IN THE MATTER OF	*	**BEFORE THE**
MEDICINE SHOPPE, #634	*	**STATE BOARD**
Permit No.: P01909	*	**OF PHARMACY**
Respondent-Pharmacy	*	

* * * * * * * * * * * * *

ORDER FOR SUMMARY SUSPENSION

Pursuant to Md. State Govt. Code Ann. §10-226 (c)(2004 Repl. Vol. and 2007 Supp.), the State Board of Pharmacy (the "Board") hereby suspends the permit to operate as a pharmacy in Maryland issued to the Medicine Shoppe #634, (the "Respondent-Pharmacy) (under the Maryland Pharmacy Act (the "Act"), Md. Health Occ. Code Ann. § 12-101, et seq., (2005 Repl. Vol. and 2007 Supp.). This Order is based on the following investigative findings, which the Board has reason to believe are true:

BACKGROUND

1. At all times relevant hereto, the Respondent-Pharmacy was permitted to operate as a pharmacy in Maryland. The Respondent-Pharmacy was first issued a permit on September 11, 1997. The Respondent-Pharmacy's permit expires on December 31, 2008.

2. At all times relevant hereto, Pamela Arrey owned the Respondent-Pharmacy located in the 5900 block of Reisterstown Road, in Baltimore City, Maryland.

3. On February 1, 2002, the Board issued an unexecuted Summary Suspension Order and on September 15, 2002, the Board issued charges against the Respondent-Pharmacy. On November 22, 2002, the Respondent-Pharmacy signed a

Consent Order based upon the following Findings of Fact found in the Summary Suspension and Charges:

A. On June 22, 2001, Jack Freedman and Cathy Putz of the Division of Drug Control (D.D.C.), and Ms. Andoll, Pharmacist Compliance Officer, arrived at the Respondent-Pharmacy at 10:00 a.m., the posted opening time. At approximately 10:15 am. they observed a person unlocking the pharmacy door and entering the premises, who later identified herself as Bertha Mbuh, a technician. Ms. Mbuh stated that a pharmacist was on the way and contacted someone by telephone. Ms. Mbuh stated that she would dispense a prescription which had been checked by the pharmacist when the pharmacist was not on duty, but would not take new prescriptions by telephone.

B. When Ms. Arrey arrived at 10:30 a.m., she stated that she had been delayed due to having to stop at the Liberty Medicine Shoppe that morning to deal with computer problems. However, Inspector Friedman was at the Liberty Medicine Shoppe that morning and only pharmacist Adekoya was there. The Respondent was not there when the pharmacy opened. In addition, there was no evidence of computer problems at that location that morning.

C. The inspectors found the Respondent-Pharmacy to be in disarray, with the dispensing counter dirty and disorganized. Drinks were kept in the refrigerator used for drugs. Purchasing invoices for Schedules

III and IV were not being signed consistently. Some contained a signature Ms. Arrey later identified to be that of Ms. Arrey's 7-year old daughter. There were also incomplete DEA 222 forms, as well as faxed prescriptions for Schedule IIs without corresponding hard copies. In addition, there were discrepancies for OxyContin tablets, which differed from that claimed in the May 16, 2001 inventory. Ms. Arrey failed to timely deliver a biennial audit to the Board, as promised.

D. On January 4, 2002, at approximately 2 p.m., Ms. Putz returned to the Respondent-Pharmacy to follow up on the problems identified in June 2001. When Ms. Putz arrived, two unlicensed individuals, Ms. Mbuh and Adolph Schwartz, were in the Respondent-Pharmacy and customers were in store. Ms. Putz was informed that Ms. Arrey had been in the Respondent-Pharmacy, but had to leave. Thereupon, Ms. Putz instructed Ms. Mbuh and Mr. Schwartz to close the Respondent-Pharmacy. Mr. Schwartz locked the Respondent-Pharmacy and they waited outside until pharmacist Enwezor arrived from the Liberty Road store.

E. Due to the Board's concerns about adequate pharmacist coverage for all Ms. Arrey's pharmacies, the Board requested that Ms. Arrey supply to the Board an accounting of the licensed pharmacists who worked at each of her three pharmacies, including the Respondent-

Pharmacy, and the hours that they worked at each store, for October, November and December, 2001. Ms. Arrey belatedly supplied schedules, purporting to show that the Respondent-Pharmacy was, in fact, staffed by Maryland licensed pharmacists during that time period. Based upon interviews with the pharmacists, discrepancies were disclosed between Ms. Arrey's list and the actual work schedules of the pharmacists.

F. Ms. Arrey submitted false documentation claiming that pharmacists were on duty when, in fact, none was on duty at the Respondent-Pharmacy, as claimed on several occasions from June 2001 through January 14, 2002.

G. During the aforecited times and dates, at the Respondent-Pharmacy, several unlicensed persons were either opening or closing the Respondent-Pharmacy, or were alone in the Respondent-Pharmacy without a licensed pharmacist on the premises.

H. As set forth in the regulations governing the operation of a pharmacy in Maryland, only licensed pharmacists may have access, e.g., the keys or security code, to the pharmacy area.

I. In addition, Ms. Arrey allowed her minor daughter to sign for pharmaceutical supplies--something which only a licensed pharmacist should do.

J. At the above Respondent-Pharmacy, serious discrepancies were

disclosed by the D.D.C. personnel on more than one occasion, including the dispensing of drugs by fax without a hard copy; a technician's dispensing prescriptions; and, unaccounted for Schedule IIs.

4. As a result of the above Findings, the Respondent-Pharmacy's permit was Suspended, and that suspension was Stayed: and, it was further Ordered that the Respondent-Pharmacy be placed on Probation for one year, with the following conditions:

A. The Respondent-Pharmacy shall submit to random inspections by the DDC on a quarterly basis;

B. The Respondent-Pharmacy shall pay a fine to the Board of Fifteen Hundred Dollars ($1500).

CURRENT INVESTIGATION

5. On July 21, 2008, an inspection of the Respondent-Pharmacy was performed by Ann Taylor, Pharmacist Compliance Officer, and Jeanelle McKnight, Pharmacy Inspector.

A. During the inspection, Ms. Taylor noted that the pharmacy was filled with many large capacity boxes and delivery totes which blocked the rear exit of the pharmacy. These boxes were taped and shrink-wrapped;

B. The staff informed the inspectors that they did not know why the boxes and totes were stored in the pharmacy. The staff contacted Ms.

Arrey by telephone to have her explain why the boxes were stored in the Respondent-Pharmacy. She explained that the boxes were in the Respondent-Pharmacy as storage, and when the in-store supply was expended, she would use the items in the boxes to restock the store. The boxes were labeled with names of sundry items (i.e., plates, knives); food items (i.e., Hershey Hot Cocoa); and, medications. None of the items was currently on the shelves in the pharmacy. Eight boxes were opened and examined to identify the contents. The contents of the boxes matched the labeling on the exterior of the boxes;

C. There were two delivery totes labeled with drug names:

(1) In Tote #1, the contents were as follows:

(a) 18 bottles of Amoxicillin Oral Suspension 250mg/5ml-150ml with the manufacturer's lot # 5K08084; manufacturer's expiration dates were removed;

(b) Seven bottles of Amoxicillin Oral Suspension 250mg/5ml-80ml with the manufacturer's lot # 5G01500; manufacturer's expiration dates were removed;

(c) 17 bottles of Amoxicillin Oral Suspension 250mg/5ml-150ml with the manufacturer's lot # 5G04874; manufacturer's expiration dates were removed;

(2) In Tote #2, the contents were as follows: 66 bottles of Amoxicillin with Clavulanate Potassium Oral Suspension 200mg/5ml-100ml, manufacturer's expiration date and lot

numbers were removed. [1]

D. In light of the recent impoundment by the DDC of similar misbranded medications at Ms. Arrey's Liberty Shoppe, the totes were sealed as follows: Tote #1 - green seal serial number 1429871 and, Tote #2 - green seal serial number 1429861. Seals were provided by staff at the Respondent-Pharmacy. They were asked not to break the seals or remove the containers from the Respondent-Pharmacy;

E. A memo was sent to the DDC to inform it of the occurrence and the location of the misbranded medications;

F. The staff on duty (pharmacist and technician) were unable to provide signed and dated records of receipts of controlled substances entered into the Respondent-Pharmacy's inventory;

G. The Schedule II invoices and DEA 222 forms were incomplete and unsigned;

H. The prescriptions for controlled substances did not contain the Federal caution labels. Several of the CDS prescriptions did not bear prescriber's DEA number;

I. The staff were unable to produce a current inventory of the quantity of Fentanyl 50mcg/hr, Duragesic 25mcg/hr, Hydromorphone 4mg; Morphine Sulfate IR 15mg; Oxycodone with Acetaminophen 7.5mg/500mg. A return request for expired medications for these

1 Amoxicillin Oral Suspension and Amoxicillin with Clavulanate Potassium Oral Suspension are antibiotic

medications was identified, however, no total inventory quantity could be provided;

J. A review of the CDS revealed the following discrepancies: shortage of 100 of methadone, 10 mg, unaccounted for, and, shortage of 102 morphine sulfate 30 mg, unaccounted for.

K. The inspector observed that the pharmacist on duty, Tamer Fandy, allowed the pharmacy technician to have unsupervised access to the safe that contained the controlled dangerous substances;

L. There were no policies and procedures to specify duties that may be performed by ancillary personnel under the supervision of a licensed pharmacist, as required. Nor did the Respondent-Pharmacy have documentation for training for all unlicensed personnel who performed tasks in the Respondent-Pharmacy, as required by law;

M. The Respondent-Pharmacy's pharmacy area was not neat, clean and organized, and lacked the current edition of the Act and regulations thereunder;

N. The required cautionary statements or auxiliary labels were missing, in non-compliance with the Act;

O. The expiration date was not indicated in some instances and the original prescriptions were dispensed more than 120 days after the issue date;

---

medications typically used to treat infections in children.

P. There were no written procedures to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care provider, as required;

Q. The Respondent-Pharmacy failed to maintain a minimum of two 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 and regarding the role and responsibility of the pharmacy staff in preventing medication errors;

R. The Respondent-Pharmacy failed to maintain invoices as required by law for accurate control and accountability of all pharmaceuticals;

S. The Respondent-Pharmacy lacked written policies and procedures for the safe handling of drug recalls; nor did it maintain records of all recalls;

T. The Respondent-Pharmacy failed to keep records of all receipts of controlled substances entered into the pharmacy inventory, as required;

U. The prescription label for controlled drugs failed to 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 an auxiliary label that contains this

warning, as required;

V. All controlled substances prescriptions failed to bear the name and address of the prescriber and patient, as required;

W. The Respondent-Pharmacy failed to have written policies and procedures for investigating discrepancies and reporting of theft or loss, as required;

X. The Respondent-Pharmacy failed to ensure that all Schedules III-V invoices were signed and dated or that Schedule II invoices and DEA 222 forms were completed;

Y. Prescription #6025281 for Albuterol Inhaler appeared to have been altered in the date area;

Z. Prescription # 4002613 had no original form, but only a faxed copy with no DEA # for the prescriber; there were also no DEA numbers for 16 more prescriptions;

AA. Staff at the Respondent-Pharmacy were unable to produce current inventory numbers/quantities for Fentanyl 50 mg; Duragesis 25 mg; Hydromorphial 4 mg; Morphine Sulfate; Oxycodone with Acetaminophen 7.5/500 mg;

BB. In addition, there were no expiration dates on 18 bottles of Amoxicillin Oral Suspension ("Susp."). 250 mg/5ml-150 ml; seven bottles of Amoxicillin Oral Susp. 250 mg/5 ml-80 ml; 17 bottles of Amoxicillin Oral Susp. 250 mg/5 ml-150 ml; and, 66 bottles

Amoxicillin/Clavulanate Potassium Oral Susp. 200 mg/5ml-100ml—the latter of which had no lot number. These were all sealed for DDC to pick up. The expiration dates and lot numbers appear to have been removed.

6. On 8/1/08, DDC signed an impoundment Order for those drugs with removed expiration dates.

7. A follow-up consultation occurred with Matthew Rosenberg at the Food and Drug Administration (FDA). Ms. Taylor was informed that the FDA had taken samples of the medication in the bulk barrels impounded from the Liberty Road pharmacy and was performing chemical assays to determine the chemicals/ drugs in each of the tablet samples.

8. The DDC also reported that the dumpsters connected to the building where the Respondent-Pharmacy is located were emptied and the FDA found other misbranded medication consistent with that found in the store.

9. Mr. Rosenberg reported that a search warrant was executed on August 6, 2008 for the Respondent-Pharmacy, as well as for the Respondent's home and the Liberty Road pharmacy, where similar expired and relabeled medications were retrieved.

10. Ms. Arrey was subsequently arrested and charged with altering labels of drugs, removing the expiration dates from the labels of drugs, and placing the labels on stock bottles of drugs that did not match the NDC numbers on the bulk drums, in violation of Federal law.

FINDINGS OF FACT

1. As set forth above, the Respondent-Pharmacy's possession of hundreds of expired, re-labeled and/or misbranded drugs, and its failure to adhere to policies to protect the public safety and the safety of its employees, is a threat to the public health, safety or welfare.

2. The above actions also constitute violations of the Act. Specifically, the Respondent-Pharmacy violated the following provisions of § 12–403:

(b) Except as otherwise provided in this section, a pharmacy for which a pharmacy permit has been issued under this title:

(1) Shall be operated in compliance with the law and with the rules and regulations of the Board;

(2) Shall be located and equipped so that the pharmacy may be operated without endangering the public health or safety;

(7) May not offer pharmaceutical services under any term or condition that tends to interfere with or impair the free and complete exercise of professional pharmaceutical judgment or skill;

(9) May not participate in any activity that is a ground for Board action against a licensed pharmacist under § 12-313 or a registered pharmacy technician under § 12-6B-09 of this title;

(10) (i) Shall maintain at all times a current reference library that is appropriate to meet the needs of:

1. The practice specialty of that pharmacy; and
2. The consumers the pharmacy serves; and

(ii) Shall comply with any regulations adopted by the Board establishing the types of texts required to be included in the reference libraries in each of the various practice specialty pharmacies;

(11) (i) Shall maintain at all times the minimum professional and technical equipment and sanitary appliances that are necessary in a pharmacy:

1. To prepare and dispense prescriptions properly; and
2. To otherwise operate a pharmacy; and

(ii) Shall:

2. Be kept in a clean and orderly manner;

(12) Shall store all prescription or nonprescription drugs or devices properly and safely subject to the rules and regulations adopted by the Board;

The Respondent-Pharmacy is also in violation of §812-409 of the Act:

(a) Subject to the hearing provisions of § 12-411 of this subtitle, the Board may suspend or revoke any pharmacy permit, if the pharmacy:

(1) Is conducted so as to endanger the public health or safety;

(2) Violates any of the standards specified in § 12-403 of this subtitle; or

(3) Otherwise is not conducted in accordance with the law.

The Respondent-Pharmacy also violated12-313:

(b) Subject to the hearing provisions of § 12-315 of this subtitle, the Board, on the affirmative vote of a majority of its members then serving, may deny a permit to any applicant, reprimand any permit, place any permit on probation, or suspend or revoke a permit if the applicant or permit:

(2) Fraudulently or deceptively uses a permit;

(7) Willfully makes or files a false report or record as part of practicing pharmacy;

(8) Willfully fails to file or record any report that is required by law;

(15) Dispenses any drug, device, or diagnostic for which a prescription is required without a written, oral, or electronically transmitted prescription from an authorized prescriber;

(17) Violates any provision of § 12-503 of this title, which concerns the labeling requirements for prescriptions for drugs, devices, or diagnostics;

(21) Is professionally, physically, or mentally incompetent;

(25) Violates any rule or regulation adopted by the Board.

The Respondent-Pharmacy also violated §12–503 of the Act:

(a) An authorized prescriber who issues a prescription shall indicate on the prescription the date of its issuance.

(b) Unless otherwise instructed by the authorized prescriber who issues the prescription, a pharmacist may not dispense any drug or device on a prescription presented more than 120 days after the date the prescription was issued.

The Respondent-Pharmacy also violated §12–505 of the Act:

(a) Except for a drug or device dispensed to an inpatient in a hospital or related institution, each container of a drug or device dispensed shall be labeled in accordance with this section.

(b) In addition to any other information required by law, the label shall include:

(1) The date the prescription is filled; and

(2) Unless otherwise required by the prescriber:

(i) An expiration date of the drugs or devices which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drugs or devices expire;
3. The appropriate expiration date for repackaged drugs or devices; or
4. A shorter period as determined by the pharmacist;

(ii) Any appropriate special handling instructions regarding proper storage of the drugs or devices; and

(iii) Subject to the provisions of subsection (c) of this section, the name and strength of the drugs or devices.

(c) (1) Except as provided in paragraph (2) of this subsection, the label shall indicate the same name for the drug or device as that used by the authorized prescriber.

(2) If, under § 12-504 of this subtitle, the pharmacist substitutes a drug or device product for that named by the authorized prescriber, the label shall indicate both the name of the drug or device product and the name of the manufacturer or distributor of the drug or device dispensed.

(d) (1) Except as provided in this subsection, if an authorized prescriber dispenses a drug or device, the prescriber shall label each container of the drug or device.

(2) In addition to any other information required by law, the authorized prescriber shall include on the label:

(i) The name and strength of the drug or device;

(ii) The date the prescription is dispensed;

(iii) An expiration date of the drug or device which shall be the lesser of:

1. 1 year from the date of dispensing;
2. The month and year when the drug or device expires; or
3. A shorter period as determined by the authorized prescriber; and

(iv) Any appropriate special handling instructions regarding proper storage of the drug or device.

(3) The labeling requirements of this subsection do not apply if the authorized prescriber dispenses the drug or device:

(i) To an inpatient in a hospital or related institution;

(ii) In an emergency situation; or

(iii) As a sample drug or device dispensed in the regular course of the authorized prescriber's operate as a.

(e) So long as any of the original contents remain in the container, a person may not alter, deface, or remove any label required by this section.

The Respondent-Pharmacy further violated the Pharmacists Code of Conduct, Code Md. Regs. tit. 10. § 34.10 (July 12, 1999):

.01 Patient Safety and Welfare.

A. A pharmacist shall:

(1) Abide by all federal and State laws relating to the operation as a pharmacy and the dispensing, distribution, storage, and labeling of drugs and devices, including but not limited to:

(a) United States Code, Title 21,

(b) Health-General Article, Titles 21 and 22, Annotated Code of Maryland,

(c) Health Occupations Article, Title 12, Annotated Code of Maryland,

(d) Criminal Law Article, Title 5, Annotated Code of Maryland, and

(e) COMAR 10.19.03;

(2) Verify the accuracy of the prescription before dispensing the drug or device if the pharmacist has reason to believe that the prescription contains an error; and

(3) Maintain proper sanitation, hygiene, biohazard precautions, and infection control when performing tasks in the prescription process.

B. A pharmacist may not:

(1) Engage in conduct which departs from the standard of care ordinarily exercised by a pharmacist;

(2) Operate as a pharmacy under circumstances or conditions which prevent the proper exercise of professional judgment; or

(3) Engage in unprofessional conduct.

CONCLUSIONS OF LAW

Based on the foregoing, the Board finds that the public health, safety or welfare imperatively requires emergency action, pursuant to Md. St. Gov't. Code Ann. §10-226(c)(2) (2004 Repl. Vol.).

ORDER

Based on the foregoing, it is therefore this 21 day of **August 2008**, by a majority vote of a quorum of the State Board of Pharmacy, by authority granted by the Board by Md. St. Govt. Code Ann. §10-226(c) (2) (2004 Repl. Vol.), the permit held by the Respondent to operate as a pharmacy in Maryland, Permit No. 11345, is hereby SUMMARILY **SUSPENDED;** and be it further

ORDERED, that upon the Board's receipt of a written request from the Respondent-Pharmacy, a Show Cause Hearing shall be scheduled within thirty days of said request, at which the Respondent-Pharmacy will be given an opportunity to be heard as to whether the Summary Suspension should be continued, regarding the Respondent-Pharmacy's fitness to operate as a pharmacy and the danger to the public; and be it further

ORDERED, that the Respondent-Pharmacy shall immediately turn over to the Board its wall certificate and wallet-sized permit to operate as a pharmacy issued by the Board; and be it further

ORDERED, that this document constitutes a final Order of the Board and is therefore a public document for purposes of public disclosure, as required by Md. State Gov't Code Ann. §10-617(h) (2004 Repl. Vol.).

LaVerne G. Naesea, Executive Director
Board of Pharmacy

NOTICE OF HEARING

A Show Cause hearing to determine whether the Summary Suspension shall be continued will be held before the Board at 4201 Patterson Avenue, Baltimore, 21215 following a written request by the Respondent for same.