

(DRAFT/UNAPPROVED)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING**

December 16, 2009
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

CALL TO ORDER: The meeting was called to order at 9:10AM.

PRESIDING: Jennifer H. Edwards, Chairman

MEMBERS PRESENT: Gill B. Abernathy
John O. Beckner
Willie Brown
Gerard Dabney
Bobby Ison
David C. Kozera
Leo H. Ross
Michael E. Stredler
Brandon K. Yi

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Sandra Whitley Ryals, Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Sharon Davenport, Administrative Assistant
Diane Powers, Director of Communications, DHP

QUORUM: With 10 members present, a quorum was established.

APPROVAL OF AGENDA: The agenda was approved as presented and amended by the Board to add minutes of December 8, 2009 special conference committee, and to add further discussion of the inspection ticketing procedures as requested by Mr. Ison who was unable to participate in the previous Board meeting discussion.

Motion: **The Board voted to allow further discussion of the inspection ticketing procedures as an addition to the agenda. (motion by Ison, second by Ross).**

APPROVAL OF MINUTES: The Board reviewed draft minutes for September 2, 2009, September 22, 2009, October 20, 2009, November 10, 2009, November 10, 2009, December 1, 2009, and December 8, 2009. Ms. Abernathy requested that the Board strike one phrase, "concerned with the lack of oversight for medication errors and" from the September 2, 2009 minutes under "new business".

Motion:

The Board voted unanimously to make the correction to the September 2, 2009 minutes as requested by Ms. Abernathy and to adopt the minutes as presented and amended by the Board. (motion by Ross, second by Kozera)

PUBLIC HEARING

The Board held a public hearing on proposed regulations to replace emergency regulations on drug donation programs. No comments were offered on these regulations during this hearing.

PUBLIC COMMENTS:

There were no public comments given to the Board during the public comment period.

DHP DIRECTOR'S REPORT

Ms. Ryals provided the Board with the latest statistics on the agency's performance measures. The Board of Pharmacy continues to meet and exceed the measures related to licensing. In the first quarter of FY2010, the Board closed 91% of its cases within 250 business days, exceeding the performance measure of 90%. Age of pending caseload was 10% cases older than 250 days, significantly exceeding the performance measure of no more than 25%. The clearance rate for cases dropped to 63% which is under the 100% goal, which means that at the Board closes at least as many cases as received. There are a number of possible reasons for the drop, but this should be watched to ensure that another backlog is not created. Ms. Ryals thanked the Board members for all the hard work in achieving the performance goal.

Ms. Ryals informed the Board that as of October 27, the prescription monitoring program was fully operational again through the web site, and that the new 24-7 functionality had been implemented and was being used extensively.

Ms. Ryals informed the Board that the agency was getting ready to implement online applications for initial licensure, where applicants will be able to pay initial licensing fees online by credit card and submit certain data online.

REGULATION UPDATE:

Ms. Yeatts provided an update on regulations currently in process to include that the fast-track regulations on Schedule II drugs in stat boxes would become effective January 7, 2010. She also stated that the permanent regulations changing facility renewal dates would be effective December 23, 1009.

- NOIRA for automated dispensing devices in hospitals

Ms. Yeatts stated that the NOIRA comment period had closed on 11/26/2009, and that a number of comments were received on Townhall supporting the elimination of the requirement for having a nurse sign for drugs placed into ADDs. Ms. Russell asked the Chairman to appoint an ad hoc committee to draft proposed

- Action Item
 - regulations for the Board to adopt at the March 2010 meeting. Ms. Edwards appointed Bobby Ison, Gill Abernathy, Brandon Yi, and herself to the ad hoc committee. Staff will schedule a meeting prior to the March Board meeting to draft proposed regulations.
- Adoption of final regulations defining unprofessional conduct
 - The Board reviewed the comment received by NACDS during the public comment period. NACDS had requested that the Board eliminate 18 VAC 110-20-25, subsection 7 of the proposed regulations which would make the failure to appropriately respond to a known dispensing error grounds for disciplinary action by the Board. The Board discussed the request and the consensus was that the language in the regulation would not negatively impact patient safety efforts by pharmacies, but would set the standard that pharmacists have an obligation to respond to and manage dispensing errors in the manner best suited to the particular error and which will minimize patient harm.
 - Motion:** **The Board voted unanimously to deny the request by NACDS and retain the proposed language as published. (motion by Abernathy, second by Ross)**
 - Motion:** **The Board voted unanimously to adopt the regulations as proposed and published as final regulations without change. (motion by Brown, second by Beckner)**
- LEGISLATION UPDATE:
 - Ms. Yeatts stated that the annual scheduling bill would be submitted by the Department. Ms. Russell stated that she and Ms. Juran had been working with the Office of the Attorney General and the Virginia Association of Community Services Boards (VACSB) to address a number of concerns related to how the community services boards (CSBs) needed to handle dispensed patient prescriptions, particularly in light of the closing of the Community Resources Pharmacy which was the state-run central pharmacy that handled most of the prescriptions for mental health patients receiving services in the community. Ms. Russell shared a draft legislative proposal which would allow the CSBs to retain prescriptions medications on behalf of CSB patients for those patients who are not able to handle maintenance of their own medications in their residence or who may be homeless. It would also authorize some repackaging of dispensed medications for patients who need assistance with self-administration by persons who have been properly trained and requires the Board to establish training requirements for unlicensed persons who want to do this. The third thing the proposal does is allow crisis stabilization units to possess certain Schedule VI controlled substances necessary to prevent hospitalization of patients in a crisis situation that the nurse may access in the absence of a prescriber. Ms. Russell stated that this is a department bill, and the Board will not be asked to take a formal position on it at this time, but that VACSB wanted the Board to review the draft and identify any concerns that

members may have at this time. The Board reviewed the draft and had no concerns with the proposal. The draft proposal would make this emergency legislation and authorize emergency regulations meaning that the Board could possibly adopt regulations as early as March. Ms. Russell asked that a committee be appointed to begin work on draft emergency regulations as required by the proposal to be adopted by the Board in March if legislation is enacted.

• Action Item

Ms. Edwards appointed Mr. Stredler, Mr. Kozera, Mr. Ross, Mr. Beckner, and herself as an ad hoc committee to begin working on regulations and directed staff to schedule a meeting of the committee and other interested parties sometime in February to work on draft regulations.

BOARD OF HEALTH
PROFESSIONS REPORT

Ms. Edwards stated that BHP is continuing its work on emerging professions and the need for licensure. The committee studying emerging professions recommended tabling any licensure recommendation for kinesiotherapists until such time as a decision was made concerning the need for an "Allied Professions Board" to handle some of the ancillary health professions. There was a recommendation that polysomnographers be licensed under the respiratory therapy board, and that legislation be proposed to implement this. There was a general agreement by the committee reviewing the need to license surgical assistants and surgical technologists that certification was needed for those persons assuming the scrub role and second assistant and that licensure was needed for those persons acting as first assistant but there is some overlap of roles, difference in levels of autonomy and that this issue should be deferred until the February meeting when additional information about scope of practice could be reviewed. The committee recommended that community health workers be added to the 2010 emerging professions work plan.

PHARMACY CONGRESS
REPORT

Ms. Russell reported on the Virginia Pharmacy Congress. She gave a brief history of the evolution of the Congress stating that it had recently been revived to try to assist with transitioning the practice of pharmacy in light of health care reform. She stated that the Congress membership consists of the Virginia pharmacy associations and pharmacy schools with the Board of Pharmacy as a non-voting member. At the December meeting, she and Ms. Edwards represented the Board. Mr. Ross and Mr. Beckner were also present representing other associations. She stated that one discussion at the recent meeting related to how to inform pharmacists who were not involved in associations about changes that health care reform would make in the practice of pharmacy. Ms. Russell stated that Gary Matzke with VCU School of Pharmacy has written an article recently published on this subject in "The Annals of Pharmacotherapy". He offered to condense the

article into a type of executive summary if the Board would agree to include it in the next newsletter edition in an attempt to educate more pharmacists about this issue. Ms. Russell stated that the next newsletter would be published in June, but could be held until after the Board meeting to allow the Board to review the article prior to inclusion. She stated that Dr. Matzke may also need to revise somewhat based on what happens with the health care reform efforts in Congress. The Board agreed in concept that it would be a good addition to the newsletter, but that it would like the opportunity to review the article first.

FURTHER DISCUSSION OF
THE NEW INSPECTION
PROCEDURES:

Mr. Ison stated that he had the opportunity to hear from VSHP members who were very concerned about the monetary penalty amounts, the new inspection processes, and they thought that the Board should not impose a monetary penalty for any deficiencies noted on the first inspection, and then impose monetary penalties on any repeated deficiencies cited on subsequent inspections. He agreed that this should be done. He stated that VSHP members are also concerned that this is a revenue-generating venture for the Board. Ms. Russell stated that although the process of the expedited consent order was new, the Board had had monetary penalties in place for many years in guidance documents that staff had been using to assess monetary penalties via regular consent orders, and that this is not new, and the amount in the new guidance document are in line with previous guidance. She assured the Board that staff will be communicating the new process with pharmacies at least 30 days prior to implementation. Staff has already put an article in the newsletter designed to encourage pharmacies to do self inspections so that there will not be deficiencies found. Additionally, letters will be sent to those facilities inspected during the first six months of the new process to give them ample notice about the new process. All inspection forms and the monetary penalty guidance document will be on the web site. Hospitals, other than possibly an advance test inspection will not be done before the March meeting when the Board will have the opportunity to review again the USP 797 inspection form. Ms. Russell stated that this will not generate any revenue for the Board as all monetary penalties go to the literary fund, not the Board or DHP, or the general fund. She stated that staff would be happy to speak at the next VSHP meeting to outline the new processes and respond to any concerns on the part of members. She stated that test inspections with volunteer pharmacies to ensure that procedures are working well, will be conducted over the next month or so, and that for the test inspections, pharmacies will not be issued the expedited consent orders. No motion to reconsider the previous board action was made.

APPROVAL OF CONSENT
ORDER:

Motion for closed meeting:

The Board voted unanimously, to enter into closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, he moved that Cathy Reiniers-Day, Scotti Russell, Caroline Juran, and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Yi, second by Kozera)

**Motion to certify the purpose
of the closed meeting:**

The Board voted unanimously, that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting. (motion by Yi, second by Beckner)

Motion:

The Board voted unanimously to accept the consent order as presented by Ms. Reiniers-Day in the matter of Lawrence E. Stell, pharmacist. (motion by Beckner, second by Stredler)

ADJOURN:

With all business concluded, the meeting adjourned at 11:30AM.

Elizabeth Scott Russell
Executive Director

Jennifer Edwards, Board Chairman

Date