FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Monday, March 23, 2015
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER: The meeting was called to order at 1:00 p.m.

PRESIDING: Empsy Munden, Committee Chairperson

MEMBERS PRESENT: Ellen B. Shinaberry

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

Pharmacy Central Distribution-
Parallon Supply Chain Solutions, HCA

The purpose of the informal conference was to act upon the Application of Parallon Supply Chain Solutions 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)(2) and 18VAC110-20-460(A). Present for the meeting from Parallon Supply Chain Solutions were Kim Biggers-Hayes – Division Director for pharmacy services, Parallon, Noel Hodges – COO, Parallon, Robin Sayles – Director of pharmacy, John Randolph Medical Center, Corey Winston – Director of Consolidated Service Center Operations, Parallon, Jennifer Scales-Hill – Director of Pharmacy, HCA Retreat, Demetrus Garrett – Pharmacy Manager, CSC Parallon, and Sherone Ruggs – Division Director of Pharmacy Operations, Parallon.

Parallon Supply Chain Solutions, which is owned by Healthcare Corporation of America (HCA), requested a waiver of 18 VAC 110-20-490 (C) that requires the delivery record of drugs placed into an automated dispensing device (ADD) in a hospital to include the initials of the pharmacist at the hospital that checked the drugs to be removed from the pharmacy and the delivery record for accuracy. Additionally, a waiver was requested of 18 VAC 110-20-460 (A) that requires a pharmacist to check all Schedule II - VI drugs prior to delivery as nursing unit floor stock, plus the requirement of initialing or signing manually, or electronically, the record of distribution verifying the accuracy of

distribution of Schedule II - IV drugs.

For the purpose of this pilot program, the Central Shared Services warehouse (permit number 0216-000033), which is owned by HCA and provides drugs via intra-company sales to HCA hospitals, intends to distribute individual quantities of Schedule VI drugs necessary to replenish specifically identified ADDs located at thirteen hospitals and three stand-alone emergency departments owned by HCA (facility). A Virginia-licensed pharmacist at the Central Shared Services warehouse will perform a 100% check of all drugs prior to the drugs being placed in a secured tote and delivered directly to facility pharmacy department. Pharmacy technicians at the facility, using barcode scanning, will directly restock the ADD with the medications that were picked, verified and secured at the warehouse. The drugs will not be checked and verified by a pharmacist at the facility to which they are delivered.

Ms. Biggers-Hayes provided an overview of the Pharmacy Central Distribution operation with assistance from Mr. Winston, Mr. Garrett, Ms. Ruggs and Mr. Hodges. They provided answers to questions the Board and staff members had with regard to the process of Pharmacy Central Distribution to facility pharmacy departments.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Shinaberry, 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 Pharmacy Central Distribution – Parallon Supply Chain Solutions. Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., and Beth O'Halloran 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. Munden 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 approval of this innovative (pilot) program is limited to Schedule VI drugs.
2. The Central Shared Services warehouse shall deliver the drugs directly to the pharmacy at each facility.
3. A pharmacist at the Central Shared Services warehouse shall verify 100% of all drugs distributed to the pharmacy at a facility to be placed into an ADD.
4. The requirement in 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from a pharmacy to be placed in an ADD to include the initials of the pharmacist checking shall be waived for those drugs received from the Central Shared Services warehouse.
5. The requirement in 18 VAC 110-20-460 (A) of the Regulations for a pharmacist to check all drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution shall be waived for the drugs received from the Central Shared Services warehouse to be placed in an ADD.
6. The Central Shared Services warehouse shall maintain a record of all drugs distributed to facilities to be placed in an ADD. The record shall include the date; drug name, dosage form, and strength; quantity; facility name, hospital unit, a unique identifier for the specific device receiving the drug; and initials of the pharmacist checking the drugs for accuracy.
7. The pharmacy at each facility shall maintain a record of the initials of the person loading the automated dispensing device.
8. All records required by this section shall be maintained at the address of the applicable warehouse or facility for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an

exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

9. Each facility receiving drugs from the Central Shared Services warehouse to be placed in an ADD shall maintain at least a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking automated dispensing devices at a facility is less than 90% for any quarter, the pharmacy at that facility shall immediately reinstitute a 100% pharmacist verification process at the receiving pharmacy until the Board approves Central Shared Services resuming the allowances within the innovative (pilot) program.
10. The assignment of the Meditech and Pyxis ID code shall be performed by a Virginia-licensed pharmacist employed by Parallon.
11. Central Shared Services shall submit to the Board a quarterly report which indicates for each facility the restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from Central Shared Services.These reports shall be submitted in March, June, September, and December.
12. The innovative (pilot) program shall be subject to two random, unannounced inspections by the Board or its designated representative within three (3) years following implementation of the program, one inspection to take place within the first twelve (12) months of implementation. Central Shared Services shall be solely responsible for the payment of an inspection fee of $150.00 each to be paid to the Board within thirty days from the date of the statement of monies owed which will be mailed following the inspection.
13. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.
14. Except as specifically waived in the Consent Order, Central Shared Services and the facilities

shall maintain compliance with all applicable federal and State laws and regulations.

15. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.

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

Empsy Munden, Committee Chairman

6-15-15
Date

J. Samuel Johnson, Jr.
Deputy Executive Director

6/15/15
Date