



MARYLAND

Department of Health

Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Robert R. Neall, Secretary

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue, Baltimore, Maryland 21215-2299

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

February 26, 2018

**BY CERTIFIED & REGULAR MAIL
RETURN RECEIPT REQUESTED
CERTIFIED NUMBER: 7015 1520 0003 1509 7242**

Friendly Pharmacy
5720 Deale Churchton Road
Deale, Maryland 20751
Attn: Raghunatha Pallerla, R.Ph.

Re: Permit No. P04580
Case No. 16-156
Finding of Deficiencies and Imposition of Civil Monetary Penalty
By Consent

Dear Mr. Pallerla:

On September 27, 2016, the Board of Pharmacy (the "Board") conducted an annual inspection of Friendly Pharmacy (the "Pharmacy") to ensure compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection indicated several deficiencies regarding medication inventory and related policies and procedures. Specifically, the Pharmacy: (1) stored food in the medication freezer; (2) maintained expired medications in the Pharmacy's inventory; (3) was unable to locate its CDS biennial inventory at the time of inspection; and (4) failed to file a DEA 106 form in response to the recent theft of CDS from the Pharmacy. In addition, the Pharmacy failed to respond to numerous Board correspondence following up on this inspection. The Pharmacy ultimately provided the Board with information indicating that the Pharmacy reported the theft to the local police and the Office of Controlled Substances Administration, and took other remedial actions to address the above deficiencies.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated September 26, 2016, and attached as Exhibit A.

Based upon the above deficiencies, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(c)(1), (12), and COMAR 10.34.05.05, 10.34.12, and 10.34.14.02.

II. 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 noted at the Pharmacy, and the subsequent mitigating factors presented by the Pharmacy, the Board hereby imposes and the Pharmacy agrees to pay a **civil monetary penalty of \$500.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

The civil monetary penalty is **due within thirty (30) days** of the date of this letter, in the form of a check made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

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

NOTE: Please include the case number, PI-16-156, on your check or money order to insure proper assignment to your case.

Upon your payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the Board's inspection on September 27, 2016, and shall be a public document in accordance with the Maryland Public Information Act.

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.

If you have any questions concerning the information or instructions contained in this letter, please contact Heather McLaughlin, Compliance Coordinator, at 410-764-4152.

Sincerely,



Deena Speights-Napata
Executive Director

cc: Linda M. Bethman, AAG, Board Counsel



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

10/6/2016
EB
FEU. Doc. +
memo pending

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name Friendly Pharmacy
Street Address 5720 Deale Churchton Rd. Deale, MD 20751
Business Telephone Number 410-867-2500 Business Fax Number 410-867-8329
Inspection Date: 09/27/2016 Arrival Time: 12:30pm Departure Time: 3:15PM
Type of Inspection: Annual Follow-up Previous Date: 02/17/2016
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: 9am-7pm Sat: 9am-2pm Sun: Closed

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 P04580 Expiration Date: 05/31/2018
CDS Registration Number 463011 Expiration Date: 01/31/2017
DEA Registration Number FB0316554 Expiration Date: 07/31/2019

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.

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws
Raghnatha R. Pallerla

Pharmacist Employees	License #	Exp Date
Raghnatha R. Pallerla	14391	03/31/2017
Eliot J. Cohen (vaccination)	09905	08/31/2107

Registered Technicians	Registration #	Exp Date
N/A	N/A	N/A

Unlicensed Personnel (non-registered)	Title	Duties
Elisha Frank	Cashier	Clerk

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: _____
Some training is through pharmcap.

- 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: _____
Raghunatha R. Pallerla 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: _____
Same hours of operation

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 42F

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

Temperature 74F

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 N/A

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:

Raghunatha R. Pallerla stated that this pharmacy does not give vaccines. Found iced coffee, and tea in the refrigerator, and there was food in the refrigerator noted on last years inspection. Suggest purchasing a separate refrigerator for food, and drinks.

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 only on label. Raghunatha R. Pallerla stated that there are no technicians working at this pharmacy as of this inspection.

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. For QA pharmacy fills out a form if there is an error.

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 shredded. _____

9. INVENTORY CONTROL PROCEDURES

Yes No N/A The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR10.34.24.03

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: _____
Raghunatha R. Pallerla stated that this pharmacy does not wholesale distribute. Reviewed policies and procedures. _____

10. CONTROLLED SUBSTANCES

Power of Attorney Raghunatha R. Pallerla

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: _____

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:

Reviewed CII-V returns through Genco. Raghunatha R. Pallerla was not able to locate the CII-V biennial inventory. Send the biennial inventory to the Board of Pharmacy by 09/27/2017.

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

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:

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.

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 pharmacy manager/owner Raghunatha R. Pallerla. Raghunatha stated that this pharmacy was robbed on 08/11/2016, as of this inspection he is waiting on the police report. Spot checked medication shelves, found #7 out dates in the pharmacy area (see attached list). Found #2 medications where the lot#, and expiration dates were covered with a label. Pharmacy does not maintain perpetual inventory. Found #1 discrepancy during the CII audit on Hydromorphone 2mg, short by #238. Reviewed policies and procedures. Verified pharmacy personnel, both pharmacist were active as of this inspection. During this inspection there was iced coffee, and tea in the refrigerator, and on last years inspection there was food in the refrigerator. Raghunatha R. Pallerla was not able to located the CII-V biennial inventory during this inspection. Reviewed policies and procedures. Raghunatha R. Pallerla stated that this pharmacy does not wholesale distribute, outsource, have any technicians, or participate in the repository/drop off program. Actions per this inspection: 1) Be sure to check the pharmacy area for out dates. 2) suggest purchasing a separate refrigerator for food. 3) Suggest keeping all Board of pharmacy documents in a binder. 4) Send the CII-V biennial inventory. 5) Address the CII perpetual inventory discrepancy, and fax findings with supporting documents on Hydromorphone 2mg short #238. Send all needed documents to the Board of Pharmacy by 10/04/2016, attention Kerri Weigley.

Inspector Signature Kerri Weigley

Pharmacist Name ((Print): Raghunatha R. Pallerla Date: 09/27/2016

Signature: [Signature]

Received a copy of this inspection report: [Signature]

Date and Pharmacist Signature

FINAL 09/02/2014

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: Friendly Pharmacy
Permit#: P04580
Date: 09/27/2016
Pharmacist Signature: *Pharmacy*

Rx#: N760938
Date Filled: 09/27/2016

DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY
Methadone 5mg	60505-7006-02	2EPO	N/A
Morphine Sulf. Er. 15mg	00378-8315-01	151	N/A
Oxycodone 20mg	42858-0004-01	2EPO	N/A
Oxycontin 30mg	59011-0430-10	112	N/A

COMMENTS:

Pharmacy does not maintain perpetual inventory. Found #1 discrepancy during the CII audit on Hydromorphone 2mg, short by #238. Address the CII perpetual inventory discrepancy, and fax findings with supporting documents on Hydromorphone 2mg short #238. Send all needed documents to the Board of Pharmacy by 10/04/2016, attention Kerri Weigley.

SCHEDULE II AUDIT

Drug Hydromorphone 2mg
Date of last Inspection/Biennial 02/17/2016 (inspection)

Amount at last inspection/biennial	<u>75</u>	(A)
Purchased since inspection/biennial	<u>1,700</u>	(B)
Total inventory	<u>1,775</u>	(C) = A + B
Quantity dispensed	<u>1,091</u>	(D)
Expected inventory	<u>684</u>	(E) = C - D
Quantity on Hand	<u>446</u>	(F)
Discrepancy		(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 # N760707-N760797-
DATE 09/22-09/23/16

COMMENTS:
None

CIII - CV # 760700-7607990
DATE 09/21-09/23/16

COMMENTS:
Regular prescriptions are filed with the CIII-V's.

FRIENDLY PHARMACY
5720 DEALE-CHURCHTON ROAD
DEALE, MD 20751 (410) 867-2500 **Rx**

Rx# **N760938** Refills Left: 0 Until: 03/28/17
9-27-16

TAKE 1 TABLET EVERY FOUR HOURS AS
NEEDED

ENDOCET 10/325MG TAB
#150

Dr. BARTH, JOHN

Discard After: 9/27/17

SC

ENDO
882263072

Rph: RP

CAUTION: Federal law prohibits transfer of this drug to any person other than the patient for whom prescribed.