permits, licenses, and registrations are posted conspicuously. HO §12-3*1, HO §12-408(b) and HO §12-6B-08 CDS Registration / 474813 CDS Exp. Date 02/28/2013

The phermacy perform sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34 19

The pharmacy provides services to Long Term Care facilities or assisted living facilities. (If yes, complete Long Term Care Inspec on Form) No VO

The pharmacy fills original prescription received via the internet

Yes The pharmacy fills original prescriptions via e-prescribing.

No The pharmacist fills mail order prescriptions.

If yes to any of the above, how do pharmacists verify that a relationship exists between the patient and the prescriber YG §21-220, COMAR 10 19 03 O2

FORMER EMPLOYEE'S LICENSES AND REGISTRATIONS ARE STILL POSTED Comments

2. PERSONNEL (COMAR 10.34.03.05)

Name of Pharmac'st/Manager who is charged with ensuring compliance with all applicable laws Pharmacist Employees LAWRENSE KOTEY Licensellurber Low Norm

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Registration #	Last Neme	£7.		.,
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	WITHROW	ANNA		9/30/2013
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	SOWARDS	GLORIA		11/30/2013
T08964	CARVEY	JULIA VI\ A	J	1/31/2013
			R	8/31/2012

Unlicensed

Name

Personnel: CHARLES CARNES

Title

Dite

Comments

HEATHER SPENCER TRIANING TECH

IN PERFORMING DUTIES LISTED ABOVE 3. PERSONNEL TRAINING

BRITTNEY WILLIAMS - CASHIER. BOTH TRAINING TECHNICIANS ARE ON DUTY DURING INSPECTION AND WERE OBSERVED There are policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed Yes Yes

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):10.34 21.03B (3)-(4) Biohazard precautious

Yes Yes

Patient confidentiality

Sanitation, hygiene, infection Control

Yes

Patient safety and medication errors COMAR 10.34.26.03

Comments SEE TRAINING TECHNICIAN DOCUMENTS ATTACHED

4. SECURITY COMAR 10.34.05 Yes

The pharmacy is designed to prevent unauthorized entry when the prescription area is closed during any period that the rest of the

The pharmacy and/or pharmacy department has a security system COMAR 10.34.05 02A(2) Yes Yes

The pharmacy analog pharmacy department has a security system. COMAR 10.34.05 02A(Z)

The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately evaluable on the premises to

Comments

5. PRYSICAL REQUIREMENTS AND EQUIPMENT

Pinarmacy area is clean, neat, and organized HO §12-403(b)(11)(ii)2

The pharmacy provides a compounding service (non-sterile procedures) Yes

If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice

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

Yes

The medication refrigerator(s) contain only prescription and OTC items CON AR 10.34.07 01B Yes No. Yes

The medication refrigerator(s) have a thermometer and the current temperature is between (36 - 46 F) USP COMAR 10 34 07 018 Temperature:

The current temperature of the pharmacy department is between 59 to 86 F. COMAR 10.34 05 02A(1)(a) Temperature:

WA

maintained at temperatures required by the medications stored within it

The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy Yes 32F, 40F, 40F, 18F and the consumers the pharmacy serves HO § 12-403(b)(10) Yes The pharmacy has online resources. HO §12-403(b)(15) Comments:

TWO OF THE FOUR MEDICATION REFRIGERATORS WERE BELOW THE REQUIRED RANGE NO MEDICATION ARE STORE PRESCRIPTION LABELING FILES AND STORAGE

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) HO §12-403(b)(13) The following label requirements are met if a drug is dispensed pursuant to a prescription. HO §12-505 Yes Yes Yes

The date the prescription was filled; HO §12-505(b) (1) and HG §21-221(a)(3) The name of the patient; HG §21-221(a) (5) (i) The serial number of the prescription, HG §21-221(a) (2)

'AS Yes

The directions for use, HO§12-505(b)(2)(ii) and HG§21-221(a)(5)(ii) Yes The name of generic magnifectures and HO§42-505(c)

The pharmacist and data entry technician initials are on prescriptions COMAR 10 34 08 01 Yes Original prescriptions are dispensed within 120 days after the issue date HO §12-503 The expiration date is indicaled, HO (12-505(b) (2)

Comments: OK

- licre are written policies that inform patients of the procedures to follow when reporting a suspected medication error to the permit holder, 10 phumacist, health care facility or other health care provider. COMAR 10 34.26 02 Ye;
- The pharmacy maintains a minimum of 2 continuous years of records clearly demonstrating the content of annual educational training provided to Unch member of the pharmacy staff involved in the medic, tion delivery system regarding the role and responsibility of pharmacy staff in preventing Commonts:
- There is an ongoing quality assurance program that documents the competincy and accuracy of all assigned tisks COMAR 10 34 21 03E Yes O. CONFIDENTIALTY
- Confidentially is main ained in the creation, storage, access disposal and disclosure of patient records. HO§12-403(b)(13),COMAR 10 34 10 03.4 and
- 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 Yes Comments:

9. INVENTORY CONTROL PROCEDURES

The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals COMAR10 34 24 03 **Yes** Comments:

The pharmacy has a procedure in place for removal of all expired drugs (both prescription and OTC) COMAR 10 34.12.01

· O. CONTROLLED SUBSTANCES

Power of Attorney 16918 A KOTEY LAWRENCE

The pharmacy has a record of the most recent required blennial inventory of Schedule II-V controlled substances COI/AR 10 19 03 05B Yes Inventory date. Pennial Inventory completed at

The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10 19 03.05 and 21 CFR 130/ 03 Yes Yes

Records are kept of all receipts of controlled substances entered into the pharmacy inventory (including DEA Form 222 or CSOS There are written policies and records for return of CII, CIII-V.

Yes

Hard copy or electronic prescription files are maintains chronologically for 5 years (CDS-Fed Law) Yes **ν**εs

Schedule II controlled substances are dispersed throughout the stock of non-controlled substances or storeo in such a manner es to obstruct Yes Yag

All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19 03 07D (1)

The perm. holder or oharmacist designee(s) has written policies and procedures for investigaling discrepancies and reporting of their or loss

Comments:

11. ALTO, ATED MEDICATION SYSTEMS (If No. go to ; 2)

No The facility uses any automated device(s) as defined in COMAR 10.34.28 02

Policies and procedures exist for (check all that apply) COMAR 10 34.28.05

There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records ŃΙΔ

Control of access to the device Training of personnel using the system N/A Accounting or medication added and removed from the system Operations during sys ≟m down r∩e

Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system If yes, describe safe guards. COWAR 10.34.28.06

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

N/A System failure reports. N/A Quality Assurance Reports.

Devices installed after Sept. 1, 2003 operate in a manner to limit simultaneous access to multiple strength, forms and drug entities and minimize the potential for misidentification of medications, dosages and dosage forms accessed from the automated medication system. COMAR 10.34.28.04 3

The pharmacy has records documents or other evidence of a quality assurance program regarding the automated medication system in

Conmicnis: NA

12. OUTSOURSING (If No. go to 113)

The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10 34 04 02 No N/A

The facility serve; as a primary pharmacy outsourcer to other pharmacies. COMAR 10 34 04 02

The facility serves as a secondary pharmacy. COMAR 10.34 04 02 NVA NIA

The permit holder employs an outside agency/business entity for the provision of any Pharmacy services, inclusive of staffing remote order entry

State of Incorporation N/A Service contracted N/A MiD Licensell N/A

Comments: 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) N/A WA

The original prescription order is filed as a prescription order at the primary pharmacy COMAR 10 34.04 06D MA

VV/ritten policies exist for maintenance of documentation regarding transfer of prescription records COMAR 10 34 04 06 VA

Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists and a record of the prepara, ons

The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner (Check all that apply) COMAR 10.34-04.06 N/A

The name of the pharmacist who transmitted the prescription order to the secondary pharmacy N/A

The name of the pharmacist at he secondary pharmacy to whom the prescription order was transmitted if the transmission occured in an oral manner MA

The date on which the prescription order was transmitted to the secondary pharmacy

The date on which the preparation was sent to the primary pharmacy N/A N/A

The primary and secondary pharmacies are both licensed in the State of Maryland or operated by the federal government COMA 34 04 065 N/A pharmacy.COMAR 10.34.04.06G

The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from secondary

The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner which includes (check all that apply) CONAR 10.34 04.07 That the prescription order was transmitted from another pharmacy.

NA NA

The name and information identifying the specific location of the primary pharmacy MA

The name of pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner MA

The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order V/A

The name of the pharmacist at the secondary pharmacy who prepared the prescription order

The date on which the prescription order was received at the secondary pharmacy ٧/A

The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy 3. Recommended Best Practices:

A perpetual inventory is maintained for Schedule II controlled substances. (Recommended) PS. es

There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records. es

The pharmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls gov

The pharmacy maintains records of all recalls. See www.recalls.gov

REVIEWED ENTIRE INSEPCTION REPORT WITH LAWRENSE KOTEY, RPH AND ANNA WITHROW, CPHT. CONDCUTED CII AUDIT, Spector ONE MINOR DIFFERENCE FOUND, ADDERALL XR 20MG (319/318), +1 EXCESS. SPOT CHECKED MEDICATION SHELVES, NO ommen s: OUTDATES FOUND, TRAINING TECHNICIAN CHARLES CARNES (FULL TIME) AND HEATHER SPENCER (PART TIME) WERE BOTH OBSERVED IN PERFORMING TECHNICIAN DUTIES DURING INSPECTION CHARLES CARNES STARTED HIS TRAINING IN THE PHARMACY ON 08/24/2011 AND HEATHER SPENCER STARTED HER TRAINING ON 06/04/2012. SEE ATTACHED. VIEWED AND PRINITED POLICIES AND PROCEDURES IN PHARMACY RETURN BINDER AND FROM PHARMACY INTRANET, SUGGESTED TO RP-1 TO KEEP THESE DOCUMENTS WITH THIS INSPECTION REPORT FOR FUTURE INSPECTION. PER THIS INSPECTION 1) MAKE SURE ALL FORMER EMPLOYEE'S LICENSES AND REGISTRATIONS ARE REMOVED. 2) MAKE SURE ALL MEDICATION REFRIGERATORS ARE WITHIN THE REQUIRED RANGE OF 36F-46F 3) SIGN AND DATE ALL CIII-V INVOICES ON THE DAY OF RECEIVING 4) ADJUST THE PERPETUAL INVENTORY OF ADERALL XR 20MG TO REFLECT THE CURRENT COUNT 4) FORWARD THE MICCINIC POLICIES IN \$7 TO MO ROARD OF PHARMARY ATTENTION VIN CHAN RY 05/20/2012

PER TIES INSPECTION I) MAKE SURE ALL FORMER EMPLOYEE'S LICENSES AND REGISTRATIONS ARE REMOVED. 2) MAKE SURE ALL MEDICATION REFRIGERATORS ARE WITHIN THE REQUIRED RANGE OF 36F-46F 3) SIGN AND DATE ALL CIII-V INVOICES ON THE DAY OF RECEIVING 4) ADJUST THE PERPETUAL INVENTORY OF ADERALL XR 20MG TO REFLECT THE CURRENT COUNT 4) FORWARD THE MISSING POLICIES IN #7 TO MD BOARD OF PHARMACY, ATTENTION YIN CHAN BY 06/20/2012

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

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Inspector Signature

Pharmacist Printed Name | LAWRENSF KOTEY Date

06/13/2012

Anna Mwithrow Anna Mwithrow

IF PREGNANT OR OF CHILDBEARING AGE, DISCUSS RISKS/BENEFITS WITH MD OR A H

MAY CAUSE DROWSINESS. ALCOHOL INTENSIFIES FFFECT. USE CARE USING MACHINES.

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Refills require authorization

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R:: # N913348 Pr day: 115A1 YMN1 ORD TAKING MORE THAN RECOMMENDED MAY CAUSE BREATHING PRORLEMS.

DO NOT DRINK ALCOHOLIC REVERAGES WHEN TAKING THIS MEDICATION.

274 received a copy of this inspection re-roof on 6/13/2012.