



STATE OF MARYLAND

**DHMH**

Department of Health and Mental Hygiene

*Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - John M. Colmers, Secretary*

**MARYLAND BOARD OF PHARMACY**

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald W. Taylor, Board President - LaVerne G. Naesea, Executive Director

**CERTIFIED MAIL RETURN RECEIPT REQUESTED**  
**ARTICLE #7008 1830 0001 1597 6475**

May 11, 2010

Mr. Steven Riggan  
CVS Pharmacy  
11729 Beltsville Drive  
Beltsville, MD 20705

Re: CVS #1451  
Permit No. P00514  
Notice of Deficiencies, Imposition of Civil Monetary Penalty, and  
Opportunity for Hearing

Dear Mr. Riggan:

On December 29, 2009, an inspection was conducted by the Board of Pharmacy (the "Board") to determine if CVS Pharmacy #1451 (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. Among other things, the Pharmacy employed approximately seven (7) unlicensed pharmacy personnel who were not registered or in training to become registered pharmacy technicians. In addition, none of the registered technicians had their registrations posted.

**I. FINDINGS AND CONCLUSION**

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated December 29, 2009, 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), §§ 12-6B-01 and 08.

**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 imposes a **civil monetary penalty of \$7,000.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Report dated December 29, 2009.

In determining whether to impose a civil monetary penalty, the Board took into consideration the following factors:

1. The extent to which the permit holder derived any financial benefit from the unprofessional or improper conduct;
2. The willfulness of the unprofessional or improper conduct;
3. The extent of actual or potential public harm caused by the unprofessional or improper conduct;
4. The permit holder's history or previous violations;
5. The existence of mitigating factors.

The civil monetary penalty is **due 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.

### **III. FOLLOW-UP INSPECTION**

Please be advised that Division of Drug Control, or other agent of the Board, will perform a follow-up inspection of the Pharmacy no later than **June 30, 2010**, to insure that the deficiencies noted the Report have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has not come into 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 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 issue formal charges and a letter of procedure. 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 Kimberly France, Pharmacist Compliance Officer, Maryland Board of Pharmacy, 4201 Patterson Ave., 1<sup>st</sup>

Floor, Baltimore, Maryland 21215, no later than thirty (30) days of the date of this Notice.

Please be advised that at the hearing you 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.

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 December 29, 2009, 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 Kimberly France, Pharmacist Compliance Officer, at 410-764-5908.

Sincerely,



LaVerne G. Naesea  
Executive Director

cc: Chandra Mouli, Deputy Chief  
Division of Drug Control  
Linda Bethman, Assistant Attorney General  
Board Counsel

Attachment

INTERED  
12/2/09  
(SY)



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DHMH

EXHIBIT

MARYLAND BOARD OF PHARMACY  
4201 Patterson Avenue • Baltimore, Maryland 21215-2299  
Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

A

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name CVS #1451  
Pharmacy Name-Doing Business as (d/b/a) or Trade Name \_\_\_\_\_  
Street Address 1620 LAUREL BOWIE RD BOWIE MD 20715  
Business Telephone Number 301.242.8400 Business Fax Number 301.2102.8403  
Inspection Date: 12.29.09 Arrival Time 10:00AM Departure Time 12:30PM  
Type of Inspection: Annual Follow-up Previous Date: \_\_\_\_\_  
Name of Inspector: Shanika Young

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: MON-FRI 7-12 SAT-SUN 7-12

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

Maryland Pharmacy Permit Number P00514 Expiration Date: 12.31.09  
CDS Registration Number 21092185 Expiration Date: 5.31.11  
DEA Registration Number A122327985 Expiration Date: 12.31.10

The pharmacy performs 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 Inspection Form) COMAR 10.34.23

Yes No

The pharmacy fills original prescriptions received via the internet.  
  The pharmacy fills original prescriptions via e-prescribing.  
  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: pharmacist verifies if he feels he should

**2. PERSONNEL**

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

SHISHIR KANE

Pharmacist Employees	License #	Exp Date
<u>LEROY BRADLEY</u>	<u>071916</u>	<u>9.30.10</u>
<u>JESSICA ROSS</u>	<u>1712213</u>	<u>12.31.11</u>
<u>SHISHIR KANE</u>	<u>178410</u>	<u>2.28.10</u>

(Attach list if necessary)

Registered Technicians	Registration #	Exp Date
<u>Jessica Hill</u>		<u>Not in system</u>
<u>Jana Janis</u>	<u>T010318</u>	<u>9.30.10</u>
<u>Ayla Goodman</u>	<u>T01702</u>	<u>Not in system 10.30.10</u>
<u>Della Land</u>		<u>Not in system</u>
<u>Tukia Newbome</u>		<u>Not in system</u>
<u>FRANCES OYANKWA</u>	<u>T02846</u>	<u>9.30.11</u>
<u>Diane Tawasha</u>	<u>T00711</u>	<u>5.31.10</u>

(Attached list if necessary)

Unlicensed Personnel (non-registered)	Title	Duties
<u>Dominic Medina</u>	<u>PSA</u>	
<u>Kestina Fern</u>	<u>PSA</u>	
<u>Wahne Jackson</u>	<u>PSA</u>	
<u>Jatek Major</u>	<u>PSA</u>	
<u>FRANCES OYANKWA</u>	<u>PSA</u>	<u>T02846 9.30.11</u>

(Attach list if necessary)

**3. PERSONNEL TRAINING**

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 and 10.34.21.05
- 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

- Maintaining records
- Patient confidentiality
- Sanitation, hygiene, infection control
- Biohazard precautions
- Patient safety and medication errors COMAR 10.34.26.03

Comments: see comments, page 8

**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)
- The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)
- 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: door, gate  
\_\_\_\_\_  
\_\_\_\_\_

### 5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes No

- Pharmacy area is clean and orderly. HO § 12-403(b) (11) (ii)2.
- 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
- The pharmacy has hot and cold running water.
- The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
- The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B

Temperature 40F, 31F, 31F  
 The current temperature of the pharmacy department is between 59 to 86 degrees F.  
COMAR 10.34.05.02A (1)(a)

N/A  If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.

Temperature \_\_\_\_\_

- 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)
- The pharmacy has online resources. HO § 12-403(b)(15)

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

## 6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No

Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)

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

Yes No

- The name and address of the pharmacy; HG § 21-221(a)(1)
- The serial number of the prescription; HG § 21-221(a)(2)
- The date the prescription was filled; HO § 12-505(b)(1) and HG § 21-221(a)(3)
- The name of the prescriber; HG § 21-221(a)(4)
- The name of the patient; HG § 21-221(a)(5)(i)
- The name and strength of the drug or devices; HO § 12-505(c)
- The directions for use; HO § 12-505(b)(2)(ii) and HG § 21-221(a)(5)(ii)
- The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii)
- The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)
- 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
- Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

Comments: viewed on pharmacy internet  
\_\_\_\_\_  
\_\_\_\_\_

**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
- 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 No

- The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03
- 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 Leroy Bradley

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: 10.9.2009
- Biennial Inventory completed at Opening of Closing (circle one)
- The inventories and records of Schedule H-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
- 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
- There are written policies and records for return of CII, CIII-V.
- Hard copy or electronic prescription files are maintained chronologically for 5 years.
- 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)
- All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)
- 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** Yes  No  (if No, go to #12)

Yes No

- 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

- 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.
- 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

Yes No

- Maintenance records.  
  System failure reports.  
  Accuracy audits.  
  Quality Assurance Reports.  
  Reports on system access and changes in access.  
  Training records.
- 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
- 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 Yes  No  (if No, go to #13)

Yes No

- The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- The facility serves 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
- 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:

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- 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:

- The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
- Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- 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

- That the prescription order was prepared by a secondary pharmacy.
- The name of the secondary pharmacy.
- The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
- The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
- The date on which the prescription order was transmitted to the secondary pharmacy.
- The date on which the medication was sent to the primary pharmacy.

Yes No

- The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F
- 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

- That the prescription order was transmitted from another pharmacy.
- The name and information identifying the specific location of the primary pharmacy.
- The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
- The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- 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.
- 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.
- 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](http://www.recalls.gov)
- The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)

**Inspectors Comments:**

There are no technician's registrations posted.  
 Please post all licenses and registrations for all to see. There are 15 technicians and pharmacy service associates (see attached).  
 During check of drug inventory, noted several R/S medication bottles with visible patient information. Pull expired medications, see attached.  
 No expired OTC items found.  
 Checked perpetual inventory.  
 2 discrepancies found. send explanation to board in 5-7 business days.  
 Viewed training for 1/2 technician in, 1/2 technician in, 1/2 technician in, 1/2 technician in. (could not view) training for employees not in pharmacy.  
 PSA should only work on register unless being trained.

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

MAY CAUSE DIZZINESS.

TAKING MORE THAN RECOMMENDED  
MAY CAUSE BREATHING PROBLEMS.

RPH: LEROY BRADLEY  
Orig: 12/29/2009  
Date filled: 12/29/2009  
Discard after: 12/29/2010

This is a WHITE, ROUND-shaped, TABLET imprinted with 512 on the front.  
NDC 60300750001  
CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS DRUG TO ANY PERSON OTHER THAN THE INDIVIDUAL FROM WHOM IT WAS PRESCRIBED.

**OXYCODONE-APAP**  
 5-325 MG TABMCK  
 SUBSTITUTED FOR: PERCOCET 5-325 MG TABLET FND  
 TAKE 1 TABLET BY MOUTH EVERY 8 HOURS AS NEEDED

Qty: 30 Refills require authorization  
 Store Phone: (301) 262-8400  
 Rx # N764018  
 Prescriber: PETER L'AMWIL

Inspector Signature

*Shanille Young*

Pharmacist Name ((Print):

*Leroy Bradley*

Date: 12-29-09

Signature:

