



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor Anthony G. Brown, Lt. Governor Joshua M. Sharfstein, M.D., Secretary



MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Michael N. Souranis, Board President - LaVerne G. Naesea, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED
ARTICLE #7011 3500 0000 7160 2319

February 19, 2013

CVS Pharmacy #1444
7300 Washington Baltimore Boulevard
College Park, Maryland 20740
Attn: Angela Odunlami, P.D.

Re: Permit No. P05177
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Ms. Odunlami:

On May 23, 2012, an inspection was conducted by the Board of Pharmacy (the "Board") to determine if CVS Pharmacy #1444 (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 the pharmacy technician became duly registered on August 14, 2012.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated May 23, 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 May 23, 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 be 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 May 23, 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: Susan DelMonico, CVS Corporate
Linda M. Bethman, Assistant Attorney General, Board Counsel
Vanessa Thomas-Gray, Compliance Investigator



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor Anthony G. Brown, Lt. Governor John M. Colner, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue? Baltimore, Maryland 21215-2299

Michael Souranis, Board President - LaVeme G. Naesca, Executive Director

Exhibit

A

CJ
6/5/12
f...

COMMUNITY PHARMACY INSPECTION REPORT

Permit: P05177

Inspection Result

Type of Inspection Annual



Inspection Date 5/23/2012

Previous Insp. Date: 5/4/2011

Inspector Jeannell M

Pharmacy Name CVS PHARMACY 1444

Corporate Name

Telephone 3012776114

Permit Exp. Date 2013

Address BALTIMORE BLVD 7300 WASHINGTON

City COLLEGE PARK State MD Zip 20740

Fax 3012772281

Departure Time 2:40pm

Arrival time 12pm

1. GENERAL INFORMATION

Yes 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 9am-9pm Saturday 9am-6pm Sunday 10am-6pm

Yes All permits, licenses, and registrations are posted conspicuously. HO §12-311, HO §12-408(b) and HO §12-6B-08

CDS Registration # 470118 CDS Exp. Date 12/31/2013 DEA # AP2321038 DEA Exp. Date 12/31/2013

No The pharmacy perform sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19
No The pharmacy provides services to Long Term Care facilities or assisted living facilities. (If yes, complete Long Term Care Inspection Form) COMAR 10.34.23

No 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. HG §21-220; COMAR 10.19.03.02
pharmacy verifies

Comments

PERSONNEL (COMAR 10.34.03.05)

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

License Number	Last Name	First Name	Expiration	Status
16502	ODUNLAMI	ANGELA	05/2014	A
Registration #	Last Name	First Name	Exp. Date	
T08843	DO	SANG	3/31/2013	T
T04330	Alford	Brian	11/30/2012	R
Unlicensed Personnel:	Name	Title	Duties	

Comments

3. PERSONNEL TRAINING

- Yes There are policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03A and 10.34.21.05
- 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)
 - Yes Maintaining records
 - Yes Patient confidentiality
 - Yes Sanitation, hygiene, infection Control
 - N/A Biohazard precautions
 - Yes Patient safety and medication errors COMAR 10.34.26.03

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 establishment is open. If yes, briefly describe how access is restricted. COMAR 10.34.05.02A(5)
 - Gates; Cameras; Alarm System
- Yes The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A(2)
- Yes 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:

5. PHYSICAL REQUIREMENTS AND EQUIPMENT

- Yes Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2.
- Yes 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. COMAR 10.34.07.02
- Yes 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 The pharmacy has hot and cold running water.
- Yes The medication refrigerator(s) contain only prescription and OTC items. COMAR 10.34.07.01B
- Yes The medication refrigerator(s) have a thermometer and the current temperature is between (36 - 46 F) USP COMAR 10.34.07.01B Temperature: 36F; 38F; 42F
- Yes The current temperature of the pharmacy department is between 59 to 86 F. COMAR 10.34.05.02A(1)(a) Temperature: 69F
- N/A If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.
- Yes The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specially of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)
- Yes The pharmacy has online resources. HO §12-403(b)(15)

Comments:

PRESCRIPTION LABELING FILES AND STORAGE

- Yes 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 The name and address of the pharmacy; HG §21-221(a) (1)
 - Yes The serial number of the prescription; HG §21-221(a) (2)
 - Yes The date the prescription was filled; HO §12-505(b) (1) and HG §21-221(a)(3)
 - Yes The name of the prescriber; HG §21-221(a) (4)
 - Yes The name of the patient; HG §21-221(a) (5) (i)
 - Yes The name and strength of the drug or devices; HO §12-505(c)
 - Yes The directions for use; HO§12-505(b)(2)(ii) and HG§21-221(a)(5)(ii)
 - Yes The required cautionary statements or auxiliary labels; HG§21-221(a)(5)(iii)
 - Yes The name of generic manufacturer; and HO §12-504(d) (2) and §12-505(c) (2)
 - Yes The expiration date is indicated; HO §12-505(b) (2)
- Yes 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

Comments:

QUALITY ASSURANCE - PATIENT SAFETY/MEDICATION ERRORS

- Yes There are written policies that inform patients of the procedures to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility or other health care provider. COMAR 10.34.26.02
- Yes The pharmacy maintains a minimum of 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

Yes There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E
Comments:

8. CONFIDENTIALTY

Yes 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 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:

9. INVENTORY CONTROL PROCEDURES

Yes The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03
Yes The pharmacy has a procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01
Comments:

10. CONTROLLED SUBSTANCES

Power of Attorney 16502 A ODUNLAMI ANGELA
Yes 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: 04/30/2011 Close
Biennial inventory completed at
Yes 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 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 There are written policies and records for return of CII, CIII-V.
Yes Hard copy or electronic prescription files are maintained chronologically for 5 years (CDS-Fed Law)
Yes 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 All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)
Yes 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:

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

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
Yes There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
N/A Operation of the system N/A Training of personnel using the system N/A Operations during system downtime
N/A Control of access to the device. N/A Accounting for medication added and removed from the system.
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
Adequate records are maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11
N/A Maintenance records. N/A System failure reports. N/A Accuracy audits.
N/A Quality Assurance Reports. N/A Reports on system access and changes in access N/A Training records.
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 10.34.28.04B
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:

12. OUTSOURCING (If No, go to #13)

- No The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- N/A The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
- N/A The facility serves as a secondary pharmacy. COMAR 10.34.04.02
- 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, COMAR 10.34.04.03E

Name of Agency:
 State of Incorporation:
 Service contracted:
 MD License#

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 If the pharmacy outsources a prescription order:
- N/A The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
- N/A Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- 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 (Check all that apply): COMAR 10.34.04.03
 - N/A The prescription order was prepared by a secondary pharmacy
 - N/A The name of second pharmacy
 - N/A The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
 - 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.
 - N/A The date on which the prescription order was transmitted to the secondary pharmacy.
 - N/A The date on which the preparation was sent to the primary pharmacy.
 - N/A The primary and secondary pharmacies are both licensed in the State of Maryland or operated by the federal government. COMAR 10.34.04.06E
 - N/A The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from secondary pharmacy. COMAR 10.34.04.06G
 - N/A 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
 - N/A That the prescription order was transmitted from another pharmacy.
 - N/A The name and information identifying the specific location of the primary pharmacy.
 - N/A The name of pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
 - N/A The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
 - N/A The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
 - N/A The date on which the prescription order was received at the secondary pharmacy.
 - N/A The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

Recommended Best Practices:

- A perpetual inventory is maintained for Schedule II controlled substances. (Recommended)
 - There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
 - 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
- Removed: Temazepam 7.5mg exp 4-12; Solodyn 135mg exp 3-12; Ropinirole 0.5mg exp 3-12; Rynatan exp 4-12 (2 bottles); Nortriptyline 75mg exp 4-12 (2bottles). Be sure that all prescriptions have the prescribing doctor that signed the prescription on labels. All full time pharmacist and technicians must post their signed original license/registration in the pharmacy. All part time pharmacist and technicians can post a copy of the signed original. Currently the pharmacy does not have a pharmacy manager. No discrepancies with CII audit. Reviewed inspection report with pharmacist on duty Angela Odunlami #16502. Technicians: Imani Johnson and Taryn Johnson are in training. Technician Arvind Sharma does not have a current registration. Technician Sonia Almonte T10567 is current and needs to post registration in the pharmacy. Training documents with hire dates are attached.

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Date of Inspection: 5-23-12
 Pharmacy: CVS # 1444
 Permit #: 205177

Rx# N521442

DRUGS	ON HAND INVENTORY	PERPETUAL INVENTORY
Adderall XR 10mg		
Oxycodone 5mg tab	270	270
Oxycodone/APAP 10-325mg	320	320
Vyvanse 30mg	107	107
	75	75

COMMENTS: No discrepancies with CII audit.

SCHEDULE II AUDIT

Drug _____
 Date of last Inspection/Biennial _____

Amount at last inspection/biennial	_____ (A)
Purchased since inspection/biennial	_____ (B)
Total inventory	_____ (C) = A + B
Quantity dispensed	_____ (D)
Expected inventory	_____ (E) = C - D
Quantity on Hand	_____ (F)
Discrepancy	_____ (G) = (F-E) or (E-F) Excess Shortage

INVOICE REVIEW

CII

OK

CIII - CV

OK

PRESCRIPTION REVIEW

CII # N0520012 - # N0520971
 DATE 5-11-12 - 5-18-12

COMMENTS: _____

OK

CIII - CV # C0520001 - # C0520977
 DATE 5-9-12 - 5-18-12

COMMENTS: _____

OK

Pharmacist Signature:

Inspector Signature:

Jannelle McKnight CPLT

Pharmacist Printed Name Angela Odunlami

Date: 5-23-12

MAY IMPAIR ABILITY TO USE
MACHINES. USE CARE UNTIL
FAMILIAR WITH EFFECTS.
MAY CAUSE DIZZINESS

DO NOT CHEW OR CRUSH BEFORE
SWALLOWING

RPH. Angela Odunlami

Orig: 04/09/2012

Date filled: 05/23/2012

Discard After: 05/23/2013

This is a WHITE, REDDISH BROWN,
OBLONG shaped CAPSULE imprinted with
UCB 581 on the one side and 30MG on the
other.

FOR THE PHARMACY
CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER
OF THIS DRUG TO ANY PERSON OTHER THAN THE
PATIENT FOR WHOM IT IS PRESCRIBED



**METADATE CD 30 MG
CAPSULE**

**TAKE ONE CAPSULE BY
MOUTH EVERY MORNING**

Qty: 30

Refill: require authorization

Store Phone: (301) 277-6114

Rx # N521442

Prescriber: NICOLE F WASHINGTON

Have copy of inspection report to pharmacist on duty Angela Odunlami.

Pharmacist Signature:

Date:

Angela Odunlami