(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Monday, June 26, 2017
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 2:00 p.m.

PRESIDING: Rafael Saenz, Committee Chairperson

MEMBERS PRESENT: Melvin Boone, Sr.

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Mykl D. Egan, Administrative Proceedings Division
Alina Kilpatrick, Administrative Proceedings Division
Sylvia Tamayo-Suijk, Executive Assistant

Ridgeline Physician Services and InstyMeds Medication Adherence System

The purpose of the informal conference was to act upon the Application of Ridgeline Physician Services and InstyMeds Medication Adherence System 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) and 18VAC110-30-240 (B) and (C). Present for the meeting from Ridgeline Physician Services was Brad Schraut, CEO of InstyMeds Corporation, Michael Burns, pharmacist and Vice President of pharmacy services at InstyMeds Corporation, and Charity Wolfe, Director at Wellspring Family Practice.

Ridgeline Physician Services requested a waiver of 18 VAC 110-30-40 (B) (2) that requires the visual inspection of the dispensed product before being delivered to the patient. Additionally, a waiver was requested of 18 VAC 110-30-240 (B) and (C) since all drugs dispensed will be sold in special packaging.

Mr. Schraut provided a background on the InstyMeds Medication Adherance System and the patient adherence model used by InstyMeds. An update to the program is a report that physicians may run to identify which patients did not fill the orders the physicians had given them and allow for a follow up call to determine why the patient has not filled the prescription. Mr. Schraut

and Mr. Burns reviewed the security of the dispensing machine which includes biometrics and alarm codes for the machine itself as well as the alarm for the office building.

Closed Meeting:

Upon a motion by Mr. Boone, and duly seconded by Mr. Saenz, 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 Ridgeline Physician Services. Additionally, he moved that Caroline D. Juran, J. Samuel Johnson, Jr., Beth O'Halloran, Mykl D. Egan, Alina Kilpatrick and Sylvia Tamayo-Suijk 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, Mr. Saenz 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 Mr. Egan:

1. An application shall be submitted for a practitioner of the healing arts to sell controlled substances license from each physician requesting the ability to dispense drugs to his own patients.
2. An application for a limited-use facility permit for Ridgeline Physician Services shall be submitted, designating one physician responsible for the drug stock, required inventories, the records of receipt and destruction, safeguards against diversion and compliance with laws and regulations.
3. Dispensing device shall have a monitored alarm within the device, separate from the facility alarm, with the alarm code restricted to the

dispensing physicians that will notify the monitoring entity and appropriate law enforcement in the event of a breach. The device shall require both a biometric as well as code access and be limited to the physician licensed to dispensed.

4. Access to the code or key for opening and loading the device shall be restricted to only times when a dispensing license is on-site and shall only be given to a registered pharmacy technician, nurse or physician assistant with training in compliance with 18 VAC 110-30-40 of the Regulations
5. A visual inspection to verify accuracy of the final dispensed drug prior to delivery as performed in the process of verifying the accuracy of the dispensed drug in its entirety as required in 18 VAC 110-30-40 of the Regulations will be waived, as well as certain provisions of 18 VAC 110-30-240 (B) and (C) of the Regulation, based on the presented information regarding the device's automation and bar-code technology and provided all drugs are dispensed in special packaging.
6. Drugs delivered for loading into the device shall be immediately placed in the device upon receipt to prevent possible diversion.
7. Ridgeline Physician Services shall be subject to two random inspections by the Board or its designated representative within a three year period, the first of which shall be conducted within 12 months of the entry of the order. Ridgeline Physician Services shall be solely responsible for the payment of the inspection fee.
8. Prior to stocking Schedule II through V drugs in the device, Ridgeline Physician Services shall provide the operating procedures for security and monitoring of the drugs to the Board for review and approval
9. All drugs that must be reconstituted shall be mixed by the dispensing physician, registered pharmacy technician, nurse, or physician assistant with training in accordance with 18 VAC 110-30-40 of the Regulations and visually inspected by the dispensing physician prior to delivery.
10. All prescription errors as well as loss or theft must be immediately reported to the Board and other authorities as necessary

11. Counseling shall be provided by the licensed physician at the facility or by a Virginia licensed pharmacist.
12. The dispensing physician shall comply with all laws and regulations regarding the dispensing of controlled substances.
13. Any operational changes or modifications to the pilot program must be reported to and approved by the Board prior to implementation.

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

Rafael Saenz, Committee Chairman

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

Date