

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: WESTBURY PHARMACY
Permit No. : 0201-002508

NOTICE OF HEARING

Pursuant to § 2.2-4020, § 2.2-4021, § 54.1-110, and § 54.1-2400(11) of the Code of Virginia (1950), as amended ("Code"), Westbury Pharmacy, Richmond, Virginia ("Westbury"), is hereby given notice that a formal administrative hearing will be held in the presence of a panel of the Board of Pharmacy ("Board"). The hearing will be held on May 29, 2015, at 9:00 a.m., at the offices of the Department of Health Professions, Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, Virginia, at which time Westbury will be afforded the opportunity to be heard in person or by counsel.

At the hearing, Westbury has the following rights, among others: the right to representation by counsel; the right to have witnesses subpoenaed and to present witnesses on its behalf; the right to present documentary evidence; and the right to cross-examine adverse witnesses. If Westbury Pharmacy desires any witnesses to appear on its behalf, it must notify the Director of the Administrative Proceedings Division, 9960 Mayland Drive, Suite 300, Richmond, Virginia 23233, in accordance with the Instructions for Requesting Subpoenas.

The purpose of the hearing is to receive and act upon evidence that Westbury may have violated certain laws and regulations governing its permit to conduct a pharmacy in Virginia, as more fully set forth in the Statement of Particulars below.

STATEMENT OF PARTICULARS

The Board alleges that unannounced inspections of Westbury on May 21 and 29, 2014, and on February 3 and 5, 2015, and a drug audit on May 29, 2014, disclosed the following deficiencies:

1. Westbury may have violated § 54.1-3316(2) and (7) of the Code and 18 VAC 110-20-25(6) of the Regulations Governing the Practice of Pharmacy ("Regulations"), in that it failed to take the necessary steps to prevent the diversion of controlled substances. More specifically, as the result of two audits,

between May 2012 and on or about July 29, 2014, it was discovered that the pharmacy lost 25,804 tablets of oxycodone 30mg (Schedule II); 21,901 tablets of oxycodone/APAP 10/325mg (Schedule II); 1,962 tablets of oxycodone/APAP 7.5/325mg (Schedule II); 561 tablets of methadone 10mg (Schedule II); 60mg of fentanyl citrate powder (Schedule II); and 261 tablets of hydrocodone/APAP 5/325 (Schedule III) due to theft by an employee.

2. Westbury may have violated § 54.1-3316(1), (2), (7), and (13) of the Code and 18 VAC 110-20-25(6) and 18 VAC 110-20-200(B) of the Regulations Governing the Practice of Pharmacy (“Regulations”) in that the Schedule II drugs were not securely stored. The drugs could be removed from the storage cabinet when it was locked.

3. Westbury may have violated § 54.1-3316(1), (7), and (13) of the Code and 18 VAC 110-20-190(B) of the Regulations in that:

a. The access code to the alarm system and the key to the code were posted on the alarm control panel in full view of all employees.

b. Between on or about January 26, 2015, and on or about February 3, 2015, a pharmacy clerk and a pharmacy technician deactivated the pharmacy alarm on multiple occasions, and five unlicensed individuals had access to the pharmacy department when a pharmacist was not present.

4. Westbury may have violated § 54.1-3316(1) and (7) of the Code and 18 VAC 110-20-240(A)(1) of the Regulations in that the perpetual inventory was not being maintained as required. The Pharmacist-in-Charge was aware that the computer system was not keeping accurate records of the inventories between June 2012 and May 2014 and he simply adjusted the totals listed in the computer system to account for any discrepancies between the theoretical and physical counts. This deficiency was noted previously in an inspection summary dated November 30, 2012.

5. Westbury may have violated § 54.1-3316(7) and § 54.1-3410.2(E) and (I)(4) of the Code and 18 VAC 110-20-321 of the Regulations in that:

a. Between January 6, and February 11, 2014, a pharmacy technician performed high-risk compounding on 24 occasions before passing his initial media-fill testing.

b. A pharmacist and pharmacy technician performing high-risk compounding had not completed their semi-annual media-fill testing or gloved finger tip testing as required by the United States Pharmacopeia–National Formulary (“USP-NF”) within the required time period.

6. Westbury may have violated § 54.1-3316(7) and § 54.1-3410.2(D), (E) and (I)(1) and (2) of the Code and 18 VAC 110-20-321 of the Regulations in that between on or about May 22, 2012, and on or about July 31, 2014, multiple sterile and non-sterile compounding records for single patient, single prescription and batch compounded products were not initialed by a pharmacist.

7. Westbury may have violated § 54.1-3316(7) and § 54.1-3410.2(E) of the Code and 18 VAC 110-20-321 of the Regulations in that between on or about January 1, 2014 and on or about August 14, 2014, sterile products containing tacrolimus (Schedule VI), a hazardous drug, were compounded in the same hood as non-hazardous drugs.

8. Westbury may have violated § 54.1-3316(7) of the Code and 18 VAC 110-20-140(A) of the Regulations in that remodeling applications were not filed with the Board when the following changes were made:

a. The security system was changed in January 2013.

b. The following structural changes were made to the prescription department after August 2014:

i. A new door was installed to the entrance of the prescription department from the warehouse storage area;

ii. Two new doors were installed with badge access scanners to the rear left and front right side of the prescription department;

iii. The locking glass doors that protected the Schedule II drugs were replaced with glass doors at the ends of the Schedule II aisles. The doors could only be opened by badge scanner access. The tops of the Schedule II bays were enclosed with wire and a 360 degree video surveillance system was installed.

9. Westbury may have violated § 54.1-3316(7) of the Code and 18 VAC 110-20-200(B) and (C) of the Regulations in that prescriptions requiring refrigeration or freezing were stored in an area accessible to the public.

10. Westbury may have violated § 54.1-3316(7) of the Code and 18 VAC 110-20-200(C) of the Regulations in that controlled paraphernalia, flu vaccines, a vial of clonidine (Schedule VI) injectable, and a tube of lidocaine-prilocaine (Schedule VI) ointment were stored in areas outside of the previously approved drug storage area.

11. Westbury may have violated § 54.1-3316(7) and § 54.1-2521(A), (B) and (C) of the Code and 18 VAC 76-20-40(A), (B), (D) and (E) of the Regulations in that between on or about May 20, 2012 and on or about July 8, 2014, incorrect and incomplete data was sent to the Prescription Monitoring Program, including failure to list a drug, listing an incorrect practitioner, and failure to name a drug product for compounded agents.

12. Westbury may have violated § 54.1-3316(7) and § 54.1-3404(B) of the Code in that the biennial inventory for Schedule III through V drugs that the pharmacy reported was taken on May 20, 2012, could not be located.

13. Westbury may have violated § 54.1-3316(1) and (7) of the Code and 18 VAC 110-20-200(D) of the Regulations in that over one hundred seventy-one (171) expired drugs were in the pharmacy mixed in with the drug stock.

14. Westbury may have violated § 54.1-3316(1) and (7) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D) and 18 VAC 110-20-355(A) and (B) of the Regulations in that:

a. At least twenty-one (21) bottles of drugs were labeled as containing one type of drugs, but contained drugs from two different manufacturers.

b. At least sixty-five (65) bottles and one blister pack of drugs either were unlabeled or did not include either the drug name, an expiration date, a lot number, or a quantity. Three of the bottles contained multiple types of tablets, and four bottles contained more drugs than listed on the label.

c. At least one hundred twenty-four (124) bottles of drugs, thirteen (13) of them Schedule II drugs, contained tablets in excess of the amount listed on the bottle label.

d. One bottle labeled as containing Afeditab CR (nifedipine, Schedule VI) 60mg contained tablets from three different manufacturers. Further, one of the tablets was amitriptyline (Schedule VI).

15. Westbury may have violated § 54.1-3316(1) and (7) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D) and 18 VAC 110-20-355(D) of the Regulations in that drugs returned by patients or their relatives after those drugs had left the pharmacy premises as well as drugs that were returned before they left the pharmacy were placed back in stock drug bottles on the shelf.

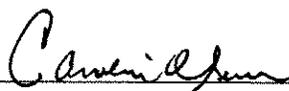
16. Westbury may have violated § 54.1-3316(1) and (7), § 54.1-3410.2(B) and § 54.1-3457(1) of the Code and 18 VAC 110-20-200(D), 18 VAC 110-20-321 and 18 VAC 110-20-355(A) and (B) of the Regulations in that, during the inspection conducted on February 3, 2015, it was determined that forty-three (43) compounded drugs either were expired, lacked lot numbers, or had no expiration dates and no compounding records.

17. Westbury may have violated § 54.1-3316(5), (7) and (13) of the Code in that:

a. Pharmacy employees engaged in a pattern of waiving and discounting co-pays for certain individuals, primarily those who ordered compounded pain medication, and fraudulently reporting them as paid to the insurance company.

b. Pharmacy employees engaged in a pattern of charging insurance company co-pays when the patients did not pick up the medication.

FOR THE BOARD



Caroline D. Juran
Executive Director

ENTERED: April 17, 2015