



STATE OF MARYLAND

**DHMH**

Department of Health and Mental Hygiene

*Martin O'Malley, Governor – Anthony G. Brown, Lt. Governor – John M. Colmers, Secretary*

**MARYLAND BOARD OF PHARMACY**

*4201 Patterson Avenue • Baltimore, Maryland 21215-2299*

*Donald W. Taylor, Board President - LaVerne G. Naesea, Executive Director*

**CERTIFIED MAIL RETURN RECEIPT REQUESTED**  
**ARTICLE #7008 1830 0001 1597 6468**

May 11, 2010

Mr. Mehran Behnamfard  
SinuRx Pharmacy  
306 Reisterstown Road  
Pikesville, MD 21208

Re: Permit No. P04471  
Notice of Deficiencies, Imposition of Civil Monetary Penalty, and  
Opportunity for Hearing

Dear Mr. Behnamfard:

On April 22, 2009, an annual inspection was conducted by the Board of Pharmacy (the "Board") to determine if SinuRx 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 substantial compliance with regulatory requirements regarding controlled drug inventory and removal of expired drugs. A follow-up inspection was conducted on May 13, 2009, which indicated that the Pharmacy still lacked sufficient recordkeeping of its controlled drug inventory. On February 23, 2010, the Board conducted an inspection, which noted that there were approximately 50 outdated drugs in the Pharmacy, incorrect recording of DEA numbers, and insufficient recordkeeping of controlled drug invoices.

**I. FINDINGS AND CONCLUSION**

The Board adopts the findings of deficiencies as set forth in the Pharmacy Inspection Reports dated April 22, 2009, May 13, 2009, and February 23, 2010, and attached as Exhibits A, B, and C.

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(b)(1) and (12), Health Gen. Art. § 21-216, COMAR 10.34.12.01, and 21 CFR §§ 1304.21 and 1305.17.

## 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 imposes a **civil monetary penalty of \$2,500.00**. The deficiencies upon which the civil monetary penalty is based are enclosed with this letter on Pharmacy Inspection Reports dated April 22, 2009, May 13, 2009, and February 23, 2010.

In determining whether to impose a civil monetary penalty, the Board took into consideration the following factors:

1. The extent to which the permit holder derived any financial benefit from the unprofessional or improper conduct;
2. The willfulness of the unprofessional or improper conduct;
3. The extent of actual or potential public harm caused by the unprofessional or improper conduct;
4. The permit holder's history or previous violations;
5. The existence of mitigating factors.

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

## III. FOLLOW-UP INSPECTION

Please be advised that the Board has directed that a follow-up inspection be performed of the Pharmacy **no later than August 15, 2010**, to insure that the deficiencies noted the Report have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has not come into 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

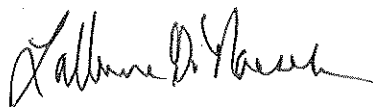
If the Pharmacy disputes any of the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall issue formal charges and a letter of procedure. 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 Kimberly France, Pharmacist Compliance Officer, Maryland Board of Pharmacy, 4201 Patterson Ave., 1<sup>st</sup> Floor, Baltimore, Maryland 21215, no later than thirty (30) days of the date of this Notice.

Please be advised that at the hearing you 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.

Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the Inspection Reports dated April 22, 2009, May 13, 2009, and February 23, 2010, 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 Kimberly France, Pharmacist Compliance Officer, at 410-764-5908.

Sincerely,



LaVerne G. Naesea  
Executive Director

cc: Chandra Mouli, Deputy Chief  
Division of Drug Control

Linda M. Bethman, Assistant Attorney General  
Board Counsel

Attachments



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene

Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - John M. Colmers, Secretary

jm entered 4-27-09

EC. 4129109 ✓  
#9 will perform reinspection in 21 days. (Reinspection was done on 5/13/09)

MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299

Donald Taylor, Board President - LaVerne G. Naesea, Executive Director

EXHIBIT

A

COMMUNITY PHARMACY INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name Sinu Rx Pharmacy  
Pharmacy Name-Doing Business As (d/b/a) or Trade Name \_\_\_\_\_  
Street Address 306 Reisterstown Rd. Pikesville, MD. 21208  
Business Telephone Number 410-486-7468 Business Fax Number \_\_\_\_\_  
Maryland Pharmacy Permit Number P04471 Expiration 12-31-09  
CDS Registration Number 462476 Expiration 6-30-10  
DEA Registration Number BS9969188 Expiration 2-29-12  
Pharmacy Hours: Mon-Thurs 8<sup>30</sup>am-7<sup>30</sup>pm Fri 8<sup>30</sup>am-4pm Sat. Closed Sun. 10am-3pm  
Inspection Date: 4-22-09 Arrival Time: 10:25am Departure Time: 1:20pm  
Type of Inspection: Opening (Annual) Follow-up Previous Date: \_\_\_\_\_  
Name of Inspector: Jeannette McKnight CPHT

Yes No

- The pharmacy department provides service 24 hours a day.  
COMAR 10.34.05.
- The pharmacy hours of operation are prominently displayed.  
COMAR 10.34.05.03B
- All permits, licenses, and registrations are posted conspicuously.  
HO §12-311, HO §12-408(b) and HO §12-6B-08
- The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19
- The pharmacy provides services to Long Term Care facilities or assisted living facilities.  
(If yes, complete Long Term Care Inspection Form)  
COMAR 10.34.23
- The pharmacy fills original prescriptions received via the internet.

If yes, how do pharmacists verify that a relationship exists between the patient and the prescriber.

HG §21-220; COMAR 10.19.03.02 and .07

2. PERSONNEL (COMAR 10.34.03.05)

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

Mehran Behnamfar

Pharmacist Employees	License #	Exp. Date
<u>Mehran Behnamfar</u>	<u>#16076</u>	<u>6-30-10</u>

(attach list if necessary)

Registered Technicians	Registration #	Exp. Date
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(attach list if necessary)

Support Personnel	Title	Duties
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(attach list if necessary)

3. PERSONNEL TRAINING

Yes No No Technicians

- There are policies and procedures to specify duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist, COMAR 10.34.21.03A and C
- All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03D

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

- Yes No
- Maintaining records
  - Patient confidentiality
  - Sanitation, hygiene, infection control
  - Biohazard precautions
  - Patient safety and medication errors COMAR 10.34.26.03

Yes No

- There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

#### 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)

- The entire scope is open during same hours.
- The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A(2)
- Entry access is restricted to pharmacists only. COMAR 10.34.05.02A(3)

#### 5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes No

- Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2.

- 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

- The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A

- The pharmacy has hot and cold running water.

- The medication refrigerator(s) contain non-prescription items. COMAR 10.34.07.01B *Medication Only*

- Corrected*  The medication refrigerator(s) have a thermometer. COMAR 10.34.07.01B

- 5/13/09*  The current temperature of the medication refrigerator(s) is between (36F-46F). USP

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

- The pharmacy maintains a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03

- The pharmacy has online resources. HO §12-403(b)(15)

- The pharmacy possesses the current edition of *The Maryland Pharmacy Laws and Regulations*. HO §12-403(b)(10)(ii)

#### 6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No

- Hard copy prescription files are maintained chronologically for 5 years. HO §12-403(b)(13)  
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)
- 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)(ii)
- 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 technician initials are on prescriptions. COMAR 10.34.08.01 *No Technicians*
- Original prescriptions are dispensed within 120 days after the issue date. HO §12-503

## 7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes No

- There are written procedures 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
- 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 role and responsibility of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

## 8. CONFIDENTIALITY

Yes No

- Confidentiality is maintained in the creating, storing, accessing, disposal and disclosure of patient records. HO §12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations
- 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

## 9. INVENTORY CONTROL PROCEDURES

Yes No

- The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03

Yes No

- The pharmacy has written policies and procedures for the safe handling of drug recalls. See [www.recalls.gov](http://www.recalls.gov)
- The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)
- The pharmacy has a procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01

Corrected  
5/13/09

### 10. CONTROLLED SUBSTANCES

Yes No

- A perpetual inventory is maintained for Schedule II controlled substances. (recommended) *Unavailable*
- The pharmacy has a copy of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B  
Inventory date: \_\_\_\_\_
- Inventory completed at Opening or Closing of business date: \_\_\_\_\_
- The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
- 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
- The prescription label for controlled drugs include the following warning: "CAUTION: *Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed*", in 6-point type or the Pharmacy utilizes an auxiliary label that contains this warning. COMAR 10.19.03.08D(1)
- 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)
- All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D(1)
- 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)

Corrected  
5/23/09

### 11. AUTOMATED MEDICATION SYSTEMS Yes No (if No, go to #12)

Yes No

- 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 10.34.28.05
- Control of access to the device.
- Accounting for medication added and removed from the system.

N/A



Yes No

- 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

- Maintenance records.
- System failure reports.
- Accuracy audits.
- Quality Assurance Reports.
- Reports on system access and changes in access.
- Training records.

Yes No

- Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, forms and 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
- 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

N/A

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

Yes No

- The facility outsources the preparation or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
- The facility serves as a secondary pharmacy. COMAR 10.34.04.02
- Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- 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

N/A

Yes No

- 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

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:

- The original prescription order is filed as a prescription order at the primary pharmacy.  
 COMAR 10.34.04.06D

The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner (Check all that apply): COMAR 10.34.04.06

Yes No

N/R

- The prescription order was prepared by a secondary pharmacy.  
  The name of the secondary pharmacy.  
  The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.  
  The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.  
  The date on which the prescription was transmitted to the secondary pharmacy.  
  The date on which the medication was sent to the primary pharmacy.

Yes No

- The primary and secondary pharmacies are both licensed in the State of Maryland, or 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 secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes (check all that apply): COMAR 10.34.04.07

N/A

Yes No

- Records of the prescription orders transmitted from another pharmacy.  
  The name and information identifying the specific location of the primary pharmacy.  
  The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.

# CONTROLLED DANGEROUS SUBSATNCES WORKSHEET

## Perpetual Scheduled II Audit

Rx # \_\_\_\_\_

	<u>Drug</u>	<u>Actual Count</u>	<u>Perpetual Inventory</u>
1.			
2.			
3.			
4.			
<b>Comments:</b>			
_____			
_____			

## Biennial Schedule II Audit

Drug \_\_\_\_\_

Inventory \_\_\_\_\_

Purchases \_\_\_\_\_

Total Available \_\_\_\_\_

Dispensed \_\_\_\_\_

Expected Inventory \_\_\_\_\_

Actual Inventory \_\_\_\_\_

Discrepancy \_\_\_\_\_

### Inspection Comments

**Schedule II Invoice Review**

Please sign and date all invoices as they are received and attach CSOS order to the invoice as well.

**Schedule III - V Invoice Review**

Please sign and date all invoices as they are received into the pharmacy

**Schedule II Prescription Review #22318 - # 23367**

Please be sure to use the correct DEA number for the prescribing physician. Frequently using DEA# AJ4149357 on CII prescriptions

**Schedule III - V Prescription Review #21400 - # 21499**

Please be sure to use the correct DEA number for the prescribing physician.

Yes No

N/A

- The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
- The date on which the prescription order was received at the secondary pharmacy.
- The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.

Inspectors Comments:

- ④ Please fax a copy of written policy and procedure for handling of drug recalls to my office Attn: Jeannelle McKnight CPLT 410-358-9512.
- ⑤ Please place a thermometer in the medication refrigerator. No temperature was able to be taken.
- ⑥ Expired Drugs: Cefdinir 250mg/5ml 2-26-09; Qualaquin 324mg 12-08; Lisinopril 40mg 12-08; Methylphenidate 20mg 1-09; Effexor XR 37.5mg 10-08; Metolazone 3-09; Sertraline 50mg 6-08; Methylin 5mg 3-09; Diclofenac 100mg 11-08; Metformin 1000mg No exp date; Coreg CR 20mg No exp date. Misbranded drug bottles pulled from shelf total of 16 bottles. No drug name, lot number, or expiration dates on the bottles.
- ⑩ Please conduct a biennial inventory of CDS. Fax: Attn: Jeannelle McKnight CPLT 410-358-9512

I will do a re-inspection of the pharmacy in 21 days.

**SINU W PHARMACY** **EPIC** No. 23500  
 306 REISTERSTOWN ROAD • PIKESVILLE, MD 21208 (410) 486-7468  
CAUTION: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed.

Dr. Brown, Ralph 410-601-8301  
 [Redacted]  
**RITALIN-LA 20MG CAP (NOVARTIS) #180**  
**TAKE 1 CAPSULE TWICE DAILY**

REFILLS: MB Exp Date: Apr 2010  
 Date Filled: 04/22/09

Inspector Signature Jeannelle McKnight CPLT  
 Pharmacist Name: Mehran Behnam Farid Date: 4-22-09  
 (Print)  
 Signature: [Signature]

FINAL 02/27/08

INSPECTION FORM REVIEWER'S NOTES

Corporate Pharmacy Name Sim Rx Pharmacy

Pharmacy Name-Doing Business As (d/b/a) or Trade Name \_\_\_\_\_

Inspection Date: \_\_\_\_\_ Maryland Pharmacy Permit Number P04471

Please conduct the CD CDS Audit  
during Next Annual Inspection to this  
facility.

EL, 9/10/09

CD  
CDS  
Audit ?  
Juanille  
can't remember.

Reviewer initials EL,

Date: 9/28/09



STATE OF MARYLAND

DHMH

Department of Health and Mental Hygiene  
Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - John M. Colmers, Secretary

EXHIBIT

B

re: section EL  
5/27/09  
6/9/09  
CDS  
Audits  
Next  
Annual  
Inspection

MARYLAND BOARD OF PHARMACY  
4201 Patterson Avenue • Baltimore, Maryland 21215-2299  
Donald Taylor, Board President - LaVerne G. Naesca, Executive Director

COMMUNITY PHARMACY INSPECTION FORM

1. PERMITS AND LICENSES

Corporate Pharmacy Name Sinu Rx Pharmacy  
Pharmacy Name-Doing Business As (d/b/a) or Trade Name \_\_\_\_\_  
Street Address 306 Reisterstown Rd. Pikesville, MD. 21208  
Business Telephone Number 410-486-7468 Business Fax Number \_\_\_\_\_  
Maryland Pharmacy Permit Number P04471 Expiration 12-31-09  
CDS Registration Number 462476 Expiration 6-30-10  
DEA Registration Number BS9969188 Expiration 2-29-12  
Pharmacy Hours: Mon-Thurs 8:30am-7:30pm Fri. 8:30am-4pm Sat. Closed. Sun. 10am-3pm  
Inspection Date: 5-13-09 Arrival Time: 1:05pm Departure Time: 2:50pm  
Type of Inspection: Opening Annual Follow-up Previous Date: 4-22-09  
Name of Inspector: Jeanette McKnight CPhT

Yes No

- The pharmacy department provides service 24 hours a day.  
COMAR 10.34.05.
- The pharmacy hours of operation are prominently displayed.  
COMAR 10.34.05.03B
- All permits, licenses, and registrations are posted conspicuously.  
HO §12-311, HO §12-408(b) and HO §12-6B-08
- The pharmacy performs sterile compounding. (If yes, complete Sterile  
Compounding Inspection Form) COMAR 10.34.19
- The pharmacy provides services to Long Term Care facilities or assisted living facilities.  
(If yes, complete Long Term Care Inspection Form)  
COMAR 10.34.23
- The pharmacy fills original prescriptions received via the internet.

If yes, how do pharmacists verify that a relationship exists between the patient and the prescriber.

HG §21-220; COMAR 10.19.03.02 and .07

2. PERSONNEL (COMAR 10.34.03.05)

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

Mehran Behnamfard

Pharmacist Employees	License #	Exp. Date
<u>Mehran Behnamfard</u>	<u>#116076</u>	<u>6-30-10</u>

(attach list if necessary)

Registered Technicians	Registration #	Exp. Date
------------------------	----------------	-----------

(attach list if necessary)

Support Personnel	Title	Duties
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(attach list if necessary)

3. PERSONNEL TRAINING

Yes No

- There are policies and procedures to specify duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist, COMAR 10.34.21.03A and C
- All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03D

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

- Yes No
- Maintaining records
- Patient confidentiality
- Sanitation, hygiene, infection control
- Biohazard precautions
- Patient safety and medication errors COMAR 10.34.26.03

Yes No

- There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

#### 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)

- The pharmacy and/or pharmacy department has a security system. COMAR 10.34.05.02A(2)

- Entry access is restricted to pharmacists only. COMAR 10.34.05.02A(3)

#### 5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes No

- Pharmacy area is clean, neat, and organized. HO §12-403(b)(11)(ii)2.

- 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

- The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A

- The pharmacy has hot and cold running water.

- The medication refrigerator(s) contain non-prescription items. COMAR 10.34.07.01B

- The medication refrigerator(s) have a thermometer. COMAR 10.34.07.01B

- The current temperature of the medication refrigerator(s) is between (36F-46F). USP 46°F

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

- The pharmacy maintains a library of current reference sources consistent with its scope of practice that is accessible to all appropriate personnel. COMAR 10.34.07.03

- The pharmacy has online resources. HO §12-403(b)(15)

- The pharmacy possesses the current edition of *The Maryland Pharmacy Laws and Regulations*. HO §12-403(b)(10)(ii)

#### 6. PRESCRIPTION LABELING, FILES, AND STORAGE

Yes No

- Hard copy prescription files are maintained chronologically for 5 years. HO §12-403(b)(13)  
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)
- 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)(ii)
- 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 technician initials are on prescriptions. COMAR 10.34.08.01
- Original prescriptions are dispensed within 120 days after the issue date. HO §12-503

## 7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS

Yes No

- There are written procedures 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
- 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 role and responsibility of pharmacy staff in preventing medication errors. COMAR 10.34.26.03B

## 8. CONFIDENTIALTY

Yes No

- Confidentiality is maintained in the creating, storing, accessing, disposal and disclosure of patient records. HO §12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations
- 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

## 9. INVENTORY CONTROL PROCEDURES

Yes No

- The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR 10.34.24.03

OK

Yes No

- The pharmacy has written policies and procedures for the safe handling of drug recalls.  
See [www.recalls.gov](http://www.recalls.gov)
- The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)
- The pharmacy has a procedure in place for removal of all expired drugs; (both prescription and OTC) COMAR 10.34.12.01

## 10. CONTROLLED SUBSTANCES

Yes No

- A perpetual inventory is maintained for Schedule II controlled substances. (*recommended*)
- The pharmacy has a copy of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B  
Inventory date: 5-8-09
- Inventory completed at Opening or Closing of business date: 5-8-09
- The inventories and records of Schedule II-V drugs are maintained and readily available.  
COMAR 10.19.03.05 and 21 CFR 1304.03
- 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
- The prescription label for controlled drugs include the following warning: "CAUTION: *Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed*", in 6-point type or the Pharmacy utilizes an auxiliary label that contains this warning. COMAR 10.19.03.08D(1)
- 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)
- All controlled substances prescriptions bear the name and address of the prescriber and patient.  
COMAR 10.19.03.07D(1)
- 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)

## 11. AUTOMATED MEDICATION SYSTEMS Yes No (if No, go to #12)

Yes No

- 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 10.34.28.05

Yes No

- Control of access to the device.
- Accounting for medication added and removed from the system.

Yes No

- 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 maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes No

- Maintenance records.
- System failure reports.
- Accuracy audits.
- Quality Assurance Reports.
- Reports on system access and changes in access.
- Training records.

Yes No

- Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, forms and 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
- 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

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

Yes No

- The facility outsources the preparation or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
- The facility serves as a secondary pharmacy. COMAR 10.34.04.02
- Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- 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

Yes No

- 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
- 
- 
- 

- 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:

- The original prescription order is filed as a prescription order at the primary pharmacy.  
COMAR 10.34.04.06D

The pharmacist from the primary pharmacy documents in a readily retrievable and identifiable manner (Check all that apply): COMAR 10.34.04.06

Yes No

- The prescription order was prepared by a secondary pharmacy.
- The name of the secondary pharmacy.
- The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
- The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
- The date on which the prescription was transmitted to the secondary pharmacy.
- The date on which the medication was sent to the primary pharmacy.

Yes No

- The primary and secondary pharmacies are both licensed in the State of Maryland, or 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 secondary pharmacy maintains documentation in a readily retrievable and identifiable manner, which includes (check all that apply): COMAR 10.34.04.07

Yes No

- Records of the prescription orders transmitted from another pharmacy.
- The name and information identifying the specific location of the primary pharmacy.
- The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.

# CONTROLLED DANGEROUS SUBSATNCES WORKSHEET

## Perpetual Scheduled II Audit

Rx # \_\_\_\_\_

<u>Drug</u>	<u>Actual Count</u>	<u>Perpetual Inventory</u>
1.		
2.		
3.		
4.		

Comments: \_\_\_\_\_  
\_\_\_\_\_

## Biennial Schedule II Audit

Drug \_\_\_\_\_  
Inventory \_\_\_\_\_  
Purchases \_\_\_\_\_  
Total Available \_\_\_\_\_  
Dispensed \_\_\_\_\_  
Expected Inventory \_\_\_\_\_  
Actual Inventory \_\_\_\_\_  
Discrepancy \_\_\_\_\_

## Inspection Comments

### Schedule II Invoice Review

\_\_\_\_\_  
\_\_\_\_\_

### Schedule III - V Invoice Review

\_\_\_\_\_  
\_\_\_\_\_

Schedule II Prescription Review # \_\_\_\_\_ - # \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

Schedule III - V Prescription Review # \_\_\_\_\_ - # \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_





STATE OF MARYLAND

DHMH

MARYLAND BOARD OF PHARMACY  
4201 Patterson Avenue • Baltimore, Maryland 21215-2299  
Donald Taylor, Board President - LaVerne G. Naesaa, Executive Director

SINU <sup>W</sup>  
PHARMACY  
306 PEISTERSTOWN ROAD • PIKEVILLE MD 21208



NO: 35273

(410) 486-7468

EL 3/3/10 # 5, 7, 9.  
New CII Audit

Department of Health and Mental Hygiene  
Martin O'Malley, Governor - Anthony G. Brown, Lt. Governor - John M. Colmers, Secretary

two many Exp. items.

3.0  
extended 2-23-10

EXHIBIT

\$ 5, 7, 9.  
CII. & Exp. it.  
make a copy  
to Colin + Disc  
at D. C. mee

COMMUNITY PHARMACY INSPECTION FORM

Corporate Pharmacy Name Sinu Rx  
Pharmacy Name-Doing Business as (d/b/a) or Trade Name \_\_\_\_\_  
Street Address 306 Peisterstown Rd. Pikesville, MD 21208  
Business Telephone Number 410-486-7468 Business Fax Number \_\_\_\_\_  
Inspection Date: 2-23-10 Arrival Time 1:15pm Departure Time 6:40pm  
Type of Inspection: Annual Follow-up Previous Date: \_\_\_\_\_  
Name of Inspector: Jeanette McKnight CPhT

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: Mon-Fri 8:30am-7:30pm Sat. Closed Sun. 10am-3pm
- All permits, licenses, and registrations are posted conspicuously.  
HO § 12-311, HO § 12-408(b) and HO § 12-6B-08

Maryland Pharmacy Permit Number P04471 Expiration Date: 12-31-11  
 CDS Registration Number 462476 Expiration Date: 6-30-10  
 DEA Registration Number B57969188 Expiration Date: 2-24-12

- The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19
- The pharmacy provides services to Long Term Care facilities or assisted living facilities. (If yes, complete Long Term Care Inspection Form) COMAR 10.34.23

Yes No

- The pharmacy fills original prescriptions received via the internet.
- The pharmacy fills original prescriptions via e-prescribing.
- 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: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws  
Mehran Behnamfard

Pharmacist Employees	License #	Exp Date
<u>Mehran Behnamfard</u>	<u>#16278</u>	<u>6-30-10</u>

(Attach list if necessary)

Registered Technicians	Registration #	Exp Date
<u>No Technicians</u>		

(Attached list if necessary)

Unlicensed Personnel (non-registered)	Title	Duties

(Attach list if necessary)

3. PERSONNEL TRAINING No Technicians

Yes No

- 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
- 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(5) and (4)

Yes No

- Maintaining records
- Patient confidentiality
- Sanitation, hygiene, infection control
- Biohazard precautions
- Patient safety and medication errors COMAR 10.34.26.03

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

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)
- 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)

Comments: \_\_\_\_\_

### 5. PHYSICAL REQUIREMENTS AND EQUIPMENT

Yes No

- Pharmacy area is clean and orderly. HO § 12-403(b) (11) (ii)2.
- 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
- The pharmacy has hot and cold running water.
- The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
- The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP COMAR 10.34.07.01B

Temperature 35°F

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

Temperature \_\_\_\_\_

- If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.

Temperature \_\_\_\_\_

- 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)
- The pharmacy has online resources. HO § 12-403(b)(15)

Comments: There should be no food in the medication refrigerator.

**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)
- 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)(ii)
- 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
- Original prescriptions are dispensed within 120 days after the issue date. HO § 12-503

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**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
- 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
- There is an ongoing quality assurance program that documents the competency and accuracy of all assigned tasks. COMAR 10.34.21.03E

Comments: The pharmacy has no technicians.  
\_\_\_\_\_  
\_\_\_\_\_

**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
- 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: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**9. INVENTORY CONTROL PROCEDURES**

Yes No

- 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 (both prescription and OTC). COMAR 10.34.12.01

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**10. CONTROLLED SUBSTANCES**

Power of Attorney Mehran Bahmanfard

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: 5-8-17  
- Biennial Inventory completed at Opening or Closing (circle one)
- The inventories and records of Schedule II-V drugs are maintained and readily available. COMAR 10.19.03.05 and 21 CFR 1304.03
- 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
- There are written policies and records for return of CII, CIII-V.
- Hard copy or electronic prescription files are maintained chronologically for 5 years.
- 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)
- All controlled substances prescriptions bear the name and address of the prescriber and patient. COMAR 10.19.03.07D (1)
- 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: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

11. AUTOMATED MEDICATION SYSTEMS Yes  No  (if No, go to #12 )

Yes No

- 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

- Operation of the system  
 Training of personnel using the system  
 Operations during system downtime  
 Control of access to the device  
 Accounting for medication added and removed from the system.
- 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 maintained for at least two years addressing the following (check all that apply). COMAR 10.34.28.11

Yes No

- Maintenance records.  
 System failure reports.  
 Accuracy audits.  
 Quality Assurance Reports.  
 Reports on system access and changes in access.  
 Training records.
- 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
- 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: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

Yes No

- The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
- The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
- The facility serves as a secondary pharmacy. COMAR 10.34.04.02
- 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:

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- 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:

- The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
- Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
- 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

- That the prescription order was prepared by a secondary pharmacy.
- The name of the secondary pharmacy.
- The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
- The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
- The date on which the prescription order was transmitted to the secondary pharmacy.
- The date on which the medication was sent to the primary pharmacy.

Yes No

- The primary and secondary pharmacies are both licensed in the State of Maryland, or 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

# CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Perpetual Schedule II Audit

Rx # \_\_\_\_\_

	<u>Drug</u>	<u>Actual Count</u>	<u>Perpetual Inventory</u>
1.			
2.			
3.			
4.			

Comments:

---



---

Biennial Schedule II Audit

Biennial  
5-8-09

Drug Fentanyl 50mcg Patch

Inventory 5  
Purchases \_\_\_\_\_  
Total Available 0  
Dispensed \_\_\_\_\_  
Expected Inventory \_\_\_\_\_  
Actual Inventory \_\_\_\_\_  
Discrepancy \_\_\_\_\_

Inspection Comments

Schedule II Invoice Review

Please be sure to attach original invoices

---

Schedule III - V Invoice Review

OK

---

Schedule II Prescription Review # 33186 - # 34497

See Comments

---

Schedule III - V Prescription Review # 34900 - # 34999

OK

---

Drug name/ strength	Quantity	Lot #	Expiration	Comment
Quinapril 20mg	1	HH9763	3-09	
Quinapril 10mg	1	HK0281	11-08	
Piroxicam 20mg	1	3P1251	7-09	
Ethacrynic Acid 25mg	1	76558	8-09	
Kitoprotein 75mg	1	28063	9-09	
Amlodipine Benazepril 10mg/20mg	1	A60030	5-09	
Flecainide 50mg	1	756696A	5-09	
Synthroid 75mcg	1	60212A813	02-09	
Zocor 40mg	1	F1218	10-09	
Folex 10	1	B6H7015	8-09	
Fluvoxamine 25mg	1	1P1951	11-08	
Cyclosporin 30mg	1	78790A1	9-09	
Lisinopril 5mg	1	LP0507027	8-09	
Vitamin 500mg	1	ML061392	10-09	
Levothyroxine 0.05mg	1	008,0611A1	12-09	
Alprazolam 2.5mg	1	223571	6-09	
Antelkikel Naproxen 500mg Sumatriptan 25mg	1	3007399038	8-09	
Levothyroxine 75mcg	1	3003199	2-10	short dated
Risperidone 1mg	1	X6511A	5-09	
Valproic Acid 250mg	1	724485	9-09	
Primidone 50mg	1	2007459360	11-09	

Drug name/ strength	Quantity	Lot #	Expiration	Comment
Glipizide 5mg	1	4KPC33A	4-1-09	
Loxastatin 20mg	1		9-09	
Alomida 0.1% ophth	1	134342F	10-09	
Pred Mild 5ml	1	47749	11-09	
Sulfacetamide 10% 15ml	1	057701	4-09	
Lercetyl 100mg	1	47563	1-09	
Carbidopa/ levodopa 5mg/20mg	1		10-09	
Klaritin 7.5mg	1	M64614	8-09	
Etochloric 50mg	1	100471	1-10	
Sertroline 100mg	1	I0709135	8-09	
Levofloxacin 150mg	1	3001696	10-09	
Desipramine 100mg	1	169040	6-09	
Lisinopril 10mg	1	3700733	4-09	
Hydrocodone 5mg-325mg	1	H112807	10-09	
Tizanidine 20mg	1	351758	11-09	
Sumatriptan 25mg	1	20420	1-10	
Levamisole 2.5mg	1	281024A	1-10	
Cimetidine 400mg	1	HP4875	1-10	
Fludrocortisone 0.1mg	1	8110711	1-10	
Methoprolol 5mg	1	057642A	9-09	
Hydrocodone 20mg	1	7040101	3-09	
Hydrocortisone 0.1mg	1	701017	7-09	



Drug name/ strength	Quantity	Lot #	Expiration	Comment
Remicidol 50mg	1	353027724	1-10	
Topamax 250mg	1	8CG254	1-10	
Levitra 10mg	1	54010CH	12-09	
Risperdal 0.25mg	1	8DC376	2-10	Short dated
Risperdal 0.25mg	1	8CG309	2-10	Short dated
Levofloxacin 500mg	1		2-10	Short dated
Risperdal 2mg	1		2-10	Short dated
Levitra 2.5mg	1	54015HG	2-10	Short dated
Estradiol 1.5mg	1		2-10	Short dated
Detrol LP 4mg	1	CC80918	2-10	Short dated
Bromjost PDX	1	09817	9-09	
Metoclopramide 5mg/5ml	1	7H39	8-09	
Ceron-DM	1		2-10	Short dated
Allen Tan Respiratoric Sup	1	011JP	7-09	
Ranitidine 150mg	1		12-09	
Amoxicillin 500mg	1	0134	12-09	
Calcitriol 2.5 DAC	2	L034JL7A	7-09	
Cheratussin DAC	1	L074AL8A	2-10	Short dated

Inspectors Comments:

- ⑦ Please fax written policies that inform patients of the procedure to follow when reporting a suspected medication error. Send Attn: Jeannelle McKnight CPT in the next 7 days. (410) 358-4512 (P)
- ⑩ Please fax written policy for return of C II - IV drugs to my office Attn: Jeannelle McKnight CPT in the next 7 days.
- ③ Please remove food items from the medication refrigerator. Pharmacist was able to get the original signed prescription for Rx# 34686. Pharmacy has purchased supplies to do blister packs for either long term care or assisted living. Pharmacist says they are not currently using blister packs.

Dr. Caplan, Steven 410-601-8383

~~XXXXXXXXXXXX~~  
VYVANSE 50MG CAP (SHIRE) #30

TAKE 1 CAPSULE IN THE MORNING

REFILLS

MR Exp Date Feb 2011  
Date Filled 02/23/10

Inspector Signature Jeannelle McKnight CPT

Pharmacist Name: \_\_\_\_\_ Date: 3-23-10  
(Print)

Signature: \_\_\_\_\_

FINAL 02/27/08

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

- That the prescription order was transmitted from another pharmacy.
- The name and information identifying the specific location of the primary pharmacy.
- The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
- The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
- The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
- The date on which the prescription order was received at the secondary pharmacy.
- 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:

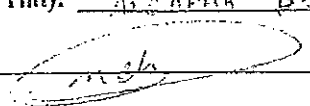
Yes No

- A perpetual inventory is maintained for Schedule II controlled substances.
- There are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
- The pharmacy has written policies and procedures for the safe handling of drug recalls. See [www.recalls.gov](http://www.recalls.gov)
- The pharmacy maintains records of all recalls. See [www.recalls.gov](http://www.recalls.gov)

Inspectors Comments:

(6) All CII invoices should be signed, dated, and attached to DEA 222 form.  
See attached list for expired drugs.  
Removed 2 bottles with no lot number and expiration.  
Rx's #33473, #34246, #33468, #33407, #33272, #32938 have the DEA # AJ4147357. Several prescriptions already have the doctor's correct DEA listed but it's not used. Rx# 34358 has the doctor as Precious Morrison-Ross and the DEA # BL9364275 was used but the correct DEA # MP1381312 is stamped on the front of the prescription.  
1 bottle of boxed CD with no signature from the doctor. In order to do complete audit (CE) from the pharmacist you will have to go back to original date. Also, you will have to go back to original date to get reports from distributor to make all CII purchases back to original date.

Comments continued on next sheet.

Inspector Signature Jeanette M. Knight CPhT  
Pharmacist Name ((Print)): ASHAN Behan Sr Date: 2-23-10  
Signature: 

INSPECTION FORM REVIEWER'S NOTES

Corporate Pharmacy Name Sinu Rx

Pharmacy Name-Doing Business As (d/b/a) or Trade Name \_\_\_\_\_

Inspection Date: 2/23/10 Maryland Pharmacy Permit Number P04471

1) Need to be discussed at Disciplinary Committee meeting ASAP.

2) Make a copy to Colin Everedley

Reviewer initials EL

Date: 3/3/10