

DRAFT/UNAPPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE REVIEW OF INNOVATIVE
PILOT APPLICATION**

March 25, 2014
Second Floor
Board Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 10:00 AM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT: Empsy Munden

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director

RIVERSIDE REGIONAL
MEDICAL CENTER:

The purpose of the informal conference was to act upon the Application of Riverside Regional Medical Center for approval of an innovative (pilot) program ("Application") and waiver of compliance with certain provisions of Board of Pharmacy Regulation 18VAC110-20-490 C and 18VAC110-20-460 A. Rebecca Schulkowski, pharmacist-in-charge of Riverside Regional Medical Center, John Campbell, Product Leader for CardinalASSIST, and Micah Siegmund, Operations Manager for CardinalASSIST appeared in person at the informal conference.

Riverside Regional Medical Center requested a waiver of 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from the pharmacy to be placed in an automated dispensing device to include the initials of the pharmacist checking. Riverside Regional Medical Center requested that the 5% check allowance in Regulation 18VAC110-20-425 for robotic pharmacy systems also apply to medications that are refilled into an automated dispensing device when utilizing CardinalASSIST technology. Riverside Regional Medical Center is currently utilizing the CardinalASSIST replenishment technology which uses individual product barcode scanning throughout the entire process.

Mr. Campbell provided an overview of the CardinalASSIST operation and Ms. Schulkowski answered questions regarding the pharmacy operations at Riverside Regional Medical Center, in particular regarding its use of bar code technology.

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 Section 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 the use of Pharmacist 100% Check Variance for CardinalASSIST Delivery by Riverside Regional Medical Center. Additionally, she moved that Caroline D. Juran and J. Samuel Johnson, Jr. 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:

Ms. Shinaberry announced the committee's decision to accept and approve an amendment of the request within the application to remove the requirement for pharmacist verification of Schedule VI drugs received from CardinalASSIST to be placed in an automated dispensing device for a period of three (3) years from the date the Order is entered by the Board and the pharmacy informs the Board it has reached a 90% restocking bar code scanning rate. The following terms and conditions also apply and were read by Ms. Juran:

1. The requirement in 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from the pharmacy to be placed in an automated dispensing device to include the initials of the pharmacist checking shall be waived for those Schedule VI drugs received from CardinalASSIST.

2. The requirement in 18 VAC 110-20-460 A of the Regulations for a pharmacist to check all Schedule VI 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 those Schedule VI drugs received from CardinalASSIST.

3. Riverside Regional Medical Center shall maintain a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking automated dispensing devices is less than 90% for any quarter, the pharmacy shall immediately reinstitute a 100% pharmacist verification process until the Board approves Riverside Regional Medical Center resuming the allowances within the innovative (pilot) program.

4. Riverside Regional Medical Center shall maintain a closed loop system throughout the entire ordering, replenishment of automated dispensing devices, and administration process.

5. The assignment of the Med ID to the national drug code (NDC) shall be performed by a pharmacist employed by Riverside Regional Medical Center.

6. Riverside Regional Medical Center shall submit to the Board a quarterly report which indicates the restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from CardinalASSIST. The reports shall be submitted in March, June, September, and December.

7. CardinalASSIST shall deliver the drugs directly to the pharmacy.

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

9. 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.

INOVA LOUDOUN
HOSPITAL:

The purpose of the informal conference was to act upon the Application of INOVA Loudoun Hospital for approval of an innovative (pilot) program ("Application") at the emergency rooms at INOVA Loudoun's main campus and its Cornwall site with a waiver of compliance of certain provisions of Board of Pharmacy Regulation 18VAC110-20-470. Specifically, the application requested the ability for emergency department physicians to dispense drugs, repackaged by the hospital pharmacy and stored in an automated dispensing device, to discharged patients from the emergency department. The application stated the proposed program would ensure medication compliance, reduce re-admission rates, increase patient satisfaction and begin INOVA Loudoun's efforts to meet new accountable care organization standards. Cathleen Cowden, pharmacist-in-charge of INOVA Loudoun Hospital Pharmacy appeared in person at the informal conference.

During the discussion and review of the application, Ms. Cowden indicated there is a pharmacy on-site at the Loudoun Hospital that operates twenty-fours a day, 7 days a week. However, she maintained that it was not feasible for the pharmacy to dispense the drugs for emergency department patients due to the inability to properly label the drug and insufficient staffing. Additionally, Ms. Cowden indicated that Loudoun County has only one community pharmacy with 24 hours operations and that it is 7.2 miles from the main hospital in Leesburg and 13.7 miles from the off-site Cornwall emergency department in Leesburg. INOVA Loudoun will operate a retail pharmacy at its Lansdowne campus in the 2014-2015 timeframe. In addition to the 24-hour on-site pharmacy, Ms. Shinaberry noted that the information provided by Ms. Cowden indicates the main campus in Loudoun issues 55% of the emergency department prescriptions issued by the INOVA Loudoun Hospitals and that this location is only 7.2 miles from the 24-hour community pharmacy.

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 Section 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 the use of Profiled Dispensing of Medications from the Emergency Room by INOVA Loudoun Hospital. Additionally, she moved that Caroline D. Juran and J. Samuel Johnson, Jr. 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:

Ms. Shinaberry announced the committee's decision to deny the application to allow physicians to dispense from the emergency departments because pharmaceutical services are otherwise available and the request did not appear to justify the waiving of regulation and possible statutory provisions.

ADJOURN: With all business concluded, the meeting adjourned at 2:45PM.

Ellen Shinaberry, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

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