



# MARYLAND

## Department of Health

Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Dennis Schrader, Secretary

### **MARYLAND BOARD OF PHARMACY**

4201, Patterson Avenue, Baltimore, Maryland 21215-2299

Mitra Gavgani, Board President • Deena Speights-Napata, Executive Director

September 20, 2017

**BY CERTIFIED AND REGULAR MAIL  
RETURN RECEIPT REQUESTED  
CERTIFIED NUMBER: 7015 1520 0003 1509 6474**

CVS Pharmacy #5706  
7095 Baltimore Annapolis Road  
Glen Burnie, Maryland 21061

Re: Permit No. P05478, Case No. PI-16-125  
Notice of Deficiencies, Recommended Civil Monetary Penalty, and  
Opportunity for Hearing

Dear Pharmacy Manager:

On March 11, 2015, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of CVS Pharmacy #5706 (the "Pharmacy") for compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated that the Pharmacy was not compliant with laws relating to general pharmacy operations. Specifically, the inspection report noted that the Pharmacy was not neat and organized; the posted CDS registration expired on February 28, 2015; the licenses posted for two pharmacy personnel were expired; and there were three (3) outdated drugs in the inventory. On January 12, 2016, the Board conducted another annual inspection. The inspection again noted: the Pharmacy was not neat and organized; the posted CDS registration expired on February 28, 2015; the licenses posted for certain pharmacy personnel were expired; and there was an outdated drug in the pharmacy inventory. The Board notes that the Pharmacy's November 15, 2016 inspection again indicated seven (7) outdated drugs in the inventory, but the remaining deficiencies had been addressed.

### **I. FINDINGS AND CONCLUSION**

The Board adopts as findings the deficiencies as stated in the Board's inspection reports, dated March 11, 2015, January 12, 2016, and November 15, 2016, and attached hereto as Exhibits A, B and C.

Based upon deficiencies 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. §§ 12-311, 12-403(c)(1), (9), (11), and (12), 12-6B-08, and COMAR 10.34.12.

## 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 \$2,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice and in Exhibits A, B and C.

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 ensure that the deficiencies noted herein 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 disciplinary 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 Lisa S. Sanderoff, Pharmacist Investigator Supervisor, Maryland Board of Pharmacy, 4201 Patterson Ave., 5th 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 its 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 the Pharmacy requests a hearing but fail to appear, the Board may nevertheless hear and determine the matter in its 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.

Please mail the check of money order to:

Maryland Board of Pharmacy  
P.O. Box 2051  
Baltimore, MD 21203-2051

***NOTE: Please include the case number, PI-16-125, on your check or money order to insure proper assignment to your case.***

Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final formal action with respect to the March 11, 2015, January 12, 2016, and November 15, 2016, inspections, and shall be a public document in accordance with the Maryland Public Information Act, General Provisions Article § 4-333.

If you have any questions concerning the instructions contained in this letter, please contact Lisa S. Sanderoff, Pharmacist Investigator Supervisor, at 410-764-4686.

Sincerely,



Deena Speights-Napata  
Executive Director

### Attachments

cc: Linda M. Bethman, Assistant Attorney General, Board Counsel

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

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# **EXHIBIT A**

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STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

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

Handwritten notes: 3/23/15, multiple, OK 4/15, hopefully improve @ next inspr

COMMUNITY PHARMACY INSPECTION FORM



Corporate Pharmacy Name CVS PHARMACY #5706
Pharmacy Name-Doing Business as (d/b/a) or Trade Name
Street Address 7095 BALTIMORE ANNAPOLIS ROAD, GLEN BURNIE, MD 21061
Business Telephone Number 410-859-3113 Business Fax Number 410-691-2646
Inspection Date: 03/11/2015 Arrival Time: 12:40PM Departure Time: 3:20PM
Type of Inspection: Annual Follow-up Previous Date: 01/02/2014
Name of Inspector: KERRI WEIGLEY

1. GENERAL INFORMATION

Yes [x] 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-8PM Sat: 8AM-6PM Sun: 10AM-6PM

Yes [x] 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 P05478 Expiration Date: 05/31/2016
CDS Registration Number 474817 Expiration Date: 02/28/2015
DEA Registration Number BR3908665 Expiration Date: 12/31/2016

Yes [ ] No [x] The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

Yes [ ] No [x] The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23

Yes [ ] No [x] The pharmacy fills original prescriptions received via the internet.

Yes [x] No [ ] The pharmacy fills original prescriptions via e-prescribing.

Yes [ ] No [x] 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: PHARMACY VERIFIES VIA PHONE/CDS LICENSES POSTED IS EXPIRED. SEND A COPY OF THE CURRENT CDS TO THE BOP BY 03/18/2015.

**2. PERSONNEL**

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws  
**AE NOK SEO**

Pharmacist Employees	License #	Exp Date
AE NOK SEO	22106	09/30/2015
PAUL R. WEBSTER	07830	12/31/2016
SAHAR TAGHVAEI	22531	09/30/2015

Registered Technicians	Registration #	Exp Date
MUHAMMAD KHAN	T15117	08/31/2016
BRANDIE L. BURGESS	T00999	10/31/2015
MADIHA QUTAB	T14138	01/31/2016
KRISTEN F. RESAVAGE	T08817	12/31/2016
ADAM LANGE	T12148	07/31/2016
ROXANE M. FISHER	T11194	05/31/2016
LILYTTTE G. TAGALA	T10795	10/31/2015

Unlicensed Personnel (non-registered)	Title	Duties
JASMINE ALEXANDER	TECHNICIAN	TRAINING

**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  
\_\_\_\_\_  
\_\_\_\_\_

- 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: \_\_\_\_\_  
N/A  
\_\_\_\_\_  
\_\_\_\_\_

**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 40F,44F

Yes  No  The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature 72F

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 0F

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:

GENERAL HOUSEKEEPING IS SUGGESTED: VACUUM FLOOR, DUST SHELVES. / ONE REFRIGERATOR HAD NO THERMOMETER, SEND PROOF OF PURCHASE OF THERMOMETER AND A WRITTEN EXPLANATION OF HOW THE TEMPERATURE WAS BEING MONITORED



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

OKAY

**10. CONTROLLED SUBSTANCES**

**Power of Attorney** PAUL WEBSTER, AND AE NOK SEO HAVE POWER OF ATTORNEY

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: 05/01/2013

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/HYDROCODONE INVENTORY WAS COMPLETED ON 10/06/2014, AND ULTRAM ON 08/18/2014.

**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  Operation of the system
- Yes  No  N/A  Training of personnel using the system
- Yes  No  N/A  Operations during system downtime
- Yes  No  N/A  Control of access to the device
- Yes  No  N/A  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  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 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:**

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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:

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 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](http://www.recalls.gov)
- Yes  No  The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)


**INSPECTOR'S COMMENTS:**

REVIEWED ENTIRE INSPECTION REPORT WITH PHARMACY MANAGER AE NOK SEO/FOUND #3 OUTDATES IN THE PHARMACY AREA/NO OUTDATES FOUND IN THE OTC AREA/NO DISCREPANCIES FOUND DURING THE CII AUDIT/SEE ATTACHED TRAINING DOCUMENTS ON JASMINE ALEXANDER/DURING THIS INSPECTION ONE OF THE REFRIGERATORS HAD NO THERMOMETER/ACTIONS PER THIS INSPECTION: 1) SEND PROOF OF PURCHASE OF THERMOMETER AND A WRITTEN EXPLANATION OF HOW THE TEMPERATURE WAS BEING MONITORED WHILE THE THERMOMETER WAS NOT AVAILABLE TO THE BOP BY 03/13/2015 ATTENTION KERRI WEIGLEY. 2) GENERAL HOUSEKEEPING IS SUGGESTED: VACUUM FLOOR, DUST SHELVES. 3) MAKE SURE ALL LICENSES ARE SIGNED. 4) POST CURRENT LICENSE FOR KRISTEN RESAVAGE, AND LILYTTE TAGALA. 5) REMOVE LICENSES FOR EMPLOYEES WHO NO LONGER WORK AT THIS PHARMACY. 6) SEND CURRENT CDS LICENSE TO THE BOP BY 03/88/2015 ATTENTION KERRI WEIGLEY.

Inspector Signature Kevin S. Wea

Pharmacist Name ((Print): AE NOK SEO Date: 03/11/2015

Signature: 

Received a copy of this inspection report:   
Date and Pharmacist Signature

FINAL 09/02/2014

# CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: CVS 5706  
Permit#: P05478  
Date: 03/11/2015

Pharmacist Signature: \_\_\_\_\_



**Rx# 1259108**

DRUGS	ON HAND INVENTORY	PERPETUAL INVENTORY
HYDROMORPHONE 4MG	195	195
METHADONE 10MG	123	123
OXYCODONE 20MG	240	240
OXCONTIN 60MG	258	258

**COMMENTS: NO DISCREPANCIES FOUND DURING THE CII AUDIT.**

### INVOICE REVIEW

**CII: OKAY**

**CIII - CV: OKAY**

### PRESCRIPTION REVIEW

**CII # N1255000-N1255999  
DATE: 02/26/2015-03/02/2015**

**COMMENTS: FOUND #2 PRESCRIPTIONS #N1255838, N1255838 WHERE THE DOCTORS DEA# AND ADDRESS DID NOT MATCH THE ADDRESS ON THE PHARMACY LABEL. FOUND #3 PRESCRIPTIONS # N1255487, N1255774, N1255959 WHERE THE DOCTORS ADDRESS DIDN'T MATCH THE ADDRESS ON THE PHARMACY LABEL.**

**CIII - CV # C1224000-C1224999  
DATE: 11/24/14-11/25/2014**

**COMMENTS: FOUND #8 PRESCRIPTIONS C1224009, C1224038, #C1224052C #1224239, C1224289, C1224629, C1224702, C1224614 WHERE THE DOCTORS ADDRESS DIDN'T MATCH THE ADDRESS ON THE PHARMACY LABEL. FOUND #1 PRESCRIPTION #**

IF PREGNANT OR OF CHILD BEARING AGE, DISCUSS RISKS/BENEFITS WITH MD OR RPH  
MAY CAUSE DROWSINESS. USE CARE WHEN OPERATING A VEHICLE, VESSEL OR MACHINE.

TAKING MORE ACETAMINOPHEN THAN RECOMMENDED MAY CAUSE SERIOUS LIVER PROBLEMS.

RPH: Ae N. Seo      Tech: A. Lang

**OXYCODONE-  
ACETAMINOPHEN 5-325**  
Common Brand(s): Percocet, Tylox

**TAKE 1 TO 2 TABLETS BY MOUTH EVERY 4 TO 6 HOURS AS NEEDED**

Qty: 50      Refills require authorization

**Store Phone: (410) 859-3113**  
**Rx # N1259108**

Prescriber: ALEC BENINGFIELD

MFR. QUALITIES  
CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER OF THIS PRESCRIPTION TO ANY OTHER PATIENT FOR WHOM IT IS PRESCRIBED



Orig: 03/11/2015      Date filled: 03/11/2015

Discard After: 03/10/2016

This is a WHITE, ROUND-shaped TABLET imprinted with 4839 V on the front.

C1224025 WHERE THE DOCTORS DEA # DIDN'T MATCH THE DEA # ON THE PHARMACY LABEL. FOUND #2 PRESCRIPTION # C1224055, C1224587 FOR A CALLED IN PRESCRIPTION WHERE IT ONLY CONTAINED THE DOCTORS LAST NAME, PATIENTS NAME, AND DRUG NAME. FOUND #1 PRESCRIPTION #C1224206 WHERE THE DOCTORS ADDRESS DIDN'T MATCH THE ADDRESS ON THE PHARMACY LABEL AND HAD NO NPI#, OR DEA#.

**EXHIBIT B**





STATE OF MARYLAND

DHMH

Maryland Department of Health and Mental Hygiene

Larry Hogan, Governor - Boyd Rutherford, Lt. Governor - Van Mitchell, Secretary

Maryland Board of Pharmacy

4201 Patterson Ave - Baltimore, MD - 21215-2299

Mitra Gavvani, President - LaVerne G. Naesea, Executive Director


GAVE COPY TO  
VANESSA ON  
2/1/16  
KRW

02/01/2016

Pharmacy: CVS Pharmacy 5706  
7095 Baltimore Annapolis Rd.  
Glen Burnie, MD 21061  
Permit #: P05478

RE: Housekeeping, licenses posted

During my Annual Inspection on 01/12/2016 the pharmacy was not neat and organized, the CDS registration had expired on 02/28/2015, and there were technicians and pharmacist licenses that had expired, they were active on the Boards website, but the current licenses were not posted. There were also employees working that didn't have a licenses posted, but were also active with the board of pharmacy. The above issues were noted on the last inspection on 03/11/2015. See attached picture of the pharmacy area.

  
Kerri Weigley

2/1/16



STATE OF MARYLAND

**DHMH**

Department of Health and Mental Hygiene  
Lawrence J. Hogan, Jr., Governor – Boyd K. Rutherford, Lt. Governor –  
Van T. Mitchell, Secretary

docs pending  
memo of 1/19/16  
docs rec'd of 2/1/16  
memo done -  
unorganized/  
unclear

**MARYLAND BOARD OF PHARMACY**

4201 Patterson Avenue • Baltimore, Maryland 21215-2299  
Mitra Gavani, Board President - LaVerne G. Naesea, Executive Director

**COMMUNITY PHARMACY INSPECTION FORM**

Corporate Pharmacy Name \_\_\_\_\_  
Pharmacy Name-Doing Business as (d/b/a) or Trade Name CVS Pharmacy #5706  
Street Address 7095 Baltimore Annapolis Rd. Glen Burnie, MD 21061  
Business Telephone Number 410-859-3113 Business Fax Number 410-691-2646  
Inspection Date: 01/12/2016 Arrival Time: 8:50am Departure Time: 11:10am  
Type of Inspection:  Annual  Follow-up Previous Date: 03/11/2015  
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-9pm Sat: 9am-6p 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 P05478 Expiration Date: 05/31/2016  
CDS Registration Number 474817 Expiration Date: 02/28/2015  
DEA Registration Number BR3908665 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: \_\_\_\_\_  
Pharmacy verifies electronic prescriptions via phone. Make sure all licenses and registrations are posted and in date. Send Current CDS Registrations to the bop by 01/19/2016, attention Kerri Weigley

**2. PERSONNEL**

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

Alexandra Grimes

Pharmacist Employees	License #	Exp Date
Alexandra Grimes	13852	02/29/2016
Sahar Taghvaei	22531	09/30/2017
Paula Lachowicz	23372	12/31/2016

Registered Technicians	Registration #	Exp Date
Brandie L. Burgess	T00999	10/31/2017
Kristen F. Resavage	T08817	12/31/2016
Lilytte G. Tagala	T10795	10/31/2017
Adam Lange	T12148	07/31/2016
Timothy McClunge	T17121	11/30/2016
Corinne Cross	T12054	05/31/2016
Danielle Brooke Odham	T17181	07/31/2017

Unlicensed Personnel (non-registered)	Title	Duties
Olubujayo Ajayi	Technician in training	Not Working
Erica hardy	Technician in training	Not Working
Gregory Johnson	Technician in Training	Not Working
Shelante Johnson	Technician in training	Not Working
Andrew Lee	Tehnician in training	Not Working
Jolisa Richardson	Technician in training	Counting pills/drugs thru, putting medications away

**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: \_\_\_\_\_  
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: \_\_\_\_\_  
Paula Lachowicz stated that this pharmacy does not 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:

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 <sup>38f, 40f, 38f</sup>

Yes  No  The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature <sup>73f</sup>

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 was not neat and organized. General Housekeeping is suggested: Vacuum floor, dust shelves, clean around the sink area.

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

Pharmacist initials are on label. Technician initials are on computer.

**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:**

Medication error procedure is posted at drop off. Training and QA are on the intra-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: 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: Paula Lachowicz stated that this pharmacy does not wholesale distribute to other pharmacies or distributors.

**10. CONTROLLED SUBSTANCES**

Power of Attorney Alexandra Grimes

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: 04/30/2015

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)

**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](http://www.recalls.gov)
- Yes  No  The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)

### INSPECTOR'S COMMENTS:

Reviewed entire inspection report with staff pharmacist Paula Lachowicz. Found #1 out dates in the pharmacy area. No out dates found in the OTC area. Found # 2 Discrepancies during the CII audit on Hydromorphone 2mg over by #1, and Methadone 10mg short by #86. Perpetual inventory is kept on the computer. The original CDS Registration posted expired on 02/15, and was noted on last years inspection. Kristen F. Resavage, and Lilytte Tagala registrations posted were expired, and was noted on last years inspection. During this inspection the shelves were dusty, the sink area was messy, and general housekeeping was suggested on last year inspection. Jolisa Richardson is a technician in training, she was working during this inspection: she was putting medications away, working the drive thru, and counting pills. Olubujayo Ajayi, Erica Hardy, Gregory Johnson, Shelante Johnson, and Andrew Lee are also technicians in training, they were not working during this inspection. Actions per this inspection.: 1) Address the CII perpetual inventory discrepancies and fax findings with supporting documents. 2.) General housekeeping is suggested: dust shelves clean around the sink area, and vacuum floor. 3) Post Registrations on Corinne Cross, Danielle Odham, Lilytte Tagala, Timothy McClung and Kristen Resavage. 4) Post Sahar Taghvaei current license. 5) Send Technician training documents on Olubujayo Ajayi, Erica Hardy, Gregory Johnson, Shelante Johnson, and Andrew Lee. 6) Send Current CDS registrations. Send all needed documents to the bop by 01/19/2015, attention Kerri Weigley

Inspector Signature

*Kerri Weigley*

Pharmacist Name ((Print): Paula Lachowicz

Date: 01/12/2016

Signature:

*Paula Lachowicz*

Received a copy of this inspection report:

*Paula Lachowicz*

Date and Pharmacist Signature

FINAL 09/02/2014

# CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Clear Form

Pharmacy: CVS Pharmacy #5706  
 Permit#: P05478  
 Date: 01/12/2016  
 Pharmacist Signature: *Paula Johnson*

Rx#: N1363988  
 Date Filled: 01/12/2016

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY
Hydromorphone 2mg	42858-0301-01	1	0
Methadone 10mg	00054-4571-25	900	986
Morphine Sulf. ER 30mg	42858-0802-01	86	88
Oxycodone 10mg	10702-0056-01	40	46

**COMMENTS:**

Found # 2 Discrepancies during the cii audit on Hydromorphone 2mg over by #1, and Methadone 10mg short by #86. Perpetual inventory is kept on the computer. Address the CII perpetual inventory discrepancies and fax findings with supporting documents, and send to the bop by 01/19/2015, attention Kerri Weigley.

**SCHEDULE II AUDIT**

Drug N/A  
 Date of last Inspection/Biennial N/A

Amount at last inspection/biennial	0	(A)
Purchased since inspection/biennial	0	(B)
Total inventory	0	(C) = A + B
Quantity dispensed	0	(D)
Expected inventory	0	(E) = C - D
Quantity on Hand	_____	(F)
Discrepancy	_____	(G) = (F-E) or (E-F)

Excess Shortage

**INVOICE REVIEW**

**CII:**  
Make sure invoices are signed and dated.  
 \_\_\_\_\_  
 \_\_\_\_\_

**CIII - CV:**  
Invoices were signed and dated.  
 \_\_\_\_\_  
 \_\_\_\_\_

**PRESCRIPTION REVIEW**

**CII #** N1358000-N1358999  
**DATE** 12/26-12/29/15

**COMMENTS:**

None

**CIII - CV #** C1355800-C1358999  
**DATE** 12/26-12/19/15

**COMMENTS:**

Found #1 prescription where the patients address didn't match the address on the pharmacy label. Make sure addresses match.

**CVS/pharmacy**  
5706  
# 5706

**OXYCODONE HCL 5 MG  
TABLET**  
Common Brand(s): Roxicodone  
**TAKE 1-2 TABLETS BY MOUTH  
EVERY 6 HOURS AS NEEDED**

Qty: 14 Refills require a thhorizat on

**Store Phone: (410) 859-3113**  
**Rx # N1363988**  
Prescriber: MEGAN KELLEY MATHIAS

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

MAY CAUSE DROWSINESS. USE  
CARE WHEN OPERATING A  
VEHICLE, VESSEL OR MACHINE.

MAY CAUSE DIZZINESS

RPH: Paula Lachowicz Tech: J.Rich  
Orig: 01/12/2016  
Date filled: 01/12/2016  
Discard After: 01/11/2017

This is a WHITE, ROUND-shaped  
TABLET imprinted with K 18 on the  
front.

MPR: XVA-TECH, INC  
CAUTION: FEDERAL LAW PROHIBITS THE TRANSFER  
OF THIS DRUG TO ANY PERSON OTHER THAN THE  
PATIENT FOR WHOM IT IS PRESCRIBED



# **EXHIBIT C**

11/22/2016  
OK. CCF



STATE OF MARYLAND

**DHMH**

**Department of Health and Mental Hygiene**  
Lawrence 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 Gaugani, Board President - Deena Speights-Napata, Executive Director

**COMMUNITY PHARMACY INSPECTION FORM**

**Corporate Pharmacy Name** Maryland CVS Pharmacy, LLC  
**Pharmacy Name-Doing Business as (d/b/a) or Trade Name** CVS Pharmacy #5706  
**Street Address** 7095 Baltimore Annapolis Rd. Glen Burnie, MD 21061  
**Business Telephone Number** 410-859-3113 **Business Fax Number** 410-691-2646  
**Inspection Date:** 11/15/2016 **Arrival Time:** 1pm **Departure Time:** 3:30pm  
**Type of Inspection:**  **Annual**  **Follow-up** **Previous Date:** 01/12/2016  
**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-9pm **Sat:** 9am-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** P05478 **Expiration Date:** 05/31/2018  
**CDS Registration Number** 474817 **Expiration Date:** 02/28/2017  
**DEA Registration Number** BR3908665 **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:** Alexandra Grimes stated that this pharmacy verifies electronic prescriptions via phone.

**2. PERSONNEL**

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

Pharmacist Employees	License #	Exp Date
Alexandra Grimes	13852	02/28/2018
Paula Lachowicz	23372	12/31/2016
Sahar Taghvaei	22531	09/20/2017

Registered Technicians	Registration #	Exp Date
Kristen F. Resavage	T08817	12/31/2016
Danielle Brooke Odham	T17181	07/31/2017
Andrew Jeongkyun Lee	T14032	02/28/2017
Timothy McClung	T17121	11/30/2016
Shelante Danielle Johnson	T17715	06/30/2017
Cassandre Amber Tiell	T18514	07/31/2018
Adam Lange	T12148	07/31/2018
Brandie L. Burgess	T00999	10/31/2017

Unlicensed Personnel (non-registered)	Title	Duties
Phuong Huynh	Technician in training	Not working during this inspection.

**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: \_\_\_\_\_  
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: \_\_\_\_\_  
Alexandra Grimes stated that this pharmacy does not wholesale distribute. \_\_\_\_\_  
\_\_\_\_\_

**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: \_\_\_\_\_  
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 39F, 38F, 36F, 36F

Yes  No  The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature 70F

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 0F

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 carries vaccines. Alexandra Grimes's CPR card was current as of this inspection.  
\_\_\_\_\_  
\_\_\_\_\_

**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)
- Yes  No  The serial number of the prescription; HG § 21-221(a)(2)
- Yes  No  The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3)
- Yes  No  The name of the prescriber; HG § 21-221(a)(4)
- Yes  No  The name of the patient; HG § 21-221(a)(5)(i)
- Yes  No  The name and strength of the drug or devices; HO § 12-505(c)
- Yes  No  The directions for use; HO § 12-505(b)(2)(ii) and HG §21-221(a)(5)(ii)
- Yes  No  The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii)
- Yes  No  The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2)
- Yes  No  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:** \_\_\_\_\_  
Both pharmacist 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 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:** \_\_\_\_\_  
Medication error procedure is posted. Training and QA are on the intra-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: \_\_\_\_\_

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: \_\_\_\_\_  
Alexandra Grimes stated that this pharmacy does not wholesale distribute.

**10. CONTROLLED SUBSTANCES**

Power of Attorney Alexandra Grimes, and Sahar Taghvaei

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: 04/30/2015

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:**

Pharmacy uses Genco for CII-V returns.

**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 <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Operation of the system                                      |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Training of personnel using the system                       |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Operations during system downtime                            |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Control of access to the device                              |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | 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 <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Maintenance records.                            |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | System failure reports.                         |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Accuracy audits.                                |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Quality Assurance Reports.                      |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | Reports on system access and changes in access. |
| Yes <input type="checkbox"/> | No <input type="checkbox"/> | N/A <input type="checkbox"/> | <input checked="" type="checkbox"/> | 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.

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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](http://www.recalls.gov)
- Yes  No  The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)

### INSPECTOR'S COMMENTS:

Reviewed entire inspection report with pharmacy manager Alexandra Grimes. Spot checked medication shelves, found #7 out dates in the pharmacy area (see attached list), out dates were also noted on last years inspection. Perpetual inventory is kept on the computer, no discrepancies found during the CII audit. All documents needed for this inspection were easily retrieved. Training, QA, and policies and procedures are kept on the intra-net. See attached technician training documents on Phuong Huynh, she was not working during this inspection. Alexandra Grimes stated that this pharmacy does not wholesale distribute, outsource, or participate in the repository/drop off program. Actions per this inspection: 1) Be sure to check the pharmacy area for out dates. 2) Have Andrew Jeongkyun Lee sign his registration.

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Inspector Signature Keri Weagy

Pharmacist Name ((Print): Alexandra Grimes Date: 11/15/20156

Signature: 

Received a copy of this inspection report: 

*Date and Pharmacist Signature*

FINAL 09/02/2014

# CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

**Pharmacy:** CVS Pharmacy #5706  
**Permit#:** P05478  
**Date:** 11/15/2016  
**Pharmacist Signature:** \_\_\_\_\_



**Rx#:** N1474713  
**Date Filled:** 11/15/2016

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY
Hydromorphone 2mg	42858-0301-01	649	649
Morphine Sulf. Er 30mg	42858-0802-01	574	574
Oxycodone 10mg	10702-0056-01	81	81
Oxycontin 10mg	59011-0410-10	58	58

**COMMENTS:**

Perpetual inventory is kept on the computer, no discrepancies found during the CII audit.  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

**SCHEDULE II AUDIT**

**Drug** N/A  
**Date of last Inspection/Biennial** N/A

Amount at last inspection/biennial	0		(A)
Purchased since inspection/biennial	0		(B)
Total inventory	0		(C) = A + B
Quantity dispensed	0		(D)
Expected inventory	0		(E) = C - D
Quantity on Hand	0		(F)
Discrepancy	0		(G) = (F-E) or (E-F)
			Excess Shortage

**INVOICE REVIEW**

**CII:**

Invoices were signed and dated.  
 \_\_\_\_\_  
 \_\_\_\_\_

**CIII - CV:**

Invoices were signed and dated.  
 \_\_\_\_\_  
 \_\_\_\_\_

**PRESCRIPTION REVIEW**

**CII #** N146900-N1469999

**DATE** 10/31-11/02/16

**COMMENTS:**

None

**CIII - CV #** C1469000-C1469999

**DATE** 10/31-11/02/16

**COMMENTS:**

None

DRUG MAY IMPAIR ABILITY TO  
OPERATE A VEHICLE, VESSEL OR  
MACHINE. USE CARE.

MAY CAUSE DIZZINESS

DO NOT CHEW OR CRUSH BEFORE  
SWALLOWING.

RPH: Ale Grimes      Tech: T.Mcd

Orig: 11/15/2016

Date filled: 11/15/2016

Discard After: 11/15/2017

This is a BROWNISH-RED,  
OBLONG-shaped TABLET imprinted  
with ALZA 54 on the front.

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

**CVS/pharmacy** # 5706  
7077 EAST PROPER AVENUE, GLEN BURNIE, MD 21061

**METHYLPHENIDATE ER**  
**54 MG TAB**

Common Brand(s): Concerta

**TAKE 1 TABLET EVERY  
DAY IN THE MORNING**

Qty:30

Refills require authorization

**Store Phone: (410) 859-3113**

**Rx # N1474713**

Prescriber: HOWARD IRA PRESSMAN



