

MA Board of Registration in Pharmacy
Inspection Summary

Pharmacy Name/Address

J.E. Pierce Apothecary, Inc. of 1180 Beacon Street, Brookline, MA 02146 (Pharmacy Reg. No. 1297)

Manager of Record/Owner

Stephen L. Grossman (PH 18342-Issued 1981)

Date of Inspection

May 19, 2009

In the Matters of

J. E. Pierce Apothecary, Inc. (Reg. No. 1297) Complaint Docket No. PHA-2009-0075
Stephen L. Grossman, R.Ph. (Reg. No. 18342) Complaint Docket No. PHA-2009-0076

Manager of Record/Owner: Stephen L. Grossman (PH 18342-Issued 1981)

History

Stephen L. Grossman, R.Ph. began operations at this location after a transfer of ownership on January 24, 1986. The Pharmacy reportedly averages 1,000 prescriptions a week, 200 of which are compounded. Pharmacy hours of operation are Monday through Friday 8 AM to 6 PM, Saturday from 10 AM to 4 PM and closed on Sunday.

May 19, 2009 Inspection

An inspection of J.E. Pierce Apothecary, Inc. (Steven L. Grossman, R.Ph., Owner and Manager of Record), a retail pharmacy with compounding specialty located at 1180 Beacon Street in Brookline, resulted in an agreement with Owner/MOR Grossman to close the Pharmacy, related to the unsanitary conditions and numerous violations of state and federal pharmacy laws and regulations observed during the inspection which were deemed to present an immediate and serious risk to the public health and safety. Patients were transitioned for continuation of care at area pharmacies.

The Board's swift action in this matter was necessary to protect the public health and safety. The violations and conditions observed during the inspection include, but are not limited to:

- a. Registrant failed to conduct a compliant biennial controlled substance inventory, in violation of 21 CFR 1304.11(c); M.G.L. c. 94C, s. 15 and 247 CMR 9.01(1);
- b. Registrant failed to maintain Pharmacy records and conduct inventories in compliance with federal and state laws, including the Board Regulations (247 CMR), in violation of 21 CFR 1304.01; M.G.L. c. 94C, s. 15; and 247 CMR 9.01(1), 9.01(2) and 9.01(14);

- c. Registrant failed to conduct Pharmacy operations in a clean and sanitary manner, in violation of 247 CMR 6.02(1) and 9.01(1);
- d. Registrant failed to provide the proper preservation and storage of prescription drug products, in violation of 247 CMR 9.01(1) and 9.01(5);
- e. Registrant failed to conduct Pharmacy operations in an area that: (1) facilitated proper preparation and compounding of prescribed medications; and (2) provided for an arrangement and storage of drugs calculated to prevent accidental misuse, in violation of 247 CMR 6.01(5)(b);
- f. Registrant failed to comply with United States Pharmacopoeia Compounding Standard 795, in violation of 247 CMR 9.01(3);
- g. Registrant failed to provide for a designated consultation area, with signage stating "Patient Consultation Area", designed to provide adequate privacy for confidential visual and auditory patient counseling, in violation of 247 CMR 6.01(5)(d)1.;
- h. Registrant failed to provide for adequate security requirements, in violation of 247 CMR 6.02(6);
- i. Registrant failed to provide adequate procedures for insuring all medications are accurately labeled and that for any medications for dispensing, the medications include an accurate beyond use date and lot number; in violation of 21 CFR § 352;
- j. Registrant failed to ensure that pharmacy interns wore appropriate name tags, in violation of 247 CMR 8.01(11); and
- k. Registrant failed to maintain adequate written description of the duties delegated to Pharmacy Interns as well as related scopes of responsibility, in violation of 247 CMR 8.06(1).

The entire pharmacy area was noted by Mr. Grossman to be 301 square feet including the compounding area.

Investigators noted the designated workable floor space in the compounding area was approximately 5 feet by 6 feet and was staffed with two other pharmacists and three pharmacy interns (students) operating on the premises. Numerous sanitary and cross contamination issues were noted as well as inappropriately labeled and dated materials. The arrangement and storage of pharmaceutical chemicals, medicinal and compounding material did not facilitate the proper preparation and compounding of drugs. The equipment and counter tops used to compound were not clean and had evidence of multiple powders and chemicals on the surfaces.

As required by U.S.P Standards and Board regulations, pharmacies engaging in compounding require appropriate, designated space for the orderly compounding of prescriptions. This area should be in good repair, clean to avoid multiple allergens, and clean to avoid cross-contaminations.

The bulk compounding supplies were observed to be stored haphazardly throughout the compounding area and on the floor. Mr. Grossman stated that he had staff remove compounding chemicals from the large bulk containers that were on the floor and place them into smaller containers for easier use when compounding. These re-packaged

containers were observed to be inappropriately labeled and the manufacturer's lot and expiration dates were not documented related to this transfer.

Investigators observed that the bulk storage area was not maintained in a clean and sanitary manner. Bulk chemicals must be stored in properly labeled containers, in a clean, dry and temperature controlled area.

There was no evidence to suggest that equipment, compounding area surfaces and floors were inspected, maintained or cleaned to avoid cross-contamination.

Stock compounds were observed to be improperly labeled, past expiration date, and stored inappropriately. The labels should bear at minimum the unique lot number assigned to a batch, the ingredient names, amounts, strengths, quantity, expiration dates, and identity of the compounder and verification pharmacist. The stock compounds should be stored in a clean, controlled manner to avoid errors or misuse.

The refrigerator was observed to be filled beyond reasonable capacity and the compounded materials were observed to be mislabeled, improperly labeled, past expiration date, and stored under unsanitary conditions. There are multiple instances of improper labeling of the compounded stock inventory in the refrigerator. The labels should bear at minimum the unique lot number assigned to a batch, the ingredient names, amounts, strengths, quantity, expiration dates, and identity of the compounder and verification pharmacist.

Of significant concern was the lack of ventilation in the compounding area as well as the pharmacy area. The use of hormones (e.g. progesterone, estrogen) and other potentially dangerous powders and substances (e.g. phosphoric acid solution, polyethylene glycol) requires proper ventilation at all times.

Warning labels on containers of progesterone included "Reproductive Hazard, Avoid Breathing Dust, Avoid Contact with Skin, and Use with Adequate Ventilation". Warning labels on polyethylene glycol containers caution against exposure and that polyethylene glycol dust may be explosive, keep away from heat source, and store in well-ventilated area. The polyethylene glycol was stored in the compounding area where a hot plate for compounding was in use.

The pharmacy staff in direct contact with the compounding area was provided with face masks. The face masks were observed to be hanging on a hook in the compounding area with staff names on them indicating that they are re-used. The pharmacy staff did not have protective apparel such as coats, aprons, gowns or arm coverings. There was no available eye wash or safety station to handle a chemical contact emergency at the pharmacy.

Of significance is that the pharmacy staff is exposed to air-borne particles due to lack of sufficient ventilation and compounding systems during their work shifts. Of concern is that a pregnant staff member was observed working in this environment.

The only sink in the pharmacy is in the compounding area. Staff states that it has intermittent hot water and that when hot water is obtained the sink must be plugged to save the hot water for cleaning. The sink also contained a sponge (source of cross-contamination), coffee cups and dishes. A fully functioning sink is necessary for hand washing, cleaning instruments, and avoiding cross-contamination of products. The sink should be used exclusively for the compounding of prescription medications.

Compounding logs and recipes were observed by investigators as not being checked at every step by a pharmacist and in some instances, and as reported by staff, was not signed by a pharmacist prior to dispensing. The compounding was being conducted by the pharmacy interns (students). Formal compounding policies and procedures were not available at the time of inspection as required by U.S.P Standards and Board regulations.

Investigators reviewed the condition of the compounding area, lack of written policy, lack of a quality related event incident reporting system and overall condition of the compounding area and pharmacy with Mr. Grossman. He stated that he should be doing more to maintain a proper pharmacy area.

Due to safety concerns for the public, as well as safety concerns for the pharmacy staff, a Cease and Desist Compounding Notice/Quarantine Order of Compounding Substances was issued. An orderly transition of patient care was authorized to another licensed independent pharmacy.

An inspection of the prescription filling area also showed an abundance of inappropriately labeled prescriptions on shelves, impassable aisles due to debris, and inappropriate work space allocated for the proper dispensing of prescriptions. Investigators observed that prescription work flow areas were not organized to facilitate the safe and proper dispensing of prescriptions.

The pharmacy controlled substance deliveries from wholesalers did not fit in the pharmacy and were observed to be left in the one aisle in the front store. The location of the delivery totes provided complete access of the controlled substances to the public. The pharmacy staff was observed to open the totes and put inventory on the pharmacy shelf. This left an open tote in the public area along with the rest of the order. Mr. Grossman stated that the wholesaler deliveries would not fit in the controlled substance area of the pharmacy.

Investigators also observed that completed prescriptions for delivery to patients were stored in the public aisle of the store. The completed prescriptions remained in the public aisle until picked by a delivery driver.

Investigators reviewed the Schedule II Inventory Log with Mr. Grossman. The review identified that perpetual inventories were not being conducted. The receipt of Schedule II Controlled Substances was also not reconciled with DEA 222 Order Forms consistently.

Mr. Grossman stated that he thought he had a system in place to conduct perpetual inventories appropriately but that he had not followed up with his staff. Mr. Grossman stated that as manager of record that the perpetual inventory was his responsibility to maintain.

An audit of Oxycontin 10 mg tablets was conducted. The Schedule II inventory log stated that 209 tablets were in stock. Actual count revealed 108 tablets in stock. An audit of Methadone 5 mg showed a shortage of 304 tablets. Mr. Grossman states that the staff does not enter into the log as transactions occur but rather enter the prescriptions numbers and transactions at a later date as time permits.

The DEA 222 Order Forms (wholesale drug purchase documents) were observed to be placed throughout the pharmacy in a haphazard manner and were not stored appropriately. Investigators were not able to determine if all DEA 222 Order Forms were accounted for. DEA 222 Order Forms were observed to be incomplete and not reconciled with the inventory log.

A completed Biennial Inventory was not available at the time of inspection. Mr. Grossman states that one was conducted and would produce it at a later time.

The pharmacy does not have a designated counseling area or designated counseling signage as required by Board regulation.

As a result of the multiple violations of state and federal statutes and regulations pertaining to the practice of pharmacy, Mr. Grossman voluntarily closed the pharmacy at the close of business on the day of the inspection (5/19/09) and transitioned the non-compounding prescriptions to another independent pharmacy and other area pharmacies of patient designation.

Related complaints PHA 2009-0075 and PHA 2009-0076 were opened.

The Board reviewed the inspection findings at its meeting on Tuesday, June 2, 2009 and determined that the Pharmacy should not re-open and that the pharmacist license of Steven Grossman should be subject to disciplinary action. The Board proposed that Owner/MOR Grossman's pharmacist license would appropriately be suspended for a minimum one year followed by probationary terms and conditions. The Board notified Mr. Grossman and his counsel of the Board's determinations on June 3, 2009 and requested the surrender of the pharmacy license; with a response to the proposed settlement to be provided to the Board by close of business on Monday June 8, 2009. Mr. Grossman, through counsel, requested that the timeline for effecting settlement of the pending matters be extended to June 19, 2009 and has provided the Board with assurances that the Pharmacy will remain closed while the matters are pending before the Board.