April 17, 2015
For Immediate Release

Editor’s Note: Because there is a hearing scheduled May 29, 2015, the Board of Pharmacy is not at liberty to grant interviews or comment on this matter.

VIRGINIA BOARD OF PHARMACY SUSPENDS WESTBURY PHARMACY PERMIT
Customers advised on how to refill prescriptions

RICHMOND--The Virginia Board of Pharmacy (BOP) today summarily suspended the pharmacy permit of Westbury Pharmacy, at 8903 Three Chopt Road, Richmond, Virginia, effective immediately.

This action was taken after evidence was presented by the Office of Attorney General Mark Herring.

The Board’s Order of Summary Suspension and Notice of Hearing are posted to the Department of Health Professions website (www.dhp.virginia.gov), under license lookup. The BOP Order and Notice are attached.

In unannounced inspections conducted in May, 2014, February 2015, and a drug audit in May, 2014, state inspectors observed significant deficiencies that raised concerns about the pharmacy’s ability to assure the quality, sterility, integrity, safety and efficacy of drugs dispensed, along with its ability to safeguard against the diversion of drugs.

These deficiencies included issues with drug storage and security which may have contributed to a loss of over 50,000 tablets of controlled substances; medications in the pharmacy’s drug stock that were expired or mislabeled; medications that were unlabeled or without expiration dates; bottles containing medications from two different manufacturers; and bottles with pills in excess of the amount listed on the label.

Additional deficiencies included compounding of sterile products in violation of United States Pharmacopeia standards, and fraudulent billing activities.

BOP is scheduled to conduct a formal hearing May 29, 2015 for further deliberation of these matters.

Because of the immediate summary suspension of the Westbury Pharmacy permit, prescriptions will no longer be able to be filled at this facility. Existing prescriptions will be transferred to Westwood Pharmacy located at 5823 Patterson Avenue Richmond, VA, telephone (804) 288-1933, with the exception of prescriptions for hospice patients which will be transferred to Rx3 located at 12230 Ironbridge Road, Suite C, Chester, VA, telephone (804) 717-5000. Patients who are not enrolled in a hospice program should contact Westwood Pharmacy at (804) 288-
1933 to refill existing prescriptions or to request transfer of their prescription to a pharmacy of their choice. Patients enrolled in a hospice program should contact their hospice provider or Rx 3 at (804) 717-5000 to refill existing prescriptions or to request transfer of their prescription to a pharmacy of their choice.

While the Virginia Board of Pharmacy is not aware of any adverse events associated with drugs recently dispensed by Westbury Pharmacy, it recommends that patients consult with a prescriber or pharmacist with any concerns about medications obtained at Westbury Pharmacy.

Westbury Pharmacy was the subject of a previous disciplinary order entered by the Board in February 2014.

The Virginia Board of Pharmacy regulates the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of drugs and devices.

BOP is one of 13 health regulatory boards in the Commonwealth that together compose the Department of Health Professions (DHP), that work to ensure safe and competent patient care by licensing health professionals, enforcing standards of practice, and providing information to health care practitioners and the public.

Complaints about possible violations of Department of Health Professions’ laws and regulations or issues with patient care may be made by calling 804/367-4691, or online at http://www.dhp.virginia.gov/Enforcement/complaints.htm

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BEFORE THE BOARD OF PHARMACY

IN RE: WESTBURY PHARMACY
Permit No: 0201-002508

ORDER OF SUMMARY SUSPENSION

Pursuant to § 54.1-2408.1(A) of the Code of Virginia (1950), as amended (“Code”), a quorum of the Board of Pharmacy ("Board") met by telephone conference call on April 16, 2015, after a good faith effort to convene a regular meeting of the Board had failed. The purpose of the meeting was to receive and act upon evidence indicating that Westbury Pharmacy may have violated certain laws and regulations governing the conduct of a pharmacy in the Commonwealth of Virginia, as more fully set forth in the Statement of Particulars, which is attached hereto and incorporated by reference herein.

WHEREUPON, pursuant to its authority under § 54.1-2408.1(A) of the Code, the Board concludes that a substantial danger to public health or safety warrants this action and ORDERS that the permit of Westbury Pharmacy to conduct a pharmacy in the Commonwealth of Virginia be and hereby is SUSPENDED. It is further ORDERED that a hearing be convened forthwith to receive and act upon evidence in this case and that the Executive Director of the Board shall be authorized to execute this Order and all other documents, notices and orders on behalf of the Board necessary to bring this matter to a hearing.

Pursuant to § 54.1-2400.2 of the Code, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public inspection or copying on request.

FOR THE BOARD

[Signature]
Caroline D. Jurán
Executive Director

Entered: April 17, 2015
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 (1)(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 (l)(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

[Signature]
Caroline D. Juran
Executive Director

ENTERED: April 17, 2015