

FINAL/APPROVED

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

May 6, 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 9:00 AM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT: Jody Allen

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

BLUE RIDGE PACE, DR.
MARK A. NEWBROUGH,
AND CAREKINESIS
PHARMACY:

The purpose of the informal conference was to act upon the Application of Dr. Mark A. Newbrough and CareKinesis Pharmacy for approval of an innovative (pilot) program ("Application") at the Blue Ridge PACE to operate in a manner similar to allowances in Regulation 18VAC110-20-276 wherein CareKinesis Pharmacy would provide remote order entry services for Dr. Newbrough who would be responsible for dispensing the drug product at the PACE facility. Dr. Newbrough, Medical Director, Blue Ridge PACE; Edward D. Rickert, Partner, Quarles & Brady, LLP; Cynthia Williams, RPh, System Director of Pharmacy, Riverside Health System; Michael Greenhalgh, RPh, Chief Operating Officer, CareKinesis; and, Sara T. Baughn, Director of Business Development, CareKinesis appeared in person at the informal conference. Requested waivers included: a waiver from the requirement that dispensing physicians are required to inspect the prescription product to verify its accuracy in all respects and a waiver from the requirement in 18VAC110-20-276 that a "pharmacy" can outsource prescription processing functions, to allow a dispensing practitioner to outsource those functions.

Mr. Greenhalgh provided an overview of the remote order entry process offered by CareKinesis and the dispensing cabinet to be located at the PACE facility which will select, label, and dispense the prescribed medication. The drug product would be dispensed pursuant to a practitioner of the healing arts to sell controlled substances license to be obtained Dr. Newbrough.

CLOSED MEETING: Upon a motion by Ms. Allen 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 Blue Ridge PACE Collaborative Prescription Medication Dispensing System by Dr. Newbrough and CareKinesis. 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:

Ms. Shinaberry announced the committee's decision to approve the innovative (pilot) program for a period of one (1) year contingent upon receipt of a policy and procedure manual consistent with Regulation 18VAC110-20-276 which identifies the roles and responsibilities of CareKinesis and Dr. Newbrough, implementation of the referenced dispensing cabinet, and the issuance of a practitioner of the healing arts to sell controlled substances license to Dr. Newbrough. The following terms and conditions also apply and were read by Ms. Juran:

1. All counseling provided to patients shall be provided by a pharmacist affiliated with CareKinesis or by Dr. Newbrough.
2. CareKinesis and Dr. Newbrough shall comply with all laws and regulations associated with licensure as a nonresident pharmacy and practitioner of the healing arts to sell controlled substances, respectively.
3. The innovative (pilot) program shall be subject to one unannounced inspection at the address of the Blue Ridge PACE program.
4. The dispensing cabinet shall be approved by the Board for the stocking and dispensing of drugs as outlined in the application, however, Dr. Newbrough shall be responsible for visibly verifying the accuracy of the drug in its entirety or the drug product, consistent with the policy and procedure manual.
5. Dr. Newbrough shall be responsible for ensuring quarterly reports are submitted to the Board. Information in the reports shall contain the number of drugs dispensed by Dr. Newbrough, any errors associated with the innovative (pilot) program, name and quantity of drugs dispensed.
6. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.
7. Any additional physicians intending to dispense drugs pursuant to this innovative (pilot) program shall first obtain a practitioner of the healing arts to sell controlled substances license.
8. Errors associated with the innovative (pilot) program shall be immediately reported to the Board.
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.

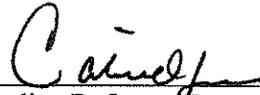
ADJOURN:

The meeting adjourned at 12:35PM.



Ellen Shinaberry, Committee Chairman

6/4/14
Date



Caroline D. Juran, Executive Director

6/4/14
Date