



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 Gavgaoni, Board President • Deena Speights-Napata, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED
ARTICLE #7016 0750 0001 0747 6270

July 13, 2017

Pharmacare of Cumberland dba
Bedford Road Pharmacy
11306 Bedford Road NE
Cumberland, Maryland 21502
Attn: James L. Kessell, R.Ph.

Re: Permit No. P00033
Case No. PI-17-229
Notice of Deficiencies, Recommended Civil Monetary Penalty, and
Opportunity for Hearing

Dear Pharmacy Manager:

On February 14, 2017, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Bedford Road Pharmacy (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 pharmacy technician registration. Specifically, the Board inspector observed an individual performing delegated pharmacy acts in the prescription area who was not duly registered with the Board. The Board's records indicate that the individual was subsequently registered by the Board on March 6, 2017.

I. FINDINGS AND CONCLUSION

410-764-4755 • Fax 410-358-6207 • Toll Free 800-542-4964
MDH 1-877-463-3464 • Maryland Relay Service 1-800-735-2258
Web Site: www.health.maryland.gov/pharmacy

The Board adopts as findings the deficiencies as stated in the Board's inspection report, dated February 14, 2017, and attached hereto as Exhibit A.

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. §§ 12-403(b)(1) and 12-6B-01.

II. RECOMMENDED CIVIL MONETARY PENALTY

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

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice and in the inspection report, dated February 14, 2017.

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 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 Vanessa Thomas Gray, Compliance Investigator, 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-17-229, 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 February 14, 2017, inspection, 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 Vanessa Thomas Gray, Compliance Investigator, at 410/764-2493.

Sincerely,



Deena Speights-Napata
Executive Director

Attachment

cc: Linda Bethman, AAG, Board Counsel

2/24/2017
Case pending



STATE OF MARYLAND

Department of Health and Mental Hygiene
Larry J. Hogan, Governor - Boyd K. Rutherford, Lt. Governor -
Dennis R. Schrader

DHMH

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue • Baltimore, Maryland 21215-2299
Mitra Gavani, Board President - Deena Speights-Napato, Executive Director

Exhibit

A

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name Bedford Road Pharmacy
Pharmacy Name-Doing Business as (d/b/a) or Trade Name Pharmacare of Bedford Road
Street Address 11306 Bedford Road NE Cumberland, MD 21502
Business Telephone Number 301 777-1100 Business Fax Number 301 777-0116
Inspection Date: 02/14/2017 Arrival Time: 1:10pm Departure Time: 4:30pm
Type of Inspection: Annual Follow-up Previous Date: 12/1/2015
Name of Inspector: Nancy Richard

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: 9am - 8pm Sat: 9am - 5pm Sun: 10am - 3pm

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 P00033 Expiration Date: 05/31/2018
CDS Registration Number 413670 Expiration Date: 10/31/2017
DEA Registration Number AB9172177 Expiration Date: 07/31/2017

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: Uses a secure site. Access's Patient and Physician information. Contact Physician for any concerns.

2. PERSONNEL

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

Pharmacist Employees	License #	Exp Date
James Leland Kessell	09606	11/30/2018
Thomas C Shern	12286	07/31/2018
Gary Getz Jr. CPR 11/2017	15780	05/31/2018

Registered Technicians	Registration #	Exp Date
Suzette M Eversole	T11152	03/31/2018
Amanda L Layton	T00535	01/31/2018
Kearston Flinn	T16562	12/31/2018
Brenda S Miller	T01747	03/31/2018
Lelsey Butler	T15870	03/31/2018

Unlicensed Personnel (non-registered)	Title	Duties
Andy Kidwell	Cpht	Technician
Betty McLuckie	Clerk	Cashier
Andy Kidwell was observed doing Cashier and pulling medications and filling the Script Pro.		
Uses Scotty Security for Deliveries		

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: _____
None. _____

- 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: _____
Does not wholesale distribute to another pharmacy or to a wholesale distributor per pharmacist Gary Getz Jr. _____

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: _____
Has the same hours. _____

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: _____

Also has motion detectors and security cameras. _____

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

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 -15F

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: _____

None. _____

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 the label. Data entry technician initials will show on the label if they perform data entry.

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:

The reporting medication error information is located in a Medication Safety Guide Pamphlet located at the register area. Preventing medication error training and QA is done through Cardinal Learner Community.

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:
All HIPAA trash is placed in blue containers then taken to the Institutional Site for Destruction.

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:
Policy and Procedures are located on the computer under Pharmicare Network.

10. CONTROLLED SUBSTANCES

Power of Attorney James Tressell and Thomas Shern

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: not available

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:

Could not located Biennial inventory. Last one seen was 6/29/2013. Please send a current Biennial Inventory to Nancy Richard @410 384-4137 by 02/20/2017.

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

Bar Scanning.

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:

Uses Script Pro. All labels on the medication bins are current with the expiration dates.

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.

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
- Yes No The pharmacy maintains records of all recalls. See www.recalls.gov

INSPECTOR'S COMMENTS:

Reviewed entire inspection report with floating pharmacist Gary Getz Jr. Could not locate Biennial inventory. Last one seen was 6/29/2013. Please send a current Biennial Inventory to Nancy Richard @410 384-4137 by 02/20/2017. Unlicensed personnel Andy Kidwell was observed doing the Cashier and pulling medications and filling the Script Pro. No out dates found during a spot check. Everything soon expiring has a label with the month it will expire. No narcotic discrepancies.

Inspector Signature Nancy Richard

Pharmacist Name ((Print): Gary Getz Jr. Date: 02/14/2017

Signature: *Gary Getz Jr.*

Received a copy of this inspection report: *Gary Getz Jr.*
Date and Pharmacist Signature