

FINAL/APPROVED
9/30/04

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

Tuesday, June 8, 2004
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:** Mark A. Szalwinski, Chairman
- MEMBERS PRESENT:** Michael J. Ayotte
John O. Beckner
Willie Brown
Michelle R. Easton
Bobby Ison
Mark A. Oley
Leo H. Ross
- MEMBERS ABSENT:** Kimberly A. Anderson
- STAFF PRESENT:** Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Ralph A. Orr, Deputy Executive Director
Elaine J. Yeatts, Senior Regulatory Analyst
Howard M. Casway, Senior Assistant Attorney General
Donna M. Lee, Administrative Assistant
- QUORUM:** With seven members of the Board present at the call to order, a quorum was established.
- APPROVAL OF AGENDA:** Mr. Ayotte moved, and the Board voted unanimously, to approve the agenda as presented with the additional agenda materials.
- Mr. Szalwinski introduced Anthony Capolino as an intern with the Attorney General's Office.
- Mr. Szalwinski informed the Board that his appointment will end June 30, 2004, and that he did not seek reappointment. He expressed his appreciation to the Board and that he has enjoyed the opportunity to serve on the Board.
- PUBLIC COMMENTS:** No public comments were received.
- APPROVAL OF MINUTES:** Mr. Szalwinski called for changes or corrections to the Minutes of April 13, 2004. Hearing no changes, the Minutes were approved as presented.

Mr. Szalwinski called for change or corrections to the Minutes of May 21, 2004 for the Regulation Committee. Hearing no changes, the Minutes were approved as presented.

Mr. Szalwinski called for changes or corrections to the Minutes of May 21, 2004 for the Subcommittee on USP Chapter 797. Hearing no changes, the Minutes were approved as presented.

**REVIEWED DRAFT
REGULATIONS TO
IMPLEMENT HB577,
DISCIPLINARY
PROCESSES:**

The Board reviewed the draft Emergency Regulations recommended by the Regulation Committee establishing the criteria for delegation of informal fact-finding proceedings needed for implementation of HB577.

Mr. Brown moved, and the Board voted unanimously, to adopt the Emergency Regulations for establishing the criteria for delegation of informal fact-finding proceedings needed for implementation of HB577, and the publication of a NOIRA to replace the Emergency Regulations (Attachment 1). The Board also recommended that staff draft a guidance document to present to the Board that will outline the processes to be used in implementing this new authority.

**REVIEWED NOIRA
COMMENTS AND
DISCUSSED
RECOMMENDATION ON
PROPOSED REGULATION
ON THE TWO YEAR TO
ONE YEAR PRN REFILL
AUTHORITY:**

The Board reviewed the comments received during the NOIRA phase concerning a regulation change from two years to one year prn refill authority. The Board of Medicine had commented opposing the change and NACDS had commented in support of the change. The Board considered both comments and determined that the change would not create significant changes in physician practice, but would significantly ease consumer confusion over refill authority. Mr. Ross moved, and the Board voted unanimously, to adopt the proposed regulation as drafted (Attachment 2).

**DISCUSSED NEED FOR
NOIRA FOR
OUTSOURCING OF DATA
ENTRY AND DUR BY
HOSPITALS AND OTHER
SETTINGS:**

Ms. Russell discussed with the Board that because of the Joint Commission requirement that medication orders in hospitals be reviewed by a pharmacist prior to administration of the medication, hospital pharmacies that are not open 24 hours a day are trying to outsource this process to pharmacists in other hospitals, contract pharmacists, and, at times, pharmacists located outside Virginia. Ms. Russell further explained that the Board has reviewed pilot applications to allow for outsourcing of data entry and DUR by hospitals and retail pharmacies, but because this need is pervasive, it needs to be addressed through regulation rather than the pilot process.

Mr. Oley moved, and the Board voted unanimously, to publish a NOIRA to begin the regulation process to address the issue of outsourcing of data entry and DUR by hospital pharmacies and pharmacies in other settings.

**REVIEWED AND
DISCUSSED POSSIBLE
CHANGES TO THE
CURRENT REGULATIONS
FOR WHOLESALE
DISTRIBUTORS:**

The Board reviewed the recommendation of the Regulation Committee concerning the need for additional regulations for wholesale distributors. Ms. Yeatts recommended that a separate set of regulations in a new chapter be established for wholesale distributors, rather than continuing to add to the general pharmacy regulations. Also, Ms. Russell recommended that a subcommittee be established to review the current regulations for needed changes as well as NABP model regulations as a starting point for drafting proposed regulations.

Mr. Beckner moved, and the Board voted unanimously, to publish a NOIRA to promulgate regulations for wholesale distributors and to appoint a subcommittee to begin work on proposed regulations. The Chair appointed Mr. Ayotte, Mr. Becker, and Ms. Easton to the subcommittee, with Mr. Ross serving as an alternate member.

**DISCUSSED THE PERIOD
REVIEW PROCESS FOR
REVISIONS OF THE
REGULATIONS FOR
PRACTITIONERS OF THE
HEALING ARTS TO SELL
CONTROLLED
SUBSTANCES:**

The Board reviewed the recommendation of the Regulation Committee to issue a notice of periodic review of regulations for chapter 18 VAC 110-30-10 due to inconsistencies with recent changes in law, pharmacy regulations and compliance with the requirement for periodic review of existing regulations. Ms. Russell advised the Board that the issue of unlicensed persons that assist physicians would need to be addressed due to the requirement for pharmacy technician registration.

Mr. Ross moved, and the Board voted unanimously, to issue a notice of periodic review of chapter 18 VAC 110-30-10.

**REVIEWED LEGISLATIVE
PROPOSAL TO UPDATE
THE DRUG CONTROL
ACT SECTIONS ON
SCHEDULING OF
CONTROLLED
SUBSTANCES TO
CONFORM TO FEDERAL
SCHEDULES:**

The Board reviewed a draft legislative proposal to update the drugs schedules primarily to conform to changes in federal regulations. Ms. Russell stated that although the Regulation Committee had discussed other methods of conforming Virginia law to federal regulations, she is not recommending a change. After some discussion with Division of Forensic Science ("DFS") chemists and a close review of the state and federal schedules, the chemists much preferred having the drugs specifically listed in state law. The primary use of this state law is by DFS personnel in identifying chemical entities for use in prosecutions. DFS prefer the state law listing as there are some errors in nomenclature in the federal schedules, as well as some deliberate discrepancies

between federal and state law. DFS believes that to attempt to incorporate federal regulations by reference will make their job much more difficult.

Mr. Ross moved, and the Board voted unanimously, to move forward with the legislative proposal to update the Drug Control Act sections on scheduling of controlled substances as drafted (Attachment 3).

Mr. Currin arrived at 10:05 a.m.

**REVIEWED LEGISLATIVE
PROPOSAL FOR
CHANGES IN THE NON-
RESIDENT PHARMACY
LAW:**

The Board discussed two draft legislative proposals related to problems with the current non-resident pharmacy law. Currently, the Board has no authority to discipline a non-resident pharmacy if a complaint has been referred to the resident state and that state initiates an investigation. There is also a problem with terminology related to "state" since not every jurisdiction where the Board may want to register a pharmacy is a state. For example, the District of Columbia is not a state.

Mr. Currin moved, and the Board voted unanimously to go forward with a legislative proposal to change the non-resident pharmacy law with the understanding that Ms. Russell and Mr. Casway will draft further clarifying language for public comment and present the draft at the September 15th Board meeting.

Mr. Currin informed the Board that June 30, 2004 will end his tenure as a Board member for the last eight years. He expressed his appreciation for being able to serve on the Board and stated that it was a great experience for him.

**REVIEWED LEGISLATIVE
PROPOSAL TO
STRENGTHEN EXISTING
CODE TO PREVENT
COUNTERFEITING:**

The Board reviewed a draft legislative proposal to deter counterfeiting of drugs by increasing the criminal penalty from a Class II misdemeanor to a Class VI felony when a person knowingly violates § 54.1-3457(15) of the Code. The Board recommended that the penalty for a violation should be amended to a Class V felony.

Mr. Brown moved, and the Board voted unanimously, to adopt the proposed legislation as amended (Attachment 4).

**REVIEWED LEGISLATIVE
PROPOSAL FOR
CHANGES TO § 54.1-
3410.2, COMPOUNDING
LAW:**

Ms. Russell stated that the Regulation Committee did discuss a legislative proposal to amend § 54.1-3410.2 pertaining to the compounding law. The original law may have had some unintended consequences and may need to be amended to take into account situations where timely administration of a compounded

medication may outweigh the risk of contamination by not complying with all the requirements. The Board may also want to consider whether a physician could supervise a pharmacy technician in the compounding of medications.

Mr. Ross moved, and the Board voted unanimously to go forward with a legislative proposal to amend the compounding law as needed and to appoint a subcommittee composed of Mr. Szalwinski, Mr. Currin and Mr. Ison to assist in drafting language.

**REVIEWED
RECOMMENDATION FOR
ENFORCEMENT OF USP-
NF CHAPTER 797
STERILE COMPOUNDING**

The Board reviewed the recommendation of the subcommittee in inspecting for compliance with USP Chapter 797. Ms. Russell stated that the subcommittee recommended that if a pharmacy doing sterile compounding does not meet the requirements of USP Chapter 797, the inspector will cite a deficiency, the pharmacy will submit within 90 days a plan to correct the deficiency and all pharmacies should be in compliance within two years from the June 2004 Board Meeting.

After discussion of the difficulty for hospitals to comply with the requirements, and an estimated cost of capital improvements between \$50,000 and \$150,000, the Board proposes amending the recommended completion date to June 30, 2007. Ms. Reiniers-Day stated that a correction should be made to the minutes of the May 21, 2004 Subcommittee on USP Chapter 797 under the topic of "Discussion of Enforcement of USP Chapter 797 Requirement". The portion of the sentence that states, "Mr. Johnson, Deputy Director of Enforcement" should read "Samuel Johnson, Deputy Director of Enforcement, "".

Mr. Ross moved, and the Board voted unanimously, to amend the minutes as stated by Ms. Reiniers-Day and that a draft guidance document be prepared for approval by the Board outlining the enforcement of USP Chapter 797 that would include a compliance date of June 30, 2007.

**REVIEWED LETTER
CONCERNING DEANS OF
SCHOOLS OF PHARMACY
HAVING A VIRGINIA
PHARMACIST LICENSE:**

Mr. Szalwinski informed the Board that he and some members of the Board received an anonymous letter expressing concern that deans of the schools of pharmacy in Virginia are not required to have a Virginia pharmacist license. One of the allegations in the letter was that the Board did not require this because the members had all graduated from Virginia schools. Mr. Szalwinski polled the Board members as to where they graduated from pharmacy school, and the result was that approximately half of the members graduated from a Virginia school of pharmacy and the remaining from an out-of-state school. Board counsel advised that unless the

deans were engaging in the practice of pharmacy, there was no legal requirement that they be licensed pharmacists. Ms. Easton further advised that the Accreditation Council for Pharmacy Education (ACPE) does not require that a dean of a school of pharmacy be a pharmacist or even eligible for licensure as a pharmacist. She advised that probably less than 50% of the deans were eligible for licensure as a pharmacist. Many, for example, may hold a doctorate degree in pharmacology or some related science.

**MINUTES FROM BOARD
OF HEALTH
PROFESSIONS:**

Ms. Easton stated that the Minutes from January 12, 2004 and April 15, 2004 accurately reflected the business conducted at the meetings. She also informed the Board that the Prescription Monitoring Program will make a presentation at a conference to be held by the Department of Health Professions on October 7 and 8, 2004, and she encouraged all the Board members to attend.

NEW BUSINESS:

Ms. Reiniers-Day informed the Board that when Guidance Document 110-19 was revised in November 2003 to incorporate Confidential Consent Agreements (“CCA”) for continuing pharmacy education violations, the ability to offer pre-hearing consent orders for those persons ineligible for a CCA was inadvertently deleted. Ms. Reiniers-Day requested that the Board reinstate the authority to offer pre-hearing consent orders to the guidance document.

Mr. Ayotte moved, and the Board voted unanimously, to reinstate the authority to offer pre-hearing consent orders to Guidance Document 110-19 as it pertains to continuing pharmacy education violations.

ADJOURN:

With all business concluded, the meeting adjourned at 11:35 a.m.

Donna M. Lee
Administrative Assistant

Elizabeth Scott Russell
Executive Director

Mark A. Szalwinski, Board Chair

Date

Minutes
Virginia Board of Pharmacy
??Date??

ATTACHMENT 1