



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene
Martin O'Malley, Governor Anthony G. Brown, Lt. Governor Joshua M. Shufstein, M.D.
Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue • Baltimore, Maryland 21215-2299
Michael N. Souranis, Board President - LaVerne G. Nuesca, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED
ARTICLE #7011 3500 0000 7160 2296

February 19, 2013

Village Pharmacists
19271 Montgomery Village Avenue
Montgomery Village, Maryland 20886
Attn: Gene Borowski, P.D.

Re: Permit No. P00807
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Mr. Borowski:

On April 19, 2012, an inspection was conducted by the Board of Pharmacy (the "Board") to determine if Village Pharmacists (the "Pharmacy") was in compliance with federal and state laws regarding the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was not in substantial compliance with regulatory requirements regarding registration of pharmacy technicians. Specifically, the Pharmacy employed a pharmacy technician who was not registered with the Board despite having completed a technician training program in October 2010. The Board's records indicate that the pharmacy technician subsequently submitted an application on May 16, 2012, and is now duly registered.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated April 19, 2012, and attached as Exhibit A.

Based upon deficiencies cited at your Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. § 12-403(b)(1)

410-764-4755 • Fax 410-358-9512 • Toll Free 800-542-4964
DHMH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258
Web Site: www.dhmh.maryland.gov/pharmacy

and § 12-6B-01.

II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Report dated April 19, 2012.

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

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

III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to insure that the deficiencies noted the Report have been addressed and corrected. Should a follow-up inspection indicate that the Pharmacy is not in substantial compliance, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the recommended civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 *et seq.*, and COMAR 10.34.01. Any

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request for a hearing must be submitted in writing to Vanessa Thomas Gray, Investigator, Maryland Board of Pharmacy, 4201 Patterson Ave., 1st Floor, Baltimore, Maryland 21215, **no later than thirty (30) days of the date of this Notice.**

Please be advised that at the hearing you would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on your own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports, the Board may suspend or revoke the pharmacy permit, or impose civil penalties, or both. If you request a hearing but fail to appear, the Board may nevertheless hear and determine the matter in your absence.

V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty **within thirty (30) days** of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy. Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the Inspection Report dated April 19, 2012, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas Gray, Investigator, at 410-764-2493.

Sincerely,



LaVerne G. Naesea
Executive Director

Attachment

cc: Linda Bethman, Board Counsel
Vanessa Thomas-Gray, Compliance Investigator



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

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

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

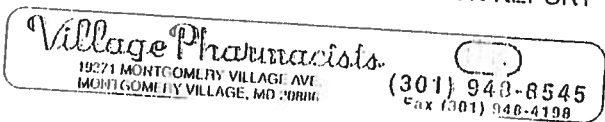
Michael Souranis, Board President - LaVene G. Naesaa, Executive Director

COMMUNITY PHARMACY INSPECTION REPORT

Permit: P00807

Inspection Result

Type of Inspection Annual



Inspection Date 4/19/2012

Previous Insp. Date: 10/29/2010

Inspector NancyR

Pharmacy Name VILLAGE PHARMACISTS INC

Corporate Name

Telephone 301 948-8545

Permit Exp. Date 2013

Address 19271 MONTGOMERY VIL AV

City MONTGOMERY State MD Zip 20886

Fax 301 948-4198

Arrival time 10:15AM

Departure Time 3:30PM

1. GENERAL INFORMATION

Yes The pharmacy hours of operation are prominently displayed if the prescription area is not open the same hours as the establishment
Pharmacy Hours M-F 9AM - 6PM Saturday 9AM - 1PM Sunday CLOSED

No All permits, licenses, and registrations are posted conspicuously. HO §12-311, HO §12-408(b) and HO §12-6B-08

CDS Registration # 409761 CDS Exp. Date 01/31/2013 DEA # AV8027098 DEA Exp. Dat 05/31/2015

No The pharmacy perform sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19

Yes The pharmacy provides services to Long Term Care facilities or assisted living facilities. (If yes, complete Long Term Care Inspection Form) COMAR 10.34.23

No The pharmacy fills original prescription received via the internet.

Yes The pharmacy fills original prescriptions via e-prescribing.

No The pharmacist fills mail order prescriptions.

If yes to any of the above, how do pharmacists verify that a relationship exists between the patient and the prescriber. HG §21-220; COMAR 10.19.03.02

SECURE SITE/ PATIENT PROFILE & HISTORY/CONTACT PHYSICIAN IF QUESTIONABLE

Comments OKAY

2. PERSONNEL (COMAR 10.34.03.05)

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

License Number	Last Name	First Name	Expiration	Status
06868	MATHENY	LINDA M	09/2012	A
06869	MATHENY II	RICHARD L	07/2013	A
09325	BOROWSKI	GENE N	08/2013	A
10134	ALLISON	JUDITH M	11/2012	A

Registration #	Last Name	First Name	MI	Exp. Date
T01360	GWIRA	KENNETH	K	1/31/2014
T05572	LACAYO	DANELIA	L	6/30/2012

Unlicensed Personnel: Name
FREIDA BRIDGES

Title
TECHNICIAN

Duties
TECHNICIAN

Comments: N/A
NEEDS FRIEDA BRIDGES CERTIFICATE FOR COMPLETION OF TRAINING PROGRAM (WAS IN TRAINING PROGRAM DURING LAS INSPECTION 10/29/2010)

3. PERSONNEL TRAINING

- Yes There are policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03A and 10.34.21.05
- Yes All Unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)
- All personnel have received training in (check all that apply):
 - Yes Maintaining records
 - Yes Biohazard precautions
 - Yes Patient confidentiality
 - Yes Patient safety and medication errors COMAR 10.34.26.03
 - Yes Sanitation, hygiene, infection Control

Comments: *****TECHNICIAN LICENSE'S ARE NOT POSTED*****

4. SECURITY COMAR 10.34.06

- N/A 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)
HAS THE SAME HOURS
- Yes The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A(2)
- Yes The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A(3)

Comments: OKAY

5. PHYSICAL REQUIREMENTS AND EQUIPMENT

- Yes Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2.
- Yes The pharmacy provides a compounding service (non-sterile procedures).
 - Yes If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02
- Yes The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
- Yes The pharmacy has hot and cold running water.
- No The medication refrigerator(s) contain only prescription and OTC items. COMAR 10.34.07.01B
- Yes The medication refrigerator(s) have a thermometer and the current temperature is between (36 - 46 F) USP COMAR 10.34.07.01B
- Yes The current temperature of the pharmacy department is between 59 to 86 F. COMAR 10.34.05.02A(1)(a) Temperature: 42
- Yes If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it. Temperature: 72
- Yes The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy
- Yes The pharmacy has online resources. HO §12-403(b)(10)

Comments: THERE IS FOOD IN THE REFRIGERATOR/ THE FREEZER HAD #4 VIALS OF ZOSTIVAX AND NO THERMOMETER

6. PRESCRIPTION LABELING FILES AND STORAGE

- Yes Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i) HO §12-403(b)(13) The following label requirements are met if a drug is dispensed pursuant to a prescription. HO §12-505
- Yes The name and address of the pharmacy; HG §21-221(a) (1) Yes The serial number of the prescription; HG §21-221(a) (2)
- Yes The date the prescription was filled; HO §12-505(b) (1) and HG §21-221(a)(3) Yes The name of the prescriber; HG §21-221(a) (4)
- Yes The name of the patient; HG §21-221(a) (5) (i) Yes The name and strength of the drug or device; HO §12-505(c)
- Yes The directions for use; HO §12-505(b)(2)(ii) and HG §21-221(a)(5)(ii) Yes The required cautionary statements or auxiliary labels; HG §21-221(a)(5)(ii)
- Yes The name of generic manufacturer; and HO §12-504(d) (2) and §12-505(c) (2) Yes The expiration date is indicated; HO §12-505(b) (2)
- Yes The pharmacist and data entry technician initials are on prescriptions. COMAR 10.34.08.01

Comments: PHARMACIST INITIALS ARE ON THE LABEL/ OKAY

QUALITY ASSURANCE - PATIENT SAFETY/MEDICATION ERRORS

Yes There are written policies that inform patients of the procedures to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility or other health care provider. COMAR 10.34.26.02
Yes The pharmacy maintains a minimum of 2 continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the role and responsibility of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B
Yes There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E
Comments: TRAINING IS DONE THROUGH PHARMCAP/ REPORTING MED ERROR SIGN IS POSTED AT REGISTER AREA/ OKAY

8. CONFIDENTIALTY

Yes Confidentiality is maintained in the creation, storage, access disposal and disclosure of patient records. HO§12-403(b)(13) COMAR 10.34.10.03A at HIPAA Regulations
Yes Any identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court or as authorized pursuant to HG §4-301 through §4-307. COMAR 10.34.10.03B
Comments: HIPPA TRASH IS PLACED IN EMPTY CARDBOARD BOXES/ WHEN FACILITY HAS A LOT IT IS THEN TAKEN TO A FACILITY FOR DISTRUCTION AND THE PHARMACY RECIEVES A CERTIFICATE OF DISTRUCTION/ OKAY

9. INVENTORY CONTROL PROCEDURES

Yes The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03
No The pharmacy has a procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01
Comments: ***NEEDS PROCEDURE FOR REMOVAL OF EXPIRED DRUGS***

10. CONTROLLED SUBSTANCES

Power of Attorney 09325 A BOROWSKI GENE N
Yes The pharmacy has a record of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B
Inventory date: 05/30/2011
Biennial inventory completed at Close
Yes The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
Yes Reports 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
No There are written policies and records for return of CII, CIII-V.
Yes Hard copy or electronic prescription files are maintains chronologically for 5 years (CDS-Fed Law)
Yes Schedule II controlled substances are dispersed throughout the stock of non-controlled substances or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)
Yes All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)
Yes The permit holder or pharmacist designee(s) has written policies and procedures for investigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B (4)
Comments: ****NEEDS POLICY FOR RETURNS OF CONTROLS****

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

No The facility uses any automated device(s) as defined in COMAR 10.34.28.02
N/A Policies and procedures exist for (check all that apply): COMAR 10.34.28.05
Yes There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
N/A Operation of the system
N/A Control of access to the device. N/A Training of personnel using the system N/A Operations during system downtime
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
N/A Maintenance records. N/A System failure reports. N/A Accuracy audits.
N/A Quality Assurance Reports. N/A Reports on system access and changes in access N/A Training records.
Devices installed after Sept. 1, 2003 operate in a manner to limit simultaneous access to multiple strength, forms and drug entities and minimize the potential for misidentification of medications, dosages and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B
The pharmacy has records, documents or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28

Comments: NO AUTOMATION SYSTEMS/ OKAY

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

- No The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- N/A The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
- N/A The facility serves as a secondary pharmacy. COMAR 10.34.04.02
- N/A The permit holder employs an outside agency/business entity for the provision of any Pharmacy services, inclusive of staffing remote order entry and management. If yes, COMAR 10.34.04.06E

Name of Agency: N/A
 State of Incorporation: N/A
 Service contracted: N/A
 MD License#: N/A

Comments:

- N/A The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B (3)
- N/A If the pharmacy outsources a prescription order:
- N/A The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
- N/A Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- N/A Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists and a record of the preparations made. COMAR 10.34.04.03 and .05
- The pharmacist from the primary pharmacy documents the following in a readily retrievable and identifiable manner (Check all that apply) COMAR 10.34.04.06
 - N/A The prescription order was prepared by a secondary pharmacy
 - N/A The name of second pharmacy
 - N/A The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
 - N/A The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
 - N/A The date on which the prescription order was transmitted to the secondary pharmacy.
 - N/A The date on which the preparation was sent to the primary pharmacy.
 - N/A The primary and secondary pharmacies are both licensed in the State of Maryland or operated by the federal government. COMAR 10.34.04.06F
 - N/A The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from secondary pharmacy. COMAR 10.34.04.06G
 - N/A The permit holder at the secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes (check all that apply): COMAR 10.34.04.07
 - N/A That the prescription order was transmitted from another pharmacy.
 - N/A The name and information identifying the specific location of the primary pharmacy.
 - N/A The name of pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
 - N/A The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
 - N/A The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
 - N/A The date on which the prescription order was received at the secondary pharmacy.
 - N/A The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

3. Recommended Best Practices:

- es. A perpetual inventory is maintained for Schedule II controlled substances. (Recommended)
- es There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
- es The pharmacy has written policies and procedures for the safe handling of drug recalls. See www.recalls.gov
- es The pharmacy maintains records of all recalls. See www.recalls.gov

Inspector

Comments: REVIEWED ENTIRE INSPECTION REPORT WITH PHARMACIST ON DUTY JUDITH ALLISON. (1) THE TECHNICIANS LICENSE ARE NOT POSTED. NEED TO HAVE ALL LICENSE PERSONNEL POSTED. (ON 10/29/2010 INSPECTION IT WAS NOTED TO POST TECHNICIAN'S LICENSE) (2.) THERE IS FOOD IN THE MEDICATION REFRIGERATOR (FOOD SHOULD NOT BE IN THE MEDICATION REFRIGERATOR WITH MEDICATIONS) (3.) HAS #4 VIALS OF ZOSTIVAX IN FREEZER WITH NO THERMOMETER (NEEDS TO HAVE A THERMOMETER IN FREEZER) PLEASE OBTAIN A THERMOMETER FOR THE FREEZER AND SEND A COPY OF THE RECEIPT TO NANCY RICHARD @410 358-9512 BY 4/27/2012. 4.) NEEDS A PROCEDURE FOR REMOVAL OF EXPIRED DRUGS (5.) NEEDS A PROCEDURE FOR RETURNS OF CONTROL MEDICATIONS FOUND #4 GLUCERNA EXPIRED 12/1/2011 IN THE OTC AREA, NO OTHER OUTDATES IN THAT AREA. FOUND #8 OUTDATES IN MAIN PHARMACY AREA. NO DISCREPANCIES FOUND DURING THE NARCOTIC AUDIT.

Pharmacist Signature:

Inspector Signature:

Judith Allison
Nancy Richard

Pharmacist Printed Name JUDITH ALLISON

Date: 04/19/2012

Date of Inspection: 04/19/2012
 Pharmacy: VILLAGE PHARMACISTS MONTGOMERY VILLAGE
 Permit #: P00807

Rx# 1009507

DRUGS	ON HAND INVENTORY	PERPETUAL INVENTORY
OXYCODONE 15MG TAB	921 + 2	922 + 2
OXYCONTIN 80MG	137	137
ADDERALL XR 20MG CAP	93	93
CONCERTA 27MG	93	93

COMMENTS: Okay

SCHEDULE II AUDIT

Drug N/A
 Rx1009507 04/19/12 ORIG 04/19/12
 TAKE FIVE (5) TABLETS BY MOUTH DAILY RPh JA
 150 ENDOCET 10/325MG TAB
 AW5417084 Mfg: ENDO LABS
 DR. C. WINCHELL 60951 0712 70
 19241 MONT. VILL. A
 (E-F)

ennial

(A) (B) (C) = A + B (D) (E) = D
 (OR (E) or Excess/Shortage)

INVOICE REVIEW

CII
ALL INVOICES ARE SIGNED AND DATED (USES CSOS HAS 222 ARCHIVE FORM ATTACHED)

CIII - CV
ALL INVOICES ARE SIGNED AND DATED

PRESCRIPTION REVIEW

1008500 - 1008999 CII #
 DATE: 04/10/2012 - 04/13/2012
 COMMENTS: EVERYTHING OKAY

1009300 - 1009399 CIII - CV
 DATE 04/17/2012 - 04/18/2012
 COMMENTS: EVERYTHING OKAY