



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 Gavani, Board President – Deena Speights-Napata, Executive Director

April 4, 2016

**CERTIFIED MAIL
RETURN RECEIPT REQUESTED
CERTIFIED NUMBER: 7014 0510 0001 0446 7413**

Olney Professional Pharmacy
18111 Prince Philip Drive, Suite 100
Olney, Maryland 20832
Attn: Helen Huo Yi, R.Ph.

**Re: Permit No. P04031
Case No. PI-16-104**
Finding of Deficiencies and Imposition of Civil Monetary Penalty
By Consent

Dear Ms. Yi:

On November 18, 2015, an annual inspection was conducted by the Board of Pharmacy (the "Board") to determine if Olney Professional Pharmacy (the "Pharmacy") was in compliance with federal and state laws regarding the operation of a pharmacy. The Inspection Report indicated that the Pharmacy was cluttered and disorganized, and employed a pharmacy technician who had completed a Board-approved training program, but was not yet registered with the Board. The Board's prior two inspections also indicated similar deficiencies. The Board held a meeting with the Pharmacy permit holder and determined that the Pharmacy was agreeable to engage in remedial actions to address the deficiencies.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated November 18, 2015 and attached as Exhibit A.

Based upon deficiencies cited at your Pharmacy, the Board finds that the Pharmacy was in violation of the Maryland Pharmacy Act and the regulations adopted thereunder. Specifically, the Board finds the Pharmacy in violation of Health Occ. Art. § 12-403(c)(1) and (11) and § 12-6B-01.

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 cited at the Pharmacy, and the subsequent mitigating factors presented by the Pharmacy, the Board hereby imposes a **civil monetary penalty of \$1,500.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on the Pharmacy Inspection Report dated November 18, 2015.

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

The civil monetary penalty is **due within ninety (90) days** of the date of this letter, in the form of a check made payable to the Maryland Board of Pharmacy. Please send the check to:

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

Please make sure to include the Case Number and the Pharmacy Permit Number on the check.

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. The Pharmacy has indicated that it will remove all excess boxes, equipment and general clutter by April 1, 2016. In addition, the Pharmacy has agreed to revise its policies and procedures to ensure that pharmacy technician trainees enrolled in the Pharmacy's technician training program are only permitted to work as a technician trainee for up to six (6) months. 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.

Olney Professional Pharmacy
Attn: Helen Huo Yi, R.Ph.
April 4, 2016
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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

Attachment

EXHIBIT A

Reviewed 11/20/15
Good pending
Blue MSA#



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COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name _____
Pharmacy Name-Doing Business as (d/b/a) or Trade Name OLNEY PROFESSIONAL PHARMACY INC.
Street Address 18111 PRINCE PHILLIP DRIVE SUITE #100 OLNEY, MD 20832
Business Telephone Number 301 774-9812 Business Fax Number 301 774-9813
Inspection Date: 11/18/2015 Arrival Time: 10AM Departure Time: 12:45PM
Type of Inspection: Annual Follow-up Previous Date: 10/10/2014
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 - 6PM Sat: 10AM - 1PM 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 P04031 Expiration Date: 05/31/2016
CDS Registration Number 456600 Expiration Date: 10/31/2017
DEA Registration Number B08747086 Expiration Date: 12/31/2018

- 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: _____
FILLS FOR #5 ASSISTED LIVING FACILITIES/ USES A SECURE SITE/ PATIENT & PHYSICIANS
PROFILE & HISTORY/ CONTACT PHYSICIAN IF QUESTIONABLE/ RECEIVES ELECTRONIC
CONTROLS

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:

COULD NOT PROVIDE DOCUMENTED TRAINING ON ELAINE CHAE (SEE COMMENTS)

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:

PHARMACY DOES NOT WHOLESALE DISTRIBUTES TO ANOTHER PHARMACY OR WHOLESALE DISTRIUTORS PER PHARMACIST HELEN YI

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 38F

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 -10F

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 IS VERY CLUTTERED AND DISORGANIZED/THIS HAS BEEN DOCUMENTED IN THE
LAST 2 INSPECTIONS

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/TECH DOES ENTER ORDERS UNDER THE PHARMACIST SCREEN/DATA ENTRY TECH INITIALS NEED TO SHOW ON THE LABEL / PLEASE HAVE FIXED AND FAX A CORRECTED LABEL TO NANCY RICHARD @410 384-4137 BY 11/23/15

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:

REPORTING MEDICATION ERROR SIGN IS POSTED AT THE REGISTER AREA/COULD NOT PROVIDE 2 YEARS OF ANNUAL EDUCATION ON PREVENTING MEDICATION ERROR TRAINING/ PLEASE SEND 2 YEARS OF DOUCMENTATION TO NANCY RICHARD@410384-4137 BY 11/25/15

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 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. 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 HELEN YI

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: 08/10/2015

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:

CONDUCTED AN AUDIT ON LIBRAX 11/18/2015 DURING BUSINESS AND ADDED TO CIII TO CV
AUDIT

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

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 INSEPCION REPORT WITH PHARMACIST KUN YI YOU. THIS IS A BOARD APPROVED TECHNICIAN TRAINING PHARMACY SINCE 1/15.

1) HAS A TECHNICIAN IN TRAINING ELAINE CHAE WHO WAS WORKING DURING THE INSPECTION AS A TECHNICIAN (PULLING, FILLING AND DATA ENTRY) MS CHAE WAS IN TRAINING PROGARM DURING THE LAST INSPECTION DONE ON 10/10/2014. COULD NOT PROVIDE ME DOCUMENTED TRAINING DURING INSPECTION.

2) PHARMACY IS VERY CLUTTERED AND DISORGANIZED/THIS HAS BEEN DOCUMENTED IN THE LAST 2 INSPECTIONS AND WAS NOTED RECOMMEND HOUSKEEPING.

3) PHARMACIST INITIALS ARE ON THE LABEL/TECH DOES ENTER ORDERS UNDER THE PHARMACIST SCREEN/DATA ENTRY TECH INITIALS NEED TO SHOW ON THE LABEL OR IN THE COMPUTER

4) COULD NOT PROVIDE 2 YEARS OF ANNUAL EDUCATION ON PREVENTING MEDICATION ERROR TRAINING.

PLEASE SEND REQUESTED DOUCMENTS OF ELAINE CHAE TRAINING/ PREVENTING MEDICATION ERROR TRAINING AND A CORRECTED PRESCRIPTION LABEL SHOWING TECHNICIAN DATA ENTRY TO NANCY RICHARD @410 384-4137 BY 11/23/15. NO OUTDATES FOUND IN THE OTC AREA. NO DISCREPANCIES FOUND DURING THE XARCOTIC AUDIT. NO OUTDATES IN THE PHARMACY.

Inspector Signature Warry Richard

Pharmacist Name ((Print): KUN YI YOU Date: 11/18/2015

Signature: Kun Yizou

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

FINAL 09/02/2014