

FINAL/APPROVED (03/08/06)

VIRGINIA BOARD OF PHARMACY MINUTES OF BOARD MEETING

Thursday, December 1, 2005
Fifth Floor
Conference Room 2

Department of Health Professions
6603 West Broad Street
Richmond, Virginia 23230

- CALL TO ORDER:** A meeting of the Board of Pharmacy was called to order at 9:10 a.m.
- PRESIDING:** Leo H. Ross, Chairman
- MEMBERS PRESENT:** Gill B. Abernathy
Toni Aust
John O. Beckner
Willie Brown
Bobby Ison
David C. Kozera
Diane Langhorst
- MEMBERS ABSENT:** Michelle R. Easton
Mark A. Oley
- STAFF PRESENT:** Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Ralph Orr, Program Manager, Prescription Monitoring Program
- QUORUM:** With eight members of the Board present, a quorum was established.
- Ms. Reiniers-Day read the emergency evacuation procedure for Conference Room 2.
- APPROVAL OF AGENDA:** There was one addition to the agenda. Ms. Russell requested the addition of the adoption of a NOIRA on the collaborative practice regulations. Hearing no other changes, Mr. Ross approved the agenda with the one addition.
- PUBLIC COMMENT:** Mr. Ross called for public comment on any item not on the agenda, not related to regulations for which an official comment period has closed, and not related to disciplinary matters. He stated that comments on agenda items would be received at the time the item is being considered by the Board. No comments were received at this time.
- APPROVAL OF MINUTES:** The minutes of the September 13, 2005 Board Meeting were approved as presented.

**PUBLIC HEARING ON
WHOLESALE
DISTRIBUTOR
REGULATIONS**

The Board held a public hearing on proposed regulations for wholesale distributors, warehousemen, and manufacturers. No comments were given at this time. Mr. Ross stated that the period to accept written comments would end December 2, 2005.

**ALTERNATE DELIVERY
SITES AND ALARM
REQUIREMENT**

Ms. Russell advised the Board that current regulations require a burglar alarm system for any person who wants to obtain a controlled substance registration (“CSR”) for the purpose of being an alternate delivery site. This was highlighted in the September 13, 2005, discussion concerning the community service boards (“CSBs”). She stated that it may not be reasonable to require an alarm system for these entities because pharmacies do not even have to maintain filled prescriptions under the alarm system. Ms. Russell stated that requiring this is creating a hardship on the CSBs. Ms. Yeatts explained that if the Board wanted to amend the regulations to remove the alarm requirement for alternate delivery sites, it could use the fast-track process as there will likely not be any opposition to this. Mr. Beckner moved that the Board adopt the draft proposed regulation in the agenda packet to remove the requirement for an alarm system for alternate delivery sites. The Board voted unanimously in favor of the motion.

**PERIODIC REVIEW FOR
18VAC110-20-10, ET SEQ**

Ms. Yeatts advised the Board that it was time for another periodic review of its main regulations as the last had been done over three years ago. Mr. Brown moved to adopt the draft notice of periodic review and request for comment in the agenda package. Mr. Ross called for discussion. Ms. Abernathy stated that she had concerns that with the holidays, the comment period, 12/26/2005 through 1/25/2006, was too short and moved for an amendment to the main motion that the comment period be extended another month. The Board voted unanimously to approve the amendment. The Board then voted unanimously to approve the main motion as amended.

**UPDATE ON REGULATION
PROCESSES**

Ms. Yeatts presented the Board with an overview of all ongoing regulation processes.

**COLLABORATIVE
PRACTICE REGULATIONS**

Ms. Russell reminded the Board that it had adopted a notice of periodic review for its collaborative practice regulations at its June meeting and had appointed members to a joint committee with the Board of Medicine to review these regulations. The collaborative practice regulations are jointly adopted by both the Boards of Medicine and Pharmacy. The committee met in November and made a number of recommendations for amendments including removing the requirement that alternate practitioners and pharmacists to be signatories to an agreement, allowing for different paths for obtaining the informed consent of the patient, removing the maximum two-year expiration on an agreement, clarifying language in the approval of protocols section to decrease confusion, and adding a requirement for notification to all parties to an agreement whenever a practitioner or pharmacist

has a change in location or ownership. Ms. Yeatts explained that the next step in the process is the adoption of a NOIRA by this Board and the Board of Medicine. Ms. Abernathy moved and the Board voted unanimously to adopt the draft NOIRA to amend the collaborative practice regulations.

DISPENSING BY PHYSICIANS FROM MOBILE VANS

Ms. Russell advised the Board that it had received several applications from physicians who operated clinics from mobile vans that served the indigent or otherwise underserved population in some areas of Virginia, one in the Richmond area serving the indigent, and one in Southwest Virginia serving indigent and underserved. The physicians are applying for a license to dispense. Ms. Russell stated that they want to be able to store prescription drugs within the mobile units. A mobile unit does not meet the requirements of regulation for an approved location. Additionally, although the units have some type of alarm, it does not meet current requirements. Also, temperature requirements may not be met for proper storage of drugs. However, there is a need for these physicians to be able to dispense to this population in order to adequately treat patients. Ms. Russell stated that if the Board wanted to construe that pharmacy services were not reasonably available to this population, these physicians could obtain a permitted physician permit and then a limited-use permit could be granted with waivers of regulations. The Chair appointed a committee of Ms. Langhorst, Ms. Aust, and Mr. Kozera to work with staff in developing a guidance document concerning dispensing from mobile vans for review and approval at the next Board meeting.

ACPE REQUEST FOR COMMENT

The Board reviewed a request from ACPE to comment on its revised "ACPE Definition of Continuing Education for the Profession of Pharmacy". ACPE is looking at three components of the definition. The first is how to define CE for the profession of pharmacy. The second is to define "applicable to the practice of pharmacy." The third is to state the responsibilities of an ACPE-accredited provider. Mr. Ison asked why ACPE wanted to make changes. Ms. Juran explained that her understanding is that one reason is to distinguish the target audience for CE programs by denoting a "P" and "T", which identifies Pharmacists and Technicians as target audiences, respectively. Mr. Ison expressed concern that this may limit the opportunities for technicians to obtain CE. Ms. Juran stated she felt ACPE was attempting to provide more appropriate programs based on educational background. Becky Snead, who sits on the Joint Commission of Pharmacy Practitioners, commented that she, too, was of the opinion that ACPE would like to provide more appropriate programs based on a specific target audience. She also noted that the designating classification may limit opportunities to Virginia pharmacy technicians since the draft definition references CE offerings for certified pharmacy technicians. She reminded the

Board that Virginia law relates to registered technicians and that registered technicians may not be PTCB certified. Mr. Ison commented that he did not agree with ACPE restricting registered technicians from attending its CE programs. It was decided that Ms. Russell should send a comment to ACPE asking them to clarify their intention in using language specific to certified pharmacy technicians versus any registered pharmacy technician. Also, she should request that ACPE remove the word "certification" from its designating classification.

ALTERNATE DELIVERY SITES AND ALARM REQUIREMENT- ENFORCEMENT

The Board revisited the issue of alarm systems for alternate delivery sites with respect to requiring an alarm system on new applications for alternate delivery sites while the Board is in the process of amending its regulations to remove this requirement. Mr. Beckner moved and the Board voted unanimously that 18 VAC 110-20-275 (C) (3) should be interpreted that alternate delivery sites that meet all requirements of 18 VAC 110-20-710 with the exception of an alarm system are in substantial compliance with the regulation for the purposes of issuing a controlled substances registration.

EXECUTIVE DIRECTOR'S REPORT

Ms. Russell stated that she will try to plan for one of the Board's 2006 meetings to be a retreat. The Board had a retreat about four or five years ago with a facilitator and conducted strategic planning exercises that helped direct the Board's policy efforts for the next several years. There was some discussion as to which meeting would be the best for a retreat, and it was decided that perhaps the September meeting would be best because of the possibility of having five new Board members appointed in July.

Ms. Russell reminded Board members that they would be receiving the annual conflict of interest forms to complete and turn in by the January deadline.

Ms. Juran reported on the progress with a contract with NABP to publish a quarterly electronic newsletter, whereby Board staff will develop two pages of articles and NABP will contribute two pages of national news on a quarterly basis beginning probably February 2006. The department will provide a list of email addresses for pharmacists and pharmacy technicians from the licensing database each quarter and NABP will email a link to these persons notifying them that a new newsletter has been posted on the website with a link to the newsletter.

Mr. Orr provided an update on the status of implementing the Prescription Monitoring Program statewide. Mr. Orr stated that the department is awaiting approval from VITA to enter into a contract with a vendor who will provide data collection services from pharmacies and other dispensers, and will also provide web-based software that will handle requests for information. The

department anticipates that it will begin to collect data under the expanded program by February 2006.

Ms. Reiniers-Day gave a report regarding the Board's disciplinary caseload and stated that, as of November 30, 2005, there were 224 cases at Enforcement level, 179 at Compliance level, 38 at Board level, 38 at APD's level, eight at Informal level and one at Formal level. Additionally, for the time period November 1, 2004 to October 21, 2005, the board closed 302+ cases.

Ms. Russell announced that Toni Aust had been appointed to represent the Board of Pharmacy on the Board of Health Professions (BHP) to replace Michelle Easton who had resigned from that Board as a result of a relocation from Virginia. She stated that the minutes from the last BHP meeting were included for Board member review in the agenda package.

Ms. Russell announced that a Request for Proposals had been issued for a new contractor for the pharmacy law examination. The current contract with Experior has expired. Experior was recently purchased by Thompson Prometric. She stated that the Examination Committee members would be contacted when a date was established to review the proposals.

BOARD CALENDAR

The Board selected its 2006 meeting dates as follows:

Wednesday, March 8, 2006

Wednesday, June 7, 2006

Wednesday, September 27, 2006 (possible retreat)

Wednesday, December 13, 2006

SUMMARY SUSPENSION:

Closed session:

Mr. Beckner moved, and the Board voted unanimously, to convene a closed meeting pursuant to Section 2.2-3711.A.28 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day, Betty Revere, Caroline Juran, Howard Casway, Clay Garrett and Jane Smith attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

TERRA A. JOHNSON,
Pharmacy Technician
Registration Number:
0230-007250

William C. Garrett, Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Jane A. Smith, DHP Adjudication Specialist was also present. Elizabeth M. Revere was present as Board staff.

Reconvene:

Mr. Beckner moved, and the Board voted unanimously, that only

public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting.

Decision:

Mr. Beckner moved, and the Board voted unanimously in favor of the motion that, according to the evidence presented, the pharmacy technician practice by Terra A. Johnson poses a substantial danger to the public; and therefore, the registration of Terra A. Johnson to practice as a pharmacy technician be summarily suspended.

Mr. Beckner moved, and the Board voted unanimously in favor of the motion, that a Consent Order be offered to Ms. Johnson for the indefinite suspension of her registration.

ADJOURN:

With all business concluded, the meeting adjourned at 11:24 a.m.

Elizabeth Scott Russell
Executive Director

Leo H. Ross, Board Chair

Date