

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Tuesday, December 29, 2015
Commonwealth Conference Center
Second Floor
Board Room 3

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: The meeting was called to order at 9:05 a.m.

PRESIDING: Jodi Allen, Committee Chairperson

MEMBERS PRESENT: Cynthia Warriner

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
Anne Joseph, Deputy Executive Director, APD

University of Virginia Health System
Pharmacy – Technology Check Technician
Pharmacy System

The purpose of the informal conference was to act upon the Application of University of Virginia Health System (UVAHS) Pharmacy for approval of an innovative (pilot) program (“Application”) and waiver of compliance with certain provisions of Board of Pharmacy Regulations 18VAC110-20-490(C) (1), 18VAC110-20-460(A), 18VAC110-20-420(A)(8)(d) and 18VAC110-20-270(C). Present for the meeting from UVAHS Pharmacy were Raphael Saenz, Administrator of Pharmacy Services and Pharmacist-In-Charge, Mathew Jenkins, Pharmacy Operations Manager, Matthew Allsbrook, PGY2 Pharmacy Administration Resident.

UVAHS Pharmacy, requested a waiver of the following Board of Pharmacy Regulations so that pharmacy technicians, rather than pharmacists, may perform specific tasks:

- 18VAC110-20-270(C), which requires a pharmacist to verify accuracy of all drugs products prior to dispensing to specific patients;
- 18VAC110-20-420(A)(8)(d), which requires the initials of the pharmacist checking and certifying the contents of a drug cart in a unit dose dispensing system;
- 18VAC110-20-460(A), which requires a pharmacist to check all Schedule VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and to initial or

sign manually or electronically the record of distribution verifying the accuracy of the distribution; and

- 18VAC110-20-490(C)(1), which requires a pharmacist to check all drugs leaving the pharmacy for distribution to automated dispensing cabinets.

Mr. Saenz and Mr. Jenkins provided an overview of the future process by which the pharmacy technician will be checking the technology in place indicating that medications go through four to five independent barcode scanning events prior to being dispensed to a patient. The pharmacy also dispenses medications to approximately 20 ambulatory care units using automated dispensing cabinets. UVAHS currently does not have the technology to perform barcode scanning of medications in its ambulatory clinics at the point of administration to the patients and plans to implement this in 2017. The request is for the pharmacist to perform a 1% check for medications dispensed for cart fill from the Talyst AutoCarousel system which is used also for first doses. Additionally, request was made for a 1% pharmacist check for medications dispensed for the intent to fill and stock the automated dispensing cabinets.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for UVAHS Pharmacy. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Allen

stated the Committee shall offer a consent order that approves the innovative (pilot) program for a period of three (3) years from the date the Order is entered by the Board with the following terms and conditions that were read by Ms. Juran:

1. The requirement of 18VAC110-20-270(C), 18VAC110-20-420(A)(8)(d), 18VAC110-20-460(A), and 18VAC110-20-490(C)(1) of the Regulations shall be waived to allow pharmacy technicians to perform final verification for accuracy of all Schedule VI and over-the-counter products prior to leaving the pharmacy and to allow pharmacists to perform a daily random check of 5.0% of medications verified by pharmacy technicians. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.
2. Any technician performing such final verification shall hold current registration with the Board.
3. Pharmacists shall retain responsibility for maintaining the UVAHS Pharmacy medication barcode library.
4. This variance is allowed for inpatient settings and for ambulatory care settings in which patient barcode scanning is utilized at the final point of administration of medications. UVAHS Pharmacy shall notify the Board when barcode scanning is implemented in its ambulatory care units.
5. UVAHS Pharmacy shall comply with all other requirements of the Regulations Governing the Practice of Pharmacy.
6. At least one year after implementation of the program, UVAHS Pharmacy shall be subject to one unannounced inspection of the program and shall be responsible for the cost of said inspection.
7. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.
8. UVAHS Pharmacy shall report any significant errors or problems to the Board immediately. The Executive Director of the Board, in consultation with the Committee Chair, is authorized to review the error report and require UVAHS Pharmacy to re-institute 100% pharmacist verification of all Schedule VI and

over-the-counter medications leaving the pharmacy pending further review.

9. Any violation of this Order shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval shall be rescinded.

Virginia Oncology Associates Lake Wright
In-Office Dispensary – Remote Prescription
Approval

The purpose of the informal conference was to act upon the Application of Virginia Oncology Associates (VOA) Lake Wright In-Office Dispensary – Remote Prescription Approval for approval of an innovative (pilot) program (“Application”) and waiver of compliance with certain provisions of Board of Pharmacy Regulations 18VAC110-30-40(B)(2). Present for the meeting from VOA Lake Wright were Mickey Dozier, Clinical Manager, Torrea Harris, Pharmacy Manager, Jennifer Lee, Senior Manager Information Services, and Joel Andres, Government Relations Director from Kemper Consulting.

VOA Lake Wright, a practice of oncologists licensed to sell controlled substances, requested a waiver of 18VAC110-30-40 (B)(2) of the Regulations which require the practitioner who is licensed to sell controlled substances, prior to dispensing the controlled substance, to inspect the prescription product to verify its accuracy in all respects, and to place his initials on the record of sale as certification of the accuracy of and responsibility for the entire transaction. Ms. Dozier and Ms. Harris presented the future process for which the physicians licensed to dispense controlled substances would inspect and verify an electronic image of the prescription and drug via email.

Closed Meeting:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A (7) of the Code of Virginia, for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for VOA Lake Wright. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O’Halloran, and Anne Joseph attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

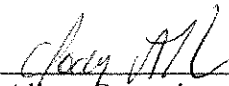
Decision:

After consideration of the application and statements concerning the innovative (pilot) program, Ms. Allen stated the Committee denied the application. The Order is entered by the Board with the following conclusions of law that were read by Ms. Joseph:


1. The selling and storage area is locked and alarmed but has no additional security measures in place to prevent and detect the diversion of controlled substances. The proposed process would allow the pharmacy technician to practice for extended periods of time within the storage and selling area without personal supervision by the practitioner during the hours of operation.
2. VOA Lake Wright presented a sample of the images that would be electronically transmitted to the prescriber for inspection and verification. The sample image does not appear to provide legible and sufficient information for safely verifying the accuracy of the drug product.
3. Based on the foregoing, the Committee concludes that the proposed waiver of the requirements of 18VAC110-30-40 (B)(2) of the Regulations for the VOA Lake Wright Remote Prescription Approval system does not adequately address the criteria enumerated in §54.1-3307.2 of the Code of Virginia.

ADJOURN:

With all business concluded, the meeting adjourned at 4:00 p.m.



Jody Allen, Committee Chairman



J. Samuel Johnson, Jr.
Deputy Executive Director

3/25/16

Date

3/25/16

Date

