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 Gavgani, Board President - Richard A. Proctor, Acting Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED ARTICLE #7013 1090 0000 3937 6070

January 29, 2016

CVS Pharmacy # 2775 2601 Riva Road Annapolis, Maryland 21401 Attn: Erica M. Richardson, R.Ph.

Re:

Permit No. P05302

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Ms. Richardson:

On October 14, 2015, an annual inspection was conducted by the Board of Pharmacy (the "Board") to determine if CVS Pharmacy #2775 (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 compliance with regulatory requirements pharmacy technician registration. Specifically, the Pharmacy had a pharmacy technician performing delegated pharmacy acts on an expired registration. The Board's records indicate that the technician was subsequently reinstated on October 28, 2015, The Board's records also indicate the Pharmacy was previously cited for a similar deficiency.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated October 14, 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 \$5,000.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Report dated October 14, 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 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 by submitted in writing to Vanessa Thomas Gray, Compliance Specialist, 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 October 14, 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 Bethman, AAG, Board Counsel

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

Attachment



STATE OF MARYLAND

Exhibit

Ned F/u. Docs

DHMH

Maryland Department of Health and Mental Hygiene

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

COMMONITY PHARMACY INSPECTION FORM
Corporate Pharmacy Name Pharmacy Name-Doing Business as (d/b/a) or Trade Name CVS PHARMACY #2775 Street Address 2601 RIVA RD., ANNAPOLIS, MD 21401 Business Telephone Number 410-571-2090 Business Fax Number 410-571-2896 Inspection Date: 10/14/2015 Arrival Time: 11:50AM Departure Time: 2:20PM Type of Inspection: Annual Follow-up Previous Date: 08/14/2014 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: 24/7 Sun: 24/7 Sun: 24/7
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 P05302 Expiration Date: 05/13/2016 CDS Registration Number 470380 Expiration Date: 02/29/2016 DEA Registration Number BA7945908 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
DKAY/PHARMACIES VERIFIES VIA PHONE.

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws ERICA M. RICHARDSON

Pharmacist Employees ERICA M. RICHARDSON	License #	Exp Date
SARAH SINNOTT	19759	02/29/2016
	23549	10/31/2016
DAVID S. BECKER	10475	04/30/2017
CHAD R. BLASZCZYK	17593	11/30/2016
MARK ALAN BRUNDENELL	22137	01/31/2017
Registered Technicians LETTITIA R. DOUGLAS-LEWIS SILVIA C. EVANS	Registration # T03719	Exp Date 05/31/2016
ALEXANDRA THOMPSON	T07840	04/30/2016
LEAH CARTER	T13379	12/31/2016
	T13212	10/31/2016
BRITTANY B. KNIGHT	T07323	10/31/2015
DUNCAN SPENCE	T12271	10/31/2016
MARIANNE HOWE	T10080	03/31/2017
ANDREA ML. LEE	T01625	06/30/2016
CAILA THOMPSON	T14748	09/30/2017
SHANEEK M. PIKNEY (NON-RENEWED)	T07475	09/30/2015
nlicensed Personnel (non-registered) HELSEA HARRIS	Title TECHNICIAN IN TRAINING	Duties
ANISHA JONES	TECHNICIAN IN TRAINING	NOT WORKING DURING THIS INSPECTION
		HOT WORKING DURING THIS PISPECTION

3. PERSONNEL T	RAINING
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 personnel have rec Yes No Comments:	All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1) eived training in: (check all that apply) COMAR 10.34.21.03B(3) and (4) N/A
	THROUGH LEARN NET.
Yes No The phaneles No N/A Tomments: STAFF PHARMACIST	rmacy wholesale distributes to another pharmacy (COMAR 10.34.37) rmacy wholesale distributes to a wholesale distributor (COMAR 10.34.37) The wholesale distribution business exceeds 5% of the pharmacy annual sales (COMAR 10.34.37) CHAD R. BLASZCZYK STATED THAT THEY DONT WHOLESALE DISTRIBUTE IES OR DISTRIBUTORS.
01	AR 10.34.05 armacy is designed to prevent unauthorized entry when the prescription area is osed during any period that the rest of the establishment is open. (If yes, briefly escribe how access is restricted.) COMAR 10.34.05.02A (5)
Yes ✓ No The pi	narmacy and/or pharmacy department has a security system. COMAR 0.34.05.02A (2)

Yes No The permit holder shall prevent an individual from being in the prescription area unless 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.
TO THE HEAT OF THE COURT OF THE
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 10.24.07.02
with equivalent or superior sensitivity. COMAR 10.34.07.01A
and the primaritedy has not an a cold furning water.
The investment of rectaints of the prescription items. COMAR 10 34 07 01 p
The medication reingerator(s) have a thermometer and the current temperature is
between (36-46F) USP. COMAR 10.34.07.01B Temperature 38F,42F,40F
remperature sor,42r,40r
Yes No The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a) Temperature
Yes ✓ No N/A If the pharmacy stocks medications requiring freezing, the freezer is
Temperature maintained at temperatures required by the medications stored within it.
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 construction
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 FLOOR,DUST SHELVES, AND CLEAN COUNTERS.
, TO SEELING COUNTERS.

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
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) Yes No
Comments: BOTH PHARMACIST AND TECHNICIAN INITIALS ARE ON LABEL.
THE THIN GIO! AND TECHNICIAN INITIALS ARE ON LABEL.
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 povider. 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 There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E
Comments:
MEDICATION ERROR PROCEDURE IS POSTED AT DROP OFF TRAINING IS TUDOUS.
MEDICATION ERROR PROCEDURE IS POSTED AT DROP OFF/TRAINING IS THROUGH LEARN
MEDICATION ERROR PROCEDURE 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. COMAR10.34.24.03 The pharmacy has a procedure in place for removal of all expired drugs (both prescription and OTC). COMAR 10.34.12.01
Yes No N/A 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 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
Community
Comments: STAFF PHARMACIST CHAD B. BLASZCZYK GTATED THE
STAFF PHARMACIST CHAD R. BLASZCZYK STATED THAT THEY DONT WHOLESALE DISTRIBUTE TO OTHER PHARMACIES OR DISTRIBUTORS.
10. CONTROLLED SUBSTANCES
Power of Attorney ERICA RICHARDSON, CHAD R. BLASZCZYK, AND DAVID BECKER
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: 05/01/2016
Biennial Inventory completed at Opening or Closing (circle one) Yes V No The inventories and records of Schedule II V drives are records of Schedule II V drives are records.
COMAR 10.19.03.05 and 21 CFR 1304.03
Records are kept of all receipts of controlled substances entered into the standard
The state of the s
There are written policies and records for return of CII. CIII-V
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 cont	trolled substances prescriptions bear the name and address of the prescriber and tient. COMAR 10.19.03.07D (1)
Yes ✓ No The per	mit holder or pharmacist designee(s) has written policies and procedures for vestigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B
(1)) S and reporting of their of loss. COMAR 10.19.03.12B
Comments:	
OKATIKE VIEWED CII-V	RETURNS THROUGH GENCO.
	EDICATION 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 proc	redures exist for (check all that apply): COMAR 10.34.28.04A Operation of the system
Yes / No N/A	
Yes V No N/A	
Yes No N/A	
Yes V No N/A	
Yes No N/A	Sufficient safeguards are in place to ensure accurate embasishment of the
BARCODE SCANNING A	medication system. If yes, describe safe guards. COMAR 10.34.28.06
	TO FILLED UNLY BY A PHARMACIST
A.J	
COMAR 10.34.28.	intained for at least two years addressing the following (check all that apply).
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	Devices installed after September 1, 2003 operate in a manner to limit
	Simultaneous access to millione strengthe donors forms and the state of
	forms accessed from the automated medication system. COMAR 10.34.28.04B
Yes V No N/A	The pharmacy has records, documents, or other evidence of a survive
	F - G
Comments:	requirements of COMAR 10.34.28
PHARMACY HAS A SCRI	PTPRO

12. OUTSOURCING	Yes No (if No, go to #13)
Yes No N/A	•
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 outsource	
Yes No N/A	The original prescription order is filed as a prescription order at the primary pharmacy.
Yes No N/A	Written policies exist for maintenance of documentation and it
Yes No N/A	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
	IAR 10.34.04.06 (Check all that apply)
Yes No N/A /	I hat the prescription order was prepared by a secondary pharmacy.
Yes No N/A	The name of the secondary pharmacy. The name of the pharmacist who tensoring to the pharmacy.
	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
	The primary and secondary pharmacies are both tierrand to the
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
Yes No N/A	includes: COMAR 10.34.04.07 (Check all that apply)
	That the prescription order was transmitted from another pharmacy.
	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	
Yes No N/A	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 F	ractices ractices
Yes No A perpe	etual inventory is maintained for Schedule II controlled substances.
Yes No There a	re documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
Yes ✓ No The ph	armacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov
Yes No The ph	
The pin	armacy maintains records of all recalls. See www.recalls.gov
INSPECTOR'S COMME	
REVIEWED ENTIRE INSPE	CTION REPORT WITH STAFF PHARMACIST CHAD R. BLASZCZYK/NO
OUTDATES FOUND IN TH	E PHARMACY AREA/NO OUTDATES FOUND IN THE OTC A DRA/FOUND #1
DISCRETANCT DORING I	TIE CIT AUDIT ON MORPHINE SHIF FR 30MG OVER BY #10 (CER
MEDICATIONS CAN DE CE	USES CVS SPECIALTY PHARMACY FOR PATIENT PRESCRIPTIONS, THE
MEDICATIONS CAM BE SE	INTIO THE PATIENTS ADDRESS OR PLACE OF WORK OR TO THIS
RETREIVED/REVIEWED T	VALL DOCUMENTS NEEDED FOT THIS INSPECTION WERE EASILY
NET/SEE ATTACHED TECH	RAINING DOCUMENTS/POLICIES AND PROCEDURES ARE ON RX
HARRIS NOT WORKING	INICIAN TRAINING DOCUMENTS ON LANISHA JONES, AND CHELSEA
BOP WERSITE SHE WAS I	DURING THIS INSPECTION/SHANEEK PIKNEY IS NON-RENEWED ON THE
ATTACHED TECHNICIAN	VORKING DURING THIS INSPECTION: SHE WAS COUNTING PILLS (SEE RENEWAL RECEIPT FROM THE MARYLAND BOP DATED
10/07/2015)/PHARMACY W	A SN'T NEAT AND ORGANIZED AS OF THE STORY
THIS INSPECTION: 1) POST	ASN'T NEAT AND ORGANIZED AS OF THIS INSPECTION/ACTIONS PER KAILA THOMPSON CURRENT REGISTRAION. 2) GENERAL
HOUSEKEEPING IS SUGGE	STED: VACUUM FLOORS, DUST SHELVES AND CLEAN COUNTER TOPS.
3) ADDRESS THE CIL PERP	ETUAL INVENTORY AND FAX FINDINGS WITH SUPPORTING
DOCUMENTS AND EXPLA	NTAION TO THE BOP BY 10/21/2015 ATTENTION KERRI WEIGLEY
	O THE BOY BY 16/21/2015 ATTENTION REIGH WEIGLEY
Inspector Signature K	un 5 Way
Pharmacist Name ((Print): CHAD R. BLASZCZYK Date: 10/14/2015
Signature: MARI	begingn
Received a copy of this in	
FINAL 09/02/2014	Daie and Pharmacist Signature

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: CVS PHARMACY #2775

Permit#: P05302 Date: 10/14/2015

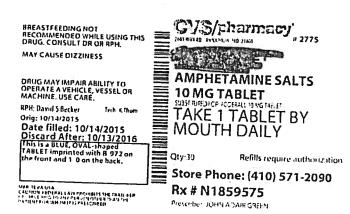
Pharmacist Signature: Mod C

Rx# N1859575

DRUGS METHADONE 5MG	NDC	ON HAND INVENTORY	PERPETUAL INVENTORY
	00054-4570-25	306	306
MORPHINE SULF. ER 30MG	42858-0802-01	1:7C	/ / -
OXYCODONE 5MG	10702-0018-01		660
OXYCONTIN 20MG	59011-0420-10	1626	1626

COMMENTS: FOUND #1 DISCREPANCY DURING THE CII AUDIT ON MORPHINE SULF. ER 30MG OVER BY #10. ADDRESS THE CII PERPETUAL INVENTORY AND FAX FINDINGS WITH SUPPORTING DOCUMENTS AND EXPLANTAION TO THE BOP BY 10/21/2015 ATTENTION KERRI WEIGLEY.

PHARMACY LABEL



THIS MEDICINE MAY BE TAKEN WITH OR WITHOUT FOOD.

CALL DR. REFORE TAKING OTC DRUGS AS SOME MAY AFFECT THE ACTION OF THIS DRUG.

INVOICE REVIEW

CII: OKAY/INVOICES WERE SIGNED AND DATED.

CIII - CV: OKAY/INVOICES WERE SIGNED AND DATED,

PRESCRIPTION REVIEW

CII # N1839000-N1839999 DATE: 09/04/2015-09/07/2015

COMMENTS: OKAY

CIII - CV # C1852000-C1852999 DATE: 09/29/2015-10-01/2015

COMMENTS: OKAY