



# 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

March 27, 2018

**BY CERTIFIED & REGULAR MAIL RETURN RECEIPT REQUESTED**  
**CERTIFIED NUMBER: 7014 2870 0000 4731 6093**

Rite Aid Pharmacy #7840  
9810 Apollo Drive  
Largo, Maryland 20774  
Attn: Robert Kabutey, R.Ph., Pharmacy Manager

Re: Permit No. P04722  
Case No. 18-077  
Notice of Deficiencies, Recommended Civil Monetary Penalty, and  
Opportunity for Hearing

Dear Pharmacy Manager:

On November 1, 2017, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Rite Aid Pharmacy #7840 (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 and drug inventory. Specifically, the Board inspector observed an unregistered pharmacy technician performing delegated pharmacy acts in the prescription area. The Pharmacy's training program documentation indicated that the technician completed a Board-approved technician training program but was not yet registered with the Board. In addition, the Pharmacy had approximately twelve (12) expired medications in its inventory.

### **I. FINDINGS AND CONCLUSION**

The Board adopts as findings the deficiencies as stated in the Board's inspection report, dated November 1, 2017, and attached as Exhibit A.

Based upon deficiencies at the Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act; specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(c)(1) and (12), 12-6B-01 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 \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice and the attached Exhibit A.

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 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.

## 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 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 Heather McLaughlin, Compliance Monitor, Maryland Board of Pharmacy, 4201 Patterson Ave., 5<sup>th</sup> 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 the Pharmacy's 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 or money order to:

Wells Fargo Bank  
Attn: State of MD - Board of Pharmacy  
Lockbox 2051  
7175 Columbia Gateway Drive  
Columbia, MD 21046

***NOTE: Please include the case number, 18-077, 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 action with respect to the inspection report dated, November 1, 2017, and shall be a public order and document in accordance with the Maryland Public Information Act.

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

Sincerely,



Deena Speights-Napata  
Executive Director

cc: Linda Bethman, Board Counsel  
Deborah Hurley, Rite Aid Corporation



**MARYLAND**  
 Department of Health  
 Larry J. Hogan, Governor - Boyd K. Rittlerford, Lt. Governor - Dennis R. Schrader, Secretary  
**MARYLAND BOARD OF PHARMACY**  
 4201 Patterson Avenue, Baltimore, Maryland 21215-2299  
 Mimi Gavagan, Board President - Deena Speigels-Napata, Executive Director

**Exhibit A**

COMMUNITY PHARMACY INSPECTION FORM

Maryland Pharmacy Permit Number: P04722  
 Corporate Pharmacy Name: RITE AID #0784D  
 Pharmacy Name-Doing Business as (d/b/a) or Trade Name:  
 Street Address: 9810 APPOLO DRIVE, LARGO, MD, 20774  
 Business Telephone Number: 301-322-9027  
 Business Fax Number: 301-322-9464  
 Inspection Date: 11/01/2017  
 Arrival Time: 13:02  
 Departure Time: 15:17:08  
 Type of Inspection:  Annual  
 Previous Date: 12/22/2016  
 Name of Inspector: [Signature]

I. 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  
 Monday: 8am-10pm Tuesday: 8am-10pm Wednesday: 8am-10pm Thursday: 8am-10pm  
 Friday: 8am-10pm Saturday: 8am-8pm Sunday: 8am-8pm

Yes  No All permits, licenses, and registrations are posted conspicuously 110 § 12-311, 110 § 12-408(b) and 110 § 12-6B-08

Maryland Pharmacy Permit Number: P04722 Expiration Date: 05/31/2018  
 CDS Registration Number: 464130 Expiration Date: 12/31/2017  
 DEA Registration Number: FR0696813 Expiration Date: 06/30/2018

- 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, 11G § 21-220; COMAR 10.19.03.02 and .07

Comments: The pharmacist verifies [Signature]

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws  
 21909 21909, ROBERT KABUTEY

Pharmacist Employee	License #	Status	Exp Date	Vaccine Certification #	Status	Exp Date
ROBERT KABUTEY	21909	Active	12/31/2018	21909	Active	12/31/2018
MYNGA V HUA	20897	Active	12/31/2017	20897	Active	
Francis Ogoegbunam	23005	Active	04/30/2018	23005	Active	04/30/2018

Registered Technicians	Registration #	Status	Exp Date
BRISHA WILLIAMS	T11932	Active	04/30/2018

Unlicensed Personnel (non-registered)	Title	Duties
Tanya Sultana	Wellness Ambassador	Clerk, phones
Briomni Jefferies	Tech in Training	pull, count, label drugs

Personnel on duty in the pharmacy during inspection: Briomni, Tanya, Brisha and Francis. Briomni stated she has completed the tech training program and sent her application to the Board approximately 1 week ago. Briomni was not found on Board's verification site.

Comments:

**3. PERSONNEL TRAINING**

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)  
 Yes No N/A

All personnel have received training in: (check all that apply) COMAR 10.34.21.03B(3) and (4)

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  
 Yes No N/A

Comments:

Personnel training is completed on the pharmacy's intra net.

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:

N/A

**4. SECURITY COMAR 10.34.05**

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)  
 Yes No

Comments:

Locked doors, metal gates, security cameras and motion detection prevents unauthorized entry when the pharmacy is closed.

Yes  No The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A (2)

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)  
 Yes No

Comments:

N/A

**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, 39F

Yes  No

The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)

Temperature

73F

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

-27F

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:

See 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 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:

None.

**8. CONFIDENTIALITY**

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:  
Ok.

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:  
None.

10. CONTROLLED SUBSTANCES

- Power of Attorney:
- 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  Closing
  - 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 controlled returns to Med-Turn.

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:

N/A

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:

N/A

- 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)

- That the prescription order was transmitted from another pharmacy.



12 OUTSOURCING  Yes  No ( if No, go to #13 )

Yes  No  N/A

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](http://www.recalls.gov)

Yes  No The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)

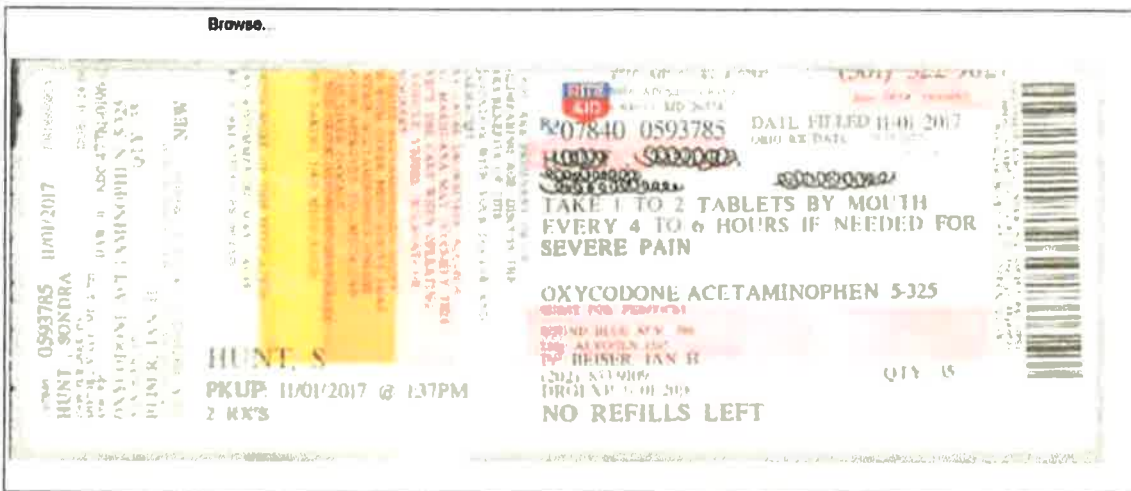
CONTROLLED DANGEROUS SUBSTANCES WORKSHEET				
Pharmacy: RITE AID #07840				
Permit# P04722				
Date 11/01/2017				
Rx# <input type="text" value="0593785"/>				
Date Filled <input type="text" value="11/01/2017"/>				
DRUG	NDC Number	ON HAND INVENTORY	PERPETUAL INVENTORY	
Oxycodone/APAP 10/325mg	42858-104-01	290	290	Clear
Adderall XR 30mg	54082-391-01	40	40	Clear
Oxycodone 10mg	88382-796-01	193	193	Clear
Morphine Sulfate IR 15mg	0054-0235-25	197	192	Clear
Comments:				

SCHEDULE II AUDIT		
Drug:	<input type="text" value="N/A"/>	
NDC Number:	<input type="text" value="N/A"/>	
Date of last Inspection/Biennial:	<input type="text" value="12/22/2016"/>	
Amount at last inspection/biennial	<input type="text" value="0.00"/>	(A)
Purchased since inspection/biennial	<input type="text" value="0.00"/>	(B)
Total inventory	<input type="text" value="0"/>	(C) = A + B

SCHEDULE II AUDIT		
Quantity Dispensed	0.00	(D)
Expected Inventory	0	(E) = C - D
Quantity on Hand	0.00	(F)
Discrepancy	0	(G) = (F-E) excess or (E-F) shortage

INVOICE REVIEW	
CII:	The pharmacy orders CII drugs via DEA 222 forms.
CIII:	Controlled invoices are signed and dated.
CV:	

PRESCRIPTION REVIEW	
CII#:	0591435-0593785
Date:	10/21/2017-10/31/2017
Comments:	None.
CII#:	592900-592909
Date:	10/27/2017-10/28/2017
Comments:	None.



Pharmacist Signature for Controlled Dangerous Substances Audit:	
---	--