

VIRGINIA BOARD OF PHARMACY
FINAL/APPROVED MINUTES OF INFORMAL CONFERENCE COMMITTEE

Wednesday, February 9, 2011
Second Floor
Board Room #2

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A meeting of an informal conference committee of the Board of Pharmacy was called to order at 3:35pm.

PRESIDING: John O. Beckner, Committee Chairman

MEMBERS PRESENT: David C. Kozera

STAFF PRESENT: Caroline D. Juran, Executive Director
Sammy Johnson, Deputy Director, Enforcement

Anita Chatman, M.D.
License # 0101-052287

Mr. Edward D. Rickert, Esq., Krieg DeVault, Julie Geason, Vice-President of Pharmacy Services, InstyMeds, and Jennifer O'Connell, Office Manager, Dulles Urgent Care Center were present to discuss the application, received December 28, 2010, for approval of an innovative (pilot) program wherein Dulles Urgent Care Center would use an automated drug delivery system manufactured by InstyMeds Corporation to dispense acute care drugs to their own patients. Because the physician licensed to dispense would not visually inspect the drug prior to patient delivery, an allowance is necessary for waiving certain provisions of Board regulation 18VAC110-30-40.

Decision: After consideration of the application and statements concerning the innovative (pilot) program, Mr. Beckner stated that the Committee approved the innovative (pilot) program for a period of one year from the date of inspection approving the dispensing device under the auspices of a limited-use practitioner of the healing arts to sell controlled substances license, and it is contingent upon receiving additional information and upon other terms and conditions.

Required additional information for submission includes:

1. An application for a limited-use practitioner of the healing arts to sell controlled substances license from each physician, to include Anita Chatman, M.D., requesting the ability to dispense drug to his own patients and the designation of a physician assuming the responsibility for the drug stock, the required inventories, the records of receipt and destruction, safeguards against diversion and compliance with the laws and regulations. Upon a change

in the responsible licensee so designated at the location, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in §54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board.

2. An amended page 12 and 18 of the application to correct a discrepancy in the request for years of approval for the innovative (pilot) program and designation of the physician responsible for overseeing the innovative (pilot) program.

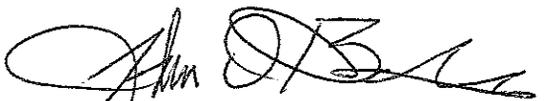
Other terms and conditions include:

1. Either the dispensing device shall be located in an area protected by a security system compliant with Regulation 18VAC110-30-120, i.e., consisting of motion detectors monitored by an outside entity that will notify appropriate law enforcement when breached with the code being restricted to dispensing physicians, or the dispensing device shall have a monitored alarm within the device with the alarm code restricted to the dispensing physicians that will notify appropriate law enforcement;
2. Access to the code or key for opening and loading the device shall be restricted to times when a dispensing licensee is on-site and shall only be given to a registered pharmacy technician, or a nurse or physician assistant with training in compliance with Regulation 18VAC110-30-40;
3. Drugs delivered for loading into the device shall be immediately placed in the device upon receipt to prevent possible diversion;
4. Dulles Urgent Care Center shall be subject to one random, unannounced inspection by the Board or its designated representative within 12 months following the implementation of the innovative (pilot) program. This inspection is independent from any routine inspection. Anita Chatman, M.D., on behalf of Dulles Urgent Care Center, shall be solely responsible for the payment of an inspection fee of \$150.00 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;
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 Board regulation 18VAC110-30-40 will be waived, as well as certain provisions of Regulation 18VAC110-30-240 B and C, based on the presented information regarding the device's automation and bar-code

- technology. Additionally, a sign shall be posted near the dispensing device informing patients that nonspecial packaging or non-safety closures are not available.
6. All drugs which must be reconstituted shall be mixed by a registered pharmacy technician, nurse or physician assistant with training in compliance with Regulation 18VAC110-30-40, or the dispensing physician prior to delivery.
 7. All prescription errors and theft or loss of any drug in Schedules II-V shall be immediately reported to the Board and other authorities as necessary.
 8. The dispensing physician is ultimately responsible for any counseling provided to the patient as required in Regulation 18VAC110-20-40.
 9. The dispensing physicians shall comply with all other laws and regulations regarding the dispensing of controlled substances.
 10. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification; and,
 11. Reports of failure to comply with the terms and conditions of the waiver as set forth 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:

With all business concluded, the meeting adjourned at approximately 5:45pm.



John O. Beckner, Chairman



Caroline D. Juran, Executive Director

Date 3-14-11