Department of Health and Mental Hygiene

Larry 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 Gavgani, Board President — Deena Speights-Napata, Executive Director

VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED ARTICLE #7013 1090 0000 3937 7503

June 30, 2016

Brookville Pharmacy 7025 Brookville Road Chevy Chase, Maryland 21815 Attn: Sean Park, Pharm.D., Manager

Re:

Permit No. P00923, Case #PI-16-189

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Pharmacist Park:

On March 29, 2016, an inspection was conducted by the Board of Pharmacy (the "Board") to determine if Brookville 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 not in compliance with regulatory requirements regarding pharmacy operations. Specifically, the Pharmacy had 15 expired medications in the Pharmacy area. These deficiencies were also noted on the Pharmacy's inspections on November 12, 2014, and October 29, 2013.

I. FINDINGS AND CONCLUSION

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Report dated March 29, 2016, 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(c)(1) and (12) 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 enclosed with this letter on Pharmacy Inspection Report dated March 29, 2016.

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 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 request for a hearing must by submitted in writing to Vanessa Thomas Gray, 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 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.

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, Pl-16-189, 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 inspection report, dated March 29, 2016, 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,

Deena Speights-Napata

Executive Director

Cc: Linda M. Bethman, AAG, Board Counsel

Attachment



STATE OF MARYLAND

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

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue • Baltimore, Maryland 21215-2200
Mitra Gavgani, Board President - Deena Speights-Napata, Executive Director

Exh	ibit
A	-

COMMUNITY PHARMAC	CY INSPECTION FORM
Corporate Pharmacy Name	
Pharmacy Name-Doing Business as (d/b/a) or Trad	e Name Brookville Pharmacy
Business Total Blockville Road, Chevy Chase,	MD, 20815
Business Telephone Number 301-652-0600 Bu Inspection Date: 03/29/2016 Arrival Time:	siness Fax Number 301-652-8261
The same of the sa	09:15am Departure Time: 12:50pm
Name of Inspection: () Annual () Follow-up	Previous Date: 11/12/2014
1. GENERAL INFORMATION	
Yes No The pharmacy hours of operation	
The pharmacy nours of operation are t	prominently displayed if the prescription area is not
DL - Post the Same Hours as the est	aonsament,
Sati	9am - 8pm Sun: 10am-3pm
Yes No All permits, licenses, and registrations 408(b) and HO § 12-6B-08	are posted conspicuously. HO § 12-311, HO § 12-
Maryland Pharmacy Permit Number P00923 CDS Registration Number 459404 DEA Registration Number BD9095111	Expiration Date: 04/30/2016
	Expiration Date: 06/30/2016
Inspection Form) COMAR 10.3	ounding. (If yes, complete Sterile Compounding
Yes No The pharmacy provides services to Co	imprehensive Care facilities or assisted living usive Inspection Form) COMAR 10.34.23
Yes No The pharmacy fills original prescription	as received via the internet
Yes No The pharmacy fills original prescription	ns via e-prescribing.
Yes No The pharmacist fills mail order prescrip	
If yes to any of the above, how does the pharmacist vand the prescriber? 21 C.F.R. § 1306.04, HG § 21-220;	erify that a relationship exists between the patient COMAR 10.19.03.02 and .07
Comments:	
E-scripts: Secure site/ patient profile & history / physicia	an can be contacted if questionable
Blister Pack: Pharmacy blister packs for 1 assisted livin	g patient (see attached)

2. PERSONNEL

Name of Pharmacist/Manager who is char Sean Park (on-duty)	17609	02/28/2017
Pharmacist Employees	License #	Exp Date
Joseph Wong Hossein Ejtemai	21012	10/31/2017
Meghedi Mehrabiansani	10600 21697	05/31/2016
megneur mentaplansam	2109/	09/30/2016
Registered Technicians	Registration #	Exp Date
Leiline Garcia (on-duty)	T03900	08/31/2016
Unlicensed Personnel (non-registered) James Spathis (on-duty)	Title Clerk	Duties Cashler
BJ Vijay	Driver	Deliveries
Scott Wilson (on-duty)	Front-end Manager	Clerk / Front-end menager
	314	

3. PERSONNEL TRAININ	IG
Yes No N/A	There are written policies and procedures to specify duties that may be performed 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 tra	aining 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:	
	Sean Park all pharmacy staff receives training listed above

es No / The pharmacy v	wholesale distributes to another pharmacy (COMAR 10.34.37)
es No / The pharmacy y	wholesale distributes to a wholesale distributor (COMAR 10.34.37)
	The wholesale distribution business exceeds 5% of the pharmacy annual sales
	COMAR 10.34,37)
Comments:	
No wholesale distribution as pe	ır Sean Park
4. SECURITY COMAR 10.	34.05
Samuel Ambert	
Yes No / The pharmacy	is designed to prevent unauthorized entry when the prescription area is
closed de	uring any period that the rest of the establishment is open. (If yes, briefly
	how access is restricted.) COMAR 10.34.05.02A (5)
Comments:	
Pharmacy and OTC area close Locked door	i at same time
Pharmacy does have a metal of	gate in door way to pharmacy
Yes No The pharmac	on and/or phormacy deportment has a secondary material COMMAN
10.34.05	y and/or pharmacy department has a security system. COMAR .02A (2)

by

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:
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 lf 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 an d 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 68F
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 (no medications in freezer)
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:
No vaccines located in fridge at time of 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
The name and address of the pharmacy; HG § 21-221(a)(1) The serial number of the prescription; HG § 21-221(a)(2) The date the prescription was filled; HO § 12-505(b)(1) and HG §21-221(a)(3) The name of the prescriber; HG § 21-221(a)(4) The name of the patient; HG § 21-221(a)(5)(i) The name and strength of the drug or devices; HO § 12-505(c) The directions for use; HO § 12-505(b)(2)(ii) and HG §21-221(a)(5)(iii) The required cautionary statements or auxiliary labels; HG § 21-221(a)(5)(iii) The name of generic manufacturer; and HO §§ 12-504(d)(2) and 12-505(c)(2) 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
Yes ✓ No Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503
Pharmacist and technician initials are both 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 povider. 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: Training is done through PRS pharmacy services for each employee (reviewed training) / Reporting
medication error sign posted at register

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 separated and sent with Iron Mountain
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
The pharmacy has a procedure in place for removal of all expired drugs (bot prescription and OTC). COMAR 10.34.12.01
The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03
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
Commenter
No wholesale distribution as per Sean Park
10. CONTROLLED SUBSTANCES
Power of Attorney Sean Park
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: 05/09/2015
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 contr	olled substances prescriptions bear the name and address of the prescriber and lent. COMAR 10.19.03.07D (1)
Yes / No The pern	nit holder or pharmacist designee(s) has written policies and procedures for estigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B
Comments:	
Uses guaranteed returns	for reverse distributor
11. AUTOMATED ME	EDICATION 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 proce	dures exist for (check all that apply): COMAR 10.34.28.04A
Yes / No N/A	
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 Bar code scanning	Sufficient safeguards are in place to ensure accurate replenishment of the automated medication system. If yes, describe safe guards. COMAR 10.34.28.06
Adequate records are main COMAR 10.34.28.1	ntained for at least two years addressing the following (check all that apply).
Yes V 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:	
Pharmacy has Scriptpro he cell and in computer.	olds 200 medication cells / lot # and expiration date is on label on medication
our and it computer.	The state of the s

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 per Se	en Porte
No outsourcing as per Se	an Park
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 outsource	s 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 identifiable manner: COM	e <u>primary</u> pharmacy documents the following in a readily retrievable and IAR 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
Yes No N/A	operated by the federal government. COMAR 10.34.04.06F 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 identifiable manner, which	secondary pharmacy n includes: COMAR 10.3	aintains documentation in a readily retrie 4.04.07 (Check all that apply)	vable and
Yes No N/A		der was transmitted from another pharmacy.	
Yes No N/A		ion identifying the specific location of the pr	
Yes No N/A	The name of the pharm	acist who transmitted the prescription to the accoursed in an oral manner.	e secondary pharmacy
Yes No N/A		nacist at the secondary pharmacy who acc	cepted the transmitted
Yes No N/A		nacist at the secondary pharmacy who pre	pared the prescription
Yes No N/A		prescription order was received at the second	ary nharmacy
Yes No N/A		prepared product was sent to the primary pl	
13. Recommended Best P	ractices		
Yes ✓ No A perpe	etual inventory is mainta	ned for Schedule II controlled substances.	
Yes No There a	re documented continge for disaster recovery of	ncy plans for continuing operations in an er required records.	nergency and
Yes No The pha	armacy has written polic See www.recalls.gov	ies and procedures for the safe handling of	drug recalls.
Yes / No The pha	ırmacy maintains record	of all recalls. See www.recalls.gov	
INSPECTOR'S COMME			
Reviewed entire inspection re	port with pharmacist Sean	Park. Pharmacist Sean Park and Joseph Wong are	
pharmacy staff on boards web	st, reviewed Sean Park CP	R certification good until 01/19/2017. Verified al	1
outdates found in OTC area. N	Jo discrepancies found dur	packs for 1 assisted living patient (see attached) ng narcotic audit. Reviewed policies and procedu	. No
located in binder and reviewed	I pharmacy staff training th	rough PRS pharmacy services. Found 15 expired	ires
medications through out pharr	nacy stock(see attached), r	ote outdates were noted on last inspection.	
Par this Inconstitute 1) Places	for some of touch West	CDD	
by 04/06/2016. 2) Please by	e sure to check all areas of	CPR certification to Amanda Barefield @ 410-38 pharmacy when checking for outdates.	84-4137
, i i i i i i i i i i i i i i i i i i i	Some to cheek all altas of	marriacy when elecking for outdates.	
			- STREET
***************************************			A
Inspector Signature			
Pharmacist Name ((Print	t): Sean Park	Date: 03/29/2016	
Signature:	KIL	700	1
Received a copy of this in	spection report:	5 RM	
		Date and Pharmacist Signature	

FINAL 09/02/2014

CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Pharmacy: Brookville Pharmacy

Permit#: P00923			
Date: 03/29/2016 Pharmacist Signature:	S 131		
a normacist Signature.	On Kille		
	204070		
Rx# <u>:</u> N12			
Date Fil	led: 03/28/2016		
DRUG	NDC Number	ON HAND	PERPETUA
Hydrocodone-Apap 5/300mg tab	64376-0648-01	INVENTORY	INVENTOR
Vyvanse 20mg cap		112	115
The state of the s	59417-0102-10	2901	201
Amphetamine salts 10mg tab	64720-0132-10	14-7	147
Oxycodone 5mg tab	00406-0552-01	719	7/4
	SCHEDULE II AUDIT		
	Date of last Inspection/Biennial 4/9		
Amount at last inspection/bienni Purchased since inspection/bienr Total inventory Quantity dispensed Expected inventory Quantity on Hand Discrepancy		(A) (B) (C) = A + B (D) (E) = C - D (F) (G) = (F-E) or (E-F) Excess Shortage	
	INVOICE REVIEW		
CH			
CII: All invoices are signed and date	4		
The lite oldes and algred and date.	4 0		
CIII - CV:			
All invoices are signed and date	d		
Particular description of the latest states of the			

PRESCRIPTION REVIEW

CII # N1215659-N1216214 DATE 02/01-02/05/16

		CHI	- CV	# 12207	83-122	0657	•
COMMENTS:		D	ATE	03/22	/16		
Control CIII-V prescription	ns are mixed in	with re	aular s	acrinte (Prescrin	tions	are filed l
filled. All prescriptions rev	viewed were fill	ed with	in 120	days of	issue d	ate.	are meu
		7					
					EDG DATACA	ev.	
BROOKVILLE PH	ED9095111		им <i>ЕХСКІІ</i> ВВСРНО	PT Flid	-888-PHARM Away* Vist Pat. 6,858,30	EX Observe Sound	
7026 BROOKVILLE RO CHEVY CHASE, MO (301) 652-0600 Fax: (301) 652	609095111 20815			T Fild	-588-PHARM Away* Vial Pat. 6,858,20	SX ∩bal™ Sotat	Sax
7026 BROOKVILLE RD CHEVY CHASE, MO (301) 652-0600 Fax: (301) 652-N1221272 N 3-28-16 Dr. CULLEN	209095111 20815 2- 8261			PT Fild 11 V.S.	-588-PHARM Away* Viat Pert. 6,858,36	EX Obal ^m Secul	Sax Sax
7026 BROOKVILLE RD CHEVY CHASE, MO (301) 652-0600 Fax: (301) 652-N1221272 N 3-28-16 Dr. CULLEN	20815 2-8261 (301) 951 0420			THE SN	-EBB-PHARMA Away* Vial. Pat. 6855,30	24 HR. REFUL LINE F. P.	147

COMMENTS:

NDC# 59417-0103-10 LOTUS BIOCHEMICANSC Discard After: 3/28/17 Orig: 3-28-16 Fill # 0 Refills: 0 RPh: SP Tech: SP STATE OF MARYLAND



Department of Health and Mental Hygiene Louvence J. Hagan, Jr., Governor - Boyd K. Rutherford, Lt. Governor -Van T. Mitchell, Secretary

MARYLAND BOARD OF PHARMACY
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SUPPLEMENTAL FORM FOR ASSISTED LIVING

PERMITS AND LICENSI	ES
Corporate Pharmacy Name Inspection Date: 03/29/2016	Brookville Pharmacy
Maryland Pharmacy Permit	Novek n00073
maryland rharmacy Fermit	Number pooses
	IG, FILES, AND STORAGE by prescription files are maintained chronologically for 5 years. HO §12-
The following la	abel requirements are met if a drug is dispensed pursuant to a tion. COMAR 10.34.23.08:
	The name and address of the pharmacy;
	The serial number of the prescription;
	The date the prescription was dispensed;
,	The name of the prescriber;
	The name of the patient;
	The name and strength of the drug or devices;
Decreed Secured Legacid	The quantity of the drug or device;
	The required precautionary information regarding controlled substances;
Towns and the same of the same	The required cautionary statements or auxiliary labels;
Trintal Trintal Edition	The name of generic manufacturer;
	The expiration date is indicated;
Yes No No N/A	(Medications in Parenteral Admixtures) The name and amount of drug(s) added;
	(Medications in Parenteral Admixtures) The name of the pharmacist responsible for the admixture;
	(Medications in Parenteral Admixtures) The rate of infusion; and (Medications in Parenteral Admixtures) The frequency of infusion
	ion provided per dosing period in a single container, slot, blister package, any other method of delivering an entire single dosing unit, or as part of a multi-dose dispensing package, are labeled with at least the following:
facing from the facing	(1) Drug name;
	(2) Drug strength;
formers formers	(3) Name of manufacturer;
lineary lineary	(4) Name of the patient;

Yes No N/A (5) Lot number; and
Yes No N/A (6) Expiration date.
Yes No N/A The pharmacist and technician initials are on prescriptions or patient drug profiles or computerized patient records. COMAR 10.34.08.01
Comments:
Lot # is hand written on label / Same pharmacist and techs who perform data entry/ checking also blister
pack No blister packs available at time of inspection
No offster packs available at time or inspection
MEDICATION PACKAGING (COMAR 10.34.23.07)
Yes No N/A The pharmacy prepares packaged medications. (If yes complete questions below)
Packaged from the original manufacturer's container:
Yes No N/A The pharmacy uses a lot number and expiration date assigned by the pharmacy instead of the distributor or manufacturer information in a master log if kept with respect to drugs that are packaged within the pharmacy facility from the original manufacturer's container which includes the:
Yes No N/A Name of drug;
Yes No N/A V Strength;
Yes No N/A / Manufacturer;
Yes No N/A / Lot Number assigned by the pharmacy;
Yes No N/A / Lot number assigned by the distributor or manufacturer;
Yes No N/A / Quantity packaged; Yes No N/A / Manufacturer's expiration date;
Yes No N/A / Manufacturer's expiration date; Yes No N/A / Lot number assigned by the distributor or manufacturer;
Yes No N/A / Date of packaging;
Yes No N/A Name of the pharmacy technician who performed packaging functions;
and Yes No N/A Name and initials of verifying licensed pharmacist.
Packaged from Another Pharmacy:
Yes No N/A The licensed pharmacist packages medication received from another pharmacy
licensed in Maryland or operated by the government of the United States provided that:
Yes No N/A (1) The licensed pharmacist determines that the medication has been handled in a manner which preserves the strength, quality, purity, and identity of the drug or device during an interim period between the time it was dispensed by the original pharmacy and to directly send medication to the packaging pharmacy;
Yes No N/A (2) The licensed pharmacist packages and dispenses all at one time the entire quantity of the prescription medications received from another pharmacy for packaging;
No N/A (3) The manufacturer's name is present on the container received from the other pharmacy; and

Yes No N/A (4) The Yes No N/A / No N/A / No N/A /	licensed pharmacist maintains a master log that includes the following information: (a) Name of the drug; (b) Lot number assigned by the packaging pharmacy; (c) Strength; (d) Manufacturer; (e) Name, address, and telephone number of the original dispensing pharmacy; (f) Prescription number for the original dispensing pharmacy; (g) Quantity packaged; (h) Expiration date as assigned by the original dispensing pharmacy; (i) Date of packaging; (j) Name of pharmacy technician who performed packing function; (k) Name and initials of verifying licensed pharmacist; and (l) Name of the patient.	
Comments:		
(See attached)		
Inspector Signature:		
Pharmacist Name: Sean Park	03/29/2016 (Print)	
Received a copy of the inspection report on	Date and Signature of the Pharmacist	