



COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Dr., Second Floor
Henrico, Virginia 23233

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Tentative Agenda of Meeting

September 8, 2010

9:00AM

<u>TOPIC</u>	<u>PAGE(S)</u>
Call to Order: Brandon Yi, Chairman	
• Welcome and Introductions	
• Introduction of new Board members	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	1-19
• June 2, 2010, Full Board meeting	
• June 17, 2010, Telephone Conference Call	
• June 30, 2010, Special Conference Committee	
• July 13, 2010, Informal Conference Committee	
 Call for public comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.	
 DHP Director's Report: Diane Reynolds-Cane, M.D.	
 Legislation: Update - Elaine Yeatts	20-29
• 2011 Legislative Proposals	
• Adding tramadol and carisoprodol to Schedule IV; adding immediate precursors to amphetamine, methamphetamine, phencyclidine, and fentanyl to Schedule II	
 Regulations: Elaine Yeatts	30-37
• Response to petition for rulemaking regarding filing of prescriptions	
 Update on Action Items: Caroline Juran	
• Pharmacy coupons - information from NABP	38-39
• Discussion regarding need for sending guidance document 110-27 to new PIC's now that attestation is included on pharmacy permit application	40-44
 Miscellaneous:	
• Request from Allergan to discuss requirements for physician dispensing of topical drugs for aesthetic purposes	45
• Update on inspection program – Caroline Juran, Sammy Johnson	Handout

- Amended guidance document 110-9
- Request from David Kozera to discuss opening disciplinary case against pharmacy permit or PIC
- Use of agency subordinates to hear disciplinary matters resulting from new routine inspection process 46-48
- Possible legislation proposal from VDH 49-50
- Discussion of vacancy for Board of Health Professions 51-52
- Set board meeting dates for 2011

Reports:

- Report on Board of Health Professions – Caroline Juran
- Acting Executive Director's Report - Caroline Juran
 - Status of recruitment for vacant staff positions
 - Issuance of RFP for contract administrator of the Virginia Federal and State Drug Law Exam
 - Upcoming NABP member forum meeting, September 22-23, 2010
 - Upcoming NABP District II meeting, October 29-31, 2010

New Business

Consideration of consent orders (if any)

Possible Summary Suspension Presentation

- Wayne Halbleib, Senior Assistant General

Adjourn

***The Board will have a working lunch at approximately 12 noon. Immediately following adjournment of the meeting, a panel will be convened for formal hearings.**

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

June 2, 2010
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 9:10 AM.

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
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Regulatory Analyst, DHP
Tiffany Mallory, Administrative Assistant (business matters)
Eusebia Joyner, Administrative Assistant (disciplinary matters)

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

APPROVAL OF AGENDA: An amended agenda was distributed before the meeting. With no additional changes to the amended agenda, the agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for March 9, 2010; March 9, 201; March 24, 2010; April 14, 2010; April 27, 2010; May 6, 2010; May 17, 2010; May 20, 2010; and May 25, 2010. With no changes to the minutes, the minutes were approved as presented.

PUBLIC COMMENTS: There were no public comments made at this time.

DHP DIRECTOR'S REPORT: Dr. Reynolds-Cane introduced herself and Chief Deputy Arne Owens and provided further details of her background which included her years of service as a Board member and Board President for the Virginia Board of Medicine, her fellowships in

health law and health policy, and her time as medical director of The Daily Planet Health Care for the Homeless Medical Clinic, a federally qualified health center in Richmond.

ELECTION OF OFFICERS:

Mr. Ross nominated Brandon K. Yi for the office of Chairman, with a second from Mr. Dabney. No other nominations were made. The Board voted unanimously to elect Mr. Yi as Chairman for the term July 1, 2010 through June 30, 2011.

Mr. Ross nominated John Beckner for the office of Vice-Chairman, with second from Mr. Kozera. No other nominations were made. The Board voted unanimously to elect Mr. Beckner as Vice-Chairman for the term July 1, 2010 through June 30, 2011.

RECOGNITION:

Ms. Edwards, Dr. Cane, and other members of the Board recognized the five Board members whose terms were expiring and thanked them for their years of service and dedication to the Board and citizens of Virginia. Mr. Ross, Mr. Ison, and Mr. Brown are completing second terms and are not eligible for reappointment. Ms. Edwards and Mr. Stredler are finishing a first term and are eligible for reappointment.

Ms. Russell announced that she is resigning her position as Executive Director for the Board of Pharmacy as of August 1 as she is retiring from state service.

REGULATION UPDATE:

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that permanent replacement of regulations for drug donation programs and emergency regulations for CSBs are still under administrative review.

- Exempt Regulations-CE and incorrect citation

Ms. Yeatts stated that the Board needed to adopt exempt regulations to correct a conflict with statute related to the length of time to maintain CE documentation. The Board had changed the requirement to three years during its recent regulation review process for ease of auditing, but it was later discovered that the statute only requires that documents be maintained for two years. The exempt correction would change the regulation requirement back to two years to be consistent with the statute. An additional change would remove an incorrect citation in 18 VAC 110-20-690.

Motion:

The Board voted unanimously to adopt the exempt changes to regulation as presented in the agenda package. (motion by Yi, second by Kozera)

- Exempt Regulations-
Electronic prescriptions

Ms. Juran reviewed draft changes to current regulations, provided as part of the amended agenda, so that the Board regulations would be in conformity with new federal rules that DEA has published,

effective June 1, 2010, allowing for electronic prescribing of Schedule II-V controlled substances. The draft changes mostly made reference to the federal regulations without repeating the language as DEA is still accepting comments on the rules and may make additional changes. Mr. Casway suggested a minor change in the definition of "electronic prescription" to make reference to the federal code cite.

Motion:

The Board voted unanimously to adopt the exempt regulation conforming Board regulations to federal regulations related to electronic prescribing of Schedule II-V controlled substances as presented in the agenda package with the addition of the federal citation in the definition of "electronic prescription". (motion by Abernathy, second by Dabney)

- Fast Track –nominal fee for duplicate licenses and written license verifications; and elimination of alarm requirement for EMS agencies that hold a CSR for the purpose of stocking only IV solutions

Ms. Russell explained that the Board has been receiving a fair number of requests for duplicate licenses particularly from pharmacy technicians who seem to lose them. Additionally, the Board receives requests from licensees who need written verification of their license status, primarily for other states in which they are licensed. License status can be verified on the department website by anyone for free, and the data is refreshed daily. Both the duplicate licenses and the written verifications take staff time away from other tasks, and cost money in terms of staff time and mailing. Other boards in the department charge a small fee for this service. Ms. Russell asked the Board to approve a nominal fee that would act as a deterrent to these requests. The draft language for fees of \$10 for duplicate licenses and \$25 for written verifications were provided in the agenda package. Ms. Russell also stated that EMS agencies may hold a CSR for the purpose of stocking their own IV solutions, and the requirement for an alarm system in this situation seemed overly burdensome. Draft language for this was also provided. Mr. Ison asked that the language make clear that the exception was only for stocking plain IV solutions with no added drug. This change was made.

Motion:

The Board voted unanimously to adopt the draft fast-track regulation establishing a fee for duplicate license and written verification requests and removing the alarm system requirements for EMS agencies stocking plain IV solutions with no added drug. (motion by Beckner, second by Brown)

- Petition for Rulemaking-addition of tramadol to Schedule IV

The Board discussed the petition to schedule tramadol as a Schedule IV controlled substance in regulation. The Board generally agreed that both tramadol and carisoprodol were known drugs of abuse, and were in agreement that they should both be scheduled, but was hesitant to begin scheduling drugs by regulation when that had always been done via legislation in the past.

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Motion:

The Board voted unanimously to deny the petition for rulemaking and to circulate a legislative proposal for comment to schedule both tramadol and carisoprol as a Schedule IV controlled substance. (motion by Beckner, second by Ross)

LEGISLATION:

- 2011 Legislative Proposals
 - Compounding

Ms. Russell reviewed a draft legislative proposal changing the "or" to an "and" in § 54.1-3410.2 (F) (2) to eliminate the ability for a pharmacy to use a drug in compounding that had not been approved for use in the United States by FDA or that had merely been distributed by a registered non-resident wholesale distributor. The current structure of the language left a loophole for compounding that is inconsistent with the language in § 54.1-3421. There was some discussion as to whether this change would inadvertently affect some legitimate and safe compounding. Ms. Russell stated that if the Board approved the proposal, she would circulate the draft to IACP for comment as part of the vetting process.

Motion:

The Board voted unanimously to approve circulating this legislative draft for comment and if there were no issues to be resolved, to go forward with the proposal. (motion by Kozera, second by Dabney)

- Multiple prescriptions per order form

Ms. Russell reviewed a draft legislative proposal that would eliminate the prohibition of more than one prescription per order form in § 54.1-3408.01. She stated that this law is antiquated in light of faxed and electronic prescriptions and causing prescribers and pharmacists unnecessary workload.

Motion:

The Board voted unanimously to approve the draft legislative proposal. (motion by Abernathy, second by Ross)

- Interpretation of HB964

The Board reviewed and discussed the need for interpretation of HB964 which implements a new requirement for obtaining photo-identification in certain circumstances for persons picking up a filled Schedule II prescription. There was discussion that language in one sentence conflicted with language in another sentence. Additionally, there was some discussion as to how this law will impact pharmacies providing services to long term care facilities or other residential settings. Tim Musselman, Executive Director, VPhA, stated that they had suggested some edits to the bill to correct problems and that the patron agreed to some of the suggested changes but did not make all the changes resulting in the passed language that is inconsistent. He stated that they may ask for clarifications next session. Meanwhile, the Board determined that a guidance document clarifying current language was

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necessary. Therefore, the Board interpreted that when proof of identity is required by law, a pharmacist shall make a photocopy or electronic copy of the identification or an electronic record documenting that proof of identity was provided and that whichever type of record is used, it must be maintained for at least one year.

Motion:

The Board voted unanimously to interpret the new law as recognizing that a pharmacist shall, when proof of identity is required by law, make a photocopy or electronic copy of the identification or an electronic record documenting that proof of identity was provided and that whichever type of record is used, it must be maintained for at least one year, and to put this interpretation into a guidance document. (motion by Brown, second by Kozera)

**SANCTION REFERENCE
EVALUATION:**

Neil Kauder, VisualResearch, Inc., gave the Board a brief overview of an upcoming evaluation of the sanction reference worksheets currently being used by the disciplinary committees that he plans to begin within the next few months. He stated that there have been a number of changes since the Board first implemented the system, such as the use of CCAs, cases against pharmacy technicians, and other factors that may need to be taken into consideration. He reminded the board that the Board's cases were generally similar in nature and that the sanctions had always been fairly consistent. Ms. Reiniers-Day stated that the Special Conference Committees appreciated the worksheets and would like to use them for pharmacy technicians.

**GUIDANCE DOCUMENT
REVISIONS:**

• 110-27 PIC Responsibilities

Ms. Juran reviewed draft changes to this guidance document to include inspection program changes and give more directed guidance to prospective PICs in avoiding inspection deficiencies. Mr. Ison requested that the Board require new PICs to conduct a self-inspection of the pharmacy prior to the Board granting a permit. Following discussion of the matter and Mr. Casway's statement that unless it was a requirement of law or regulation, the Board could not require it, the Board came to an agreement that this was not feasible. After further discussion, there was a consensus that a copy of the guidance document and website link to the inspection form could be attached to the application, and that there could be an attestation on the pharmacy permit application for designating a new PIC to state that the PIC had reviewed the materials related to potential monetary penalties associated with inspection deficiencies. Additionally, the draft guidance document was amended to include the word "strongly" related to the suggestion that the PIC conduct a self-inspection of the pharmacy.

Motion:

The Board voted unanimously to adopt the guidance document as amended and include an attestation on the application that the new PIC has read and understood guidance document 110-27 and the associated information regarding the inspection process. (motion by Ison, second by Dabney.)

- 110-34 Wholesale Distributors

Ms. Juran explained that this is an existing guidance document regarding licensure requirements that is provided to nonresident manufacturers and wholesale distributors that do not physically ship prescription drug into Virginia, but rather use a third party logistics company to physically ship the drug. Due to similar licensure questions received recently by staff for facilities located in Virginia using a third party logistics company to ship drugs, Ms. Juran discussed amended language that would similarly address those licensure issues.

Motion:

The Board voted unanimously to adopt the guidance document amendments as presented with the agenda. (motion by Kozera, second by Ross)

- 110-35 Prescription Requirements

The Board reviewed draft changes to this guidance document to conform with changes related to the new DEA electronic prescribing regulations.

Motion:

The Board voted unanimously to approve the changes to the guidance document. (motion by Ross, second by Brown)

- 110-9 Inspection Monetary Penalty Guide

Ms. Juran reviewed the draft changes to this guidance document based on lessons learned while piloting the new procedures, as well as changes recommended by the ad hoc committee for inspecting for compliance with USP 797 and USP 795. Ms. Abernathy suggested amending the draft language as presented for major deficiency 25 to clarify that the deficiency for improperly storing drugs intended to only address the storage of drugs intended for use.

Motion:

The Board voted unanimously to approve this guidance document with the amendments. (motion by Beckner, second by Ison)

MISCELLANEOUS:

- Update on the inspection program

Ms. Juran reviewed statistics resulting from the 105 pilot inspections of retail pharmacies performed through May 20, 2010, explaining that 30% of the inspections would have resulted in no deficiencies, 33% would have resulted in a cited deficiency and 36% would have resulted in a monetary penalty. She and Sammy Johnson, Assistant Director of Enforcement, confirmed that the

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overall piloting process was going well and that inspectors planned to go live with retail/community pharmacy inspections in the first part of July 2010. Inspectors will continue to telephone retail/community pharmacies until September 1, 2010, alerting them that an inspection will be performed sometime within the following two weeks. After September 1, 2010, inspections will again be performed unannounced. Additionally, Ms. Juran reviewed the draft inspection report for USP 797 and USP 795 resulting from the recently held committee meeting. There was discussion regarding the documentation for evaluation of airborne microorganisms in the controlled air environment and how often this evaluation must be performed. Mr. Ison recommended at least every six months which could be performed during the certification process of the ISO environments and the Board concurred. Additionally, Ms. Abernathy recommended amending the language regarding the daily accuracy assessment of automated compounding devices so that it did not solely address devices used only for parenteral nutrition compounding, but addressed automated compounding devices in general. The Board agreed with her suggestion. Ms. Juran and Mr. Johnson then explained that the inspectors planned to begin piloting the new inspection process in the hospital or other institutional pharmacies in July and would provide notifications similar to those provided to the retail/community pharmacies. No monetary penalties will be issued to the hospital or institutional pharmacies during this piloting phase.

- Changes to HIPDB/NPDB reporting

Ms. Russell advised the Board that the national databases HIPDB and NPDB were eventually going to be merged into one databank, but that a new requirement became effective as of January 2010 for agencies to report actions currently and previously taken against health care entities, specifically pharmacies, as well as certain health care professionals. The agency has been reporting actions against pharmacists for years, but has not been reporting pharmacies as it was not a requirement. The data department is now obtaining back data for pharmacies reported and will be including these actions in future reporting. This will also mean that with the new inspection deficiencies being docketed against the pharmacy permit, there will be an increase in pharmacies reported to the databases. There was some discussion about the appropriateness of docketing against the pharmacy permit versus the PIC, and the Board did not make any changes at this time to its original direction to docket against the pharmacy permit.

- Pharmacy Residents

Mr. Ison had asked that the Board discuss the problem with pharmacy residencies beginning July 1 and some residents not having obtained their pharmacist license by that time. He wondered if there was some way to expedite the process. Ms. Russell stated

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that for most persons graduating in May, there was no reason why they could not be licensed by July 1, provided they passed the NAPLEX and law exam on the first try. She stated that she really had no way to expedite the process anymore than it was.

- Pharmacy Coupons

Ms. Edwards reviewed a letter received by the Board from a pharmacy student at VCU expressing concern for the "widespread use" of pharmacy coupons explaining that he believed it created a patient safety issue for persons to have multiple prescriptions at multiple pharmacies and impedes a pharmacist's ability to perform a satisfactory prospective and/or retrospective DUR process. There was much discussion regarding the pros and cons of pharmacy coupons. Ms. Russell explained that prohibiting the use of coupons may be considered a restraint of trade, but thought New York and New Jersey may currently have restrictions on their use. The Board requested staff to research this topic through NABP to determine how this issue is being addressed nationally.

BOARD OF HEALTH
PROFESSIONS ("BHP")
REPORT:

Ms. Edwards gave the Board an update on BHP activities to include new advisory boards for the Board of Medicine to regulate polysomnographers and surgical assistants and/or technicians. BHP will also be reviewing kinesiotherapists, medication aides in nursing homes, and genetic counselors to determine if there is a need for licensure or registration through DHP.

EXECUTIVE DIRECTOR'S
REPORT:

Ms. Russell gave a brief report of resolutions adopted at the recent NABP meeting. Her report included a Recognition Resolution that acknowledged the deaths of Carl F. Emswiler, Jr. and S. Wallace Cunduff, former Board members, stating that they had made significant contributions to NABP, the protection of the public health, and the profession of pharmacy.

Additionally, Ms. Russell stated that she would be attending a DEA Meeting in two weeks.

Jennifer Edwards departed at 2:00 p.m.

SUMMARY SUSPENSION:

Closed meeting:

Mr. Kozera moved, and the Board voted unanimously, to convene a closed meeting pursuant to § 2.2-3711.A.27 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, Caroline Juran, Eusebia Joyner, Howard Casway, Wayne Halbleib and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.



DORIAN DOWNHAM
Pharmacy Technician
Registration Number:
0230-003973

Wayne Halbleib, Senior Assistant Attorney General, presented a summary of the evidence in the case for the Board to consider a summary suspension. Mykl D. Egan, DHP Adjudication Specialist, was also present.

Reconvene:

Mr. Kozera 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. Kozera moved, and the Board voted unanimously in favor of the motion that, with the evidence presented, the pharmacy technician practice by Dorian Downham poses a substantial danger to the public; and therefore, the registration of Dorian Downham to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Downham for the indefinite suspension of her registration for not less than two (2) years in lieu of a formal administrative hearing.

FORMAL ADMINISTRATIVE
HEARING

JERMAINE L. MOON
Pharmacy Technician
Registration Number:
0230-003098

Brandon Yi presided as the Chairman for a formal administrative hearing held in the matter of Jermaine L. Moon. The hearing was held to discuss his petition for reinstatement of his pharmacy technician registration that was mandatorily suspended on December 1, 2009, and allegations that he may have violated certain laws or regulations governing the practice of pharmacy technicians in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist. Mr. Moon appeared and was not represented by counsel.

Ann S. Hardy, DHP Senior Investigator, testified on behalf of the Commonwealth.

Jermaine L. Moon testified on his own behalf.

Closed Meeting:

Mr. Kozera moved and the Board voted unanimously, to enter into a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of Jermaine L. Moon. Additionally, he moved that Scotti Russell, Cathy Reiniers-Day and Howard Casway attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation

Reconvene: Mr. Kozera moved, and 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.

Decision: Mr. Dabney moved, and the Board voted unanimously, to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the Board and read by Mr. Casway.

Mr. Dabney moved, and the Board voted eight in favor of the motion, that Mr. Moon's petition for the reinstatement of his pharmacy technician registration be denied.

ADJOURN: With all business concluded, the meeting adjourned at 4:15 p.m.

Elizabeth Scott Russell
Executive Director

Jennifer Edwards, Board Chairman

Brandon K. Yi, Formal Administrative
Hearing Chairman

Date

Date

(FINAL /APPROVED 09/08/2010)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Thursday, June 17, 2010

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463

Orders/Consent Orders referred to in these minutes are available upon request

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 8:45 a.m., on June 17, 2010, to consider the summary suspension of the registration of LaDawn M. Bodrick, to practice as a pharmacy technician and Arianne E. Camphire, to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: John O. Beckner, Chair

MEMBERS PRESENT: Gill B. Abernathy
Willie Brown
Jennifer H. Edwards
David C. Kozera
Leo H. Ross
Michael E. Stredler

STAFF PRESENT: Elizabeth Scott Russell, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist
Corie Tillman-Wolf, Assistant Attorney General

POLL OF MEMBERS: The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension case. The Board members stated that they would not have been able to attend.

With seven members participating and three members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

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LADAWN M. BODRICK
Registration No. 0230-010742

Corie Tillman-Wolf presented a summary of the evidence in this case.

Upon a motion by Willie Brown and duly seconded by Mickey Stredler, the Board unanimously voted that with the evidence presented, the practice as a pharmacy technician by LaDawn M. Bodrick poses a substantial danger to the public; and therefore, that the registration of Ms. Bodrick to practice as a pharmacy technician be summarily suspended; and that a Consent Order be offered to Ms. Bodrick for the indefinite suspension of her registration for not less than two years, in lieu of a hearing.

ARIANNE E. CAMPHIRE
License No. 0202-209670

Corie Tillman-Wolf presented a summary of the evidence in this case.

Decision:

Upon a motion by David Kozera and duly seconded by Mickey Stredler, the Board unanimously voted that with the evidence presented, the practice as a pharmacist by Ms. Camphire poses a substantial danger to the public; and therefore, that the license of Ms. Camphire to practice pharmacy be summarily suspended; and that a Consent Order be offered to Ms. Camphire for the indefinite suspension of her license, in lieu of a hearing.

ADJOURN:

With all business concluded, the conference call adjourned at 9:05 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

John O. Beckner, TCC Chair

Date

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(FINAL/APPROVED 09/08/2010)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, June 30, 2010
Commonwealth Conference Center
Second Floor
Training Room 2

Department of Health Professions
Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233

CALL TO ORDER: A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.

PRESIDING: Brandon K. Yi, Committee Chair

MEMBERS PRESENT: Leo H. Ross, Committee Member

STAFF PRESENT: Cathy M. Reiniers-Day, Deputy Executive Director
Mykl D. Egan, DHP Adjudication Specialist

HEATHER T. PARRA
Registration No. 0230-011895
Heather T. Parra appeared with her attorney, Gary L. Denton, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the June 9, 2010, Notice.

Closed Meeting: Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Heather T. Parra. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision: Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee closed this case as undetermined.

KRISTINE H. HATLEY
License No. 0202-205324
Kristine H. Hatley appeared with her attorney, Dante M. Filetti, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 9, 2010, Notice.

Closed Meeting:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A.(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Kristine H. Hatley. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee closed this case as no violation.

KIMBERLI T. HOGAN
Registration No. 0230-011669

Kimberli T. Hogan did not appear at the informal conference. The Committee chose to proceed in her absence as the notice was mailed to Ms. Hogan's legal address of record. The Committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the June 9, 2010, Notice.

Closed Meeting:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Kimberli T. Hogan. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms.

Hogan a Consent Order for the indefinite suspension for not less than two years of her pharmacy technician registration.

ROBERT W. KENNEDY
License No. 0202-004470

Robert W. Kennedy did not appear at the informal conference. The committee chose to proceed in his absence as the notice was mailed to Mr. Kennedy's legal address of record and he requested that the conference be held in his absence. The committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 9, 2010, Notice.

Closed Meeting:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Robert W. Kennedy. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan 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 § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Mr. Ross, and duly seconded by Mr. Yi, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Kennedy a reprimand.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Kennedy, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Kennedy within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period. Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

CHRISTY H. HART
Registration No. 0230-006131

The scheduled informal conference was not held. Ms. Hart did not appear and the Committee referred this matter to a formal administrative hearing.

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ADJOURN:

With all business concluded, the meeting adjourned at
3:40 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Brandon K. Yi, Chair

Date

(FINAL/APPROVED 09/08/2010)

**VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE**

Tuesday, July 13, 2010
Second Floor
Board Room #4

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 3:15pm.
- PRESIDING:** John O. Beckner, Committee Chairman
- MEMBERS PRESENT:** David C. Kozera
- STAFF PRESENT:** Elizabeth Scott Russell, Executive Director
Caroline D. Juran, Deputy Executive Director
Sammy Johnson, Assistant Director, Enforcement
- Khurram Rashid, M.D.
License # 0101-050539
- Mr. Edward D. Rickert, Esq., Krieg DeVault, and Julie Geason, Vice-President of Pharmacy Services, InstyMeds, were present to discuss the application, received June 8, 2010, for approval of an innovative (pilot) program wherein Medics USA Primary and Urgent Care Centers ("MedicsUSA") 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 first 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 Khurram Rashid, M.D., requesting the ability to dispense drug to his own patients and the designation of a physician at each location 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

each 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.

Other terms and conditions include:

1. A waiver, if necessary, of the requirement for 60 square feet in the designated controlled substances storage and selling area as required in Regulation 18VAC110-30-90;
2. 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 and the device shall be located in an area protected by motion detectors that when breached shall notify appropriate law enforcement, with a waiver on the restriction regarding who may have access to the alarm code;
3. Access to the code or key for opening 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;
4. Drugs delivered for loading into the device shall be placed in the device within a reasonable period of time, not to exceed 24 hours from delivery, to prevent possible diversion;
5. Each participating MedicsUSA 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. Khurram Rashid, M.D., on behalf of MedicsUSA, shall be solely responsible for the payment of an inspection fee of \$150.00 each to be paid to the Board within thirty days from the date of the statement of monies owed that will be mailed following the inspection;
6. 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

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technology. Additionally, a sign shall be posted near the dispensing device informing patients that nonspecial packaging or non-safety closures are not available.

7. All prescription errors and the 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.

Caroline D. Juran, Deputy Executive Director

John O. Beckner, Chairman

Date

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Agenda Item: Legislative Report

Enclosed:

A copy of the draft bill for scheduling certain precursors in Schedule II and two drugs in Schedule IV

Staff note:

There were two legislative proposals that were not submitted:

- 1) One script per page repeal
- 2) Compounding amendments

Board Action:

None required

**Department of Health Professions
2011 Session of the General Assembly**

Draft Legislation

A BILL to amend and reenact §54.1-3448 of the Code of Virginia, relating to the addition of immediate precursors to amphetamine, methamphetamine, phencyclidine and fentanyl in Schedule II. Furthermore, this bill is to amend and reenact §54.1-3452 of the Code of Virginia, relating to the addition of carisoprodol and tramadol in Schedule IV.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3448 and §54.1-3452 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3448. Schedule II.

The controlled substances listed in this section are included in Schedule II:

1. Any of the following substances, except those narcotic drugs listed in other schedules, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by combination of extraction and chemical synthesis:

Opium and opiate, and any salt, compound, derivative, or preparation of opium or opiate, excluding apomorphine, thebaine-derived butorphanol, dextrorphan, nalbuphine, nalmefene, naloxone naltrexone and their respective salts, but including the following:

Raw opium;

Opium extracts;

Opium fluid extracts;

Powdered opium;

Granulated opium;

Tincture of opium;

Codeine;

Dihydroetorphine;

Ethylmorphine;

Etorphine hydrochloride;

Hydrocodone;

Hydromorphone;

Metopon;

Oripavine (3-O-demethylthebaine or 6,7,8,14-tetrahydro-4,
5- α -epoxy-6-methoxy-17-methylmorphinan-3-ol);

Morphine;

Oxycodone;

Oxymorphone;

Thebaine.

Any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in this subdivision, but not including the isoquinoline alkaloids of opium.

Opium poppy and poppy straw.

Coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extractions which do not contain cocaine or ecgonine; cocaine or any salt or isomer thereof.

Concentrate of poppy straw, the crude extract of poppy straw in either liquid, solid or powder form, which contains the phenanthrene alkaloids of the opium poppy.

2. Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, whenever the existence of these isomers, esters, ethers and salts is possible within the specific chemical designation:

Alfentanil;

Alphaprodine;

Anileridine;

Bezitramide;

Bulk dextropropoxyphene (nondosage forms);

Carfentanil;

Dihydrocodeine;

Diphenoxylate;

Fentanyl;

Isomethadone;

Levo-alpha-acetylmethadol (levo-alpha-acetylmethadol)

(levomethadyl acetate) (LAAM);

Levomethorphan;

Levorphanol;

Metazocine;

Methadone;

Methadone - Intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

Moramide - Intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;

Pethidine (other name: meperidine);

Pethidine - Intermediate - A, 4-cyano-1-methyl-4-phenylpiperidine;

Pethidine - Intermediate - B, ethyl-4-phenylpiperidine-4-carboxylate;

Pethidine - Intermediate - C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

Phenazocine;

Piminodine;

Racemethorphan;

Racemorphan;

Remifentanyl;

Sufentanyl;

Tapentadol.

3. Any material, compound, mixture or preparation which contains any quantity of the following substances having a potential for abuse associated with a stimulant effect on the central nervous system:

Amphetamine, its salts, optical isomers, and salts of its optical isomers;

Phenmetrazine and its salts;

Any substance which contains any quantity of methamphetamine, including its salts, isomers, and salts of isomers;

Methylphenidate;

Lisdexamfetamine, its salts, isomers, and salts of its isomers.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Amobarbital;

Glutethimide;

Secobarbital;

Pentobarbital;

Phencyclidine.

5. The following hallucinogenic substance:

Nabilone.

~~6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are immediate precursors to amphetamine and methamphetamine or phencyclidine:~~

~~Phenylacetone;~~

~~1-phenylcyclohexylamine;~~

~~1-piperidinocyclohexanecarbonitrile (other name: PCC).~~

6. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances which are:

a. Immediate precursors to amphetamine and methamphetamine:

Phenylacetone;

b. Immediate precursor to phencyclidine:

1-phenylcyclohexylamine;

1-piperidinocyclohexanecarbonitrile (other name: PCC);

c. Immediate precursor to fentanyl:

4-anilino-N-phenethyl-4-piperidine (ANPP)

§ 54.1-3452. Schedule IV.

The controlled substances listed in this section are included in Schedule IV unless specifically excepted or listed in another schedule:

1. Any material, compound, mixture, or preparation which contains any quantity of the following substances having a potential for abuse associated with a depressant effect on the central nervous system:

Alprazolam;

Barbital;

Bromazepam;

Camazepam;

Carisoprodol;

Chloral betaine;

Chloral hydrate;

Chlordiazepoxide;

Clobazam;

Clonazepam;

Clorazepate;

Clotiazepam;

Cloxazolam;
Delorazepam;
Diazepam;
Dichloralphenazone;
Estazolam;
Ethchlorvynol;
Ethinamate;
Ethyl loflazepate;
Fludiazepam;
Flunitrazepam;
Flurazepam;
Halazepam;
Haloxazolam;
Ketazolam;
Loprazolam;
Lorazepam;
Lormetazepam;
Mebutamate;
Medazepam;
Methohexital;
Meprobamate;
Methylphenobarbital;
Midazolam;

Nimetazepam;

Nitrazepam;

Nordiazepam;

Oxazepam;

Oxazolam;

Paraldehyde;

Petrichloral;

Phenobarbital;

Pinazepam;

Prazepam;

Quazepam;

Temazepam;

Tetrazepam;

Triazolam;

Zaleplon;

Zolpidem;

Zopiclone.

2. Any compound, mixture or preparation which contains any quantity of the following substances including any salts or isomers thereof:

Fenfluramine.

3. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers (whether optical, position, or geometric), and salts of such isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

Cathine (+)-norpseudoephedrine;

Diethylpropion;

Fencamfamin;

Fenproporex;

Mazindol;

Mefenorex;

Modafinil;

Phentermine;

Pemoline (including organometallic complexes and chelates thereof);

Pipradrol;

Sibutramine;

SPA (-)-1-dimethylamino-1, 2-diphenylethane.

4. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs, or their salts calculated as the free anhydrous base or alkaloid, in limited quantities as set forth below:

Dextropropoxyphene (alpha-(+)-4-dimethylamino-1, 2-diphenyl-3-methyl-2-propionoxy butane);

Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

5. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts:

Butorphanol (including its optical isomers);

Pentazocine;

Tramadol.

6. The Board may except by regulation any compound, mixture, or preparation containing any depressant substance listed in subdivision 1 from the application of all or any part of this chapter if the compound, mixture, or preparation contains one or more active medicinal ingredients not having a depressant effect on the central nervous system, and if the admixtures are included therein in combinations, quantity, proportion, or concentration that vitiate the potential for abuse of the substances which have a depressant effect on the central nervous system.

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

Staff Note: Status of regulations for the Board as of mailing of agenda

Action: None – provided for information only

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Repackaging in CSB's and BHA's – Emergency bill effective 3/4/10.</p> <p><u>Stage:</u> Emergency/NOIRA - At Governor's Office</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Signing of automated dispensing devices in hospitals – response to petition for rulemaking</p> <p><u>Stage:</u> Fast-Track - At Governor's Office</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Addition of administrative fees and elimination of alarm system for certain EMS agencies</p> <p><u>Stage:</u> Fast-Track - At Governor's Office</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u> Drug donation program</p> <p><u>Stage:</u> Final - At Governor's Office Emergency regulations expire on 10/6/10</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u>  Correction of regulation cite and conformity to Code</p> <p><u>Stage:</u> Final - Register Date: 7/5/10 Effective: 8/4/10</p>
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	<p><u>Action:</u>  Conformity to DEA rules</p> <p><u>Stage:</u> Final - Register Date: 7/5/10 Effective: 8/4/10</p>

Agenda Item: Response to Petition for Rulemaking

Included in your agenda package are:

A copy of the petition received from Eric Haas

A copy of the initial Agency Notice published in the Register of Regulations

Copy of comments on the petition

Staff Note:

There was a comment period on the petition until July 21, 2010. Comments were received by hard copy sent to the Board, email or through the Virginia Regulatory Townhall.

Board action:

The Board may accept the petitioner's request for amendments to regulations and initiate rulemaking by adoption of a Notice of Intended Regulatory Action

OR

The Board may reject the petitioner's request for amendments. If the petition is rejected, the Board must state its reasons for denying the petition.



COMMONWEALTH OF VIRGINIA Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, Virginia 23233-1463

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition.

Please provide the information requested below. (Print or Type)

Petitioner's full name (Last, First, Middle initial, Suffix,)		
Haas, Eric, C		
Street Address		Area Code and Telephone Number
3820 Ingalls Ave.		(571)970-4232 / (703)593-3340
City	State	Zip Code
Alexandria	VA	22302
Email Address (optional)	Fax (optional)	
ehaas2010@gmail.com		

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

18VAC110-20-240

B. Prescriptions.

1. A hard copy prescription shall be placed on file for every initial prescription dispensed and be maintained for two years from the date of last refill. All prescriptions shall be filed chronologically by date of initial dispensing.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. Change the following: "All prescriptions shall be filed chronologically by date of initial dispensing."

New Language should be similar to the following: "All prescriptions shall be filed chronologically by date of initial dispensing or initial entry into pharmacy electronic record keeping system if such a system is employed for use in the pharmacy."

Rationale: Prescriptions are often placed into electronic record keeping systems for later dispensing, and retrieval and reassignment is a cumbersome process which is unnecessary and likely to promote errors in the patient record.



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July 2002

2010-05-14

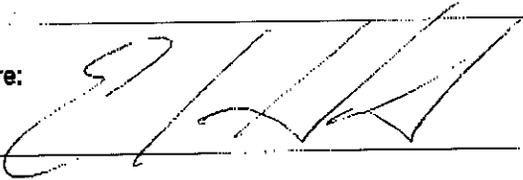


3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

§ 54.1-2400.6 To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title.

§ 54.1-2400.13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.

Signature:



Date:

5-14-2010

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July 2002

Date/Time Filed with Registrar of Regulations

VA.R. Document Number: R _____ - _____

Date of Publication in Virginia Register:

Commonwealth of Virginia

RESPONSE TO PETITION FOR RULEMAKING

Check one: Initial Agency Notice Agency Decision

Regulatory Coordinator: Elaine J. Yeatts

Telephone: (804) 367-4688

E-mail: elaine.yeatts@dhp.virginia.gov

Agency Name: Board of Pharmacy, Department of Health Professions

Chapters affected:

VAC No.

(e.g., 4 VAC 20-490):

Chapter Name (e.g., Regulations Pertaining to Sharks):

18 VAC 110-20

Regulations Governing the Practice of Pharmacy

Statutory Authority: 54.1-2400 and Chapter 34 of Title 54.1

Name of petitioner: Eric Haas

Nature of petitioner's request: Amend requirement for filing prescriptions to allow filing by date of initial dispensing or date of initial entry into pharmacy electronic record keeping system if such a system is employed by the pharmacy. The rationale for the request is that prescriptions are often placed into electronic systems for later dispensing, and retrieval and reassignment of the date is cumbersome and unnecessary and may promote errors in a patient's record.

INITIAL AGENCY NOTICE

Agency's plan for disposition of the request: The Board will receive public comment on the petition for rule-making and will review the petition and any comment at its meeting on September 8, 2010 to make decision on whether to initiate rule-making.

Comments may be submitted until July 21, 2010

AGENCY DECISION

Request Granted

Request Denied

Statement of reasons for decision:

Agency Contact for Further Information:

Name: Elizabeth Scott Russell

Title: Executive Director, Board of Pharmacy

Address: 9960 Mayland Drive, Henrico, VA 23233

Telephone: (804) 367-4456 **Fax:** (804) 527-4472

Toll Free: 1- -

E-mail: scotti.russell@dhp.virginia.gov

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Kaiser Permanente

2101 East Jefferson Street
Pharmacy, 3-West
Rockville, MD 20852

July 21, 2010

Ms. Elizabeth Scott Russell
Executive Director, Board of Pharmacy
9960 Mayland Drive
Henrico, Virginia 23233

Dear Ms. Russell:

Thank you for the opportunity to provide comments on the petition for rulemaking affecting 18VAC110-20 Regulations Governing the Practice of Pharmacy. Kaiser Permanente strongly supports the petition to amend requirements for filing prescriptions to allow filing by date of initial dispensing or date of initial entry into the pharmacy electronic record keeping system, if such system is employed by the pharmacy.

Kaiser Permanente of the Mid-Atlantic States owns and operates 34 pharmacies, including 12 located in our Northern Virginia outpatient medical centers. Most of our members' prescriptions are filled using this integrated network of pharmacies. Since Permanente Medical Group physicians practice in our medical facilities, we use electronic prescribing for non-Controlled prescriptions. Kaiser Permanente pharmacies make use of computerized systems, which are linked and have a shared database. The patient profile is viewable at any Kaiser Permanente pharmacy.

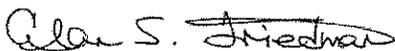
Electronic prescriptions received from physicians in our medical centers may be entered into the pharmacy system, regardless of whether the patient wishes it to be dispensed that particular day or not. Often, members have enough medication on hand, and request the prescription be entered in our computer system for future dispensing. Other times, it may be too soon to actually fill the prescription because of pharmacy benefit considerations. Filing and retrieving prescriptions only by date of dispensing, necessitates software programming of a holding or unique numbering system for prescription processing, which is costly, time consuming and unnecessarily burdensome. The same may be said of filing hard copies this way. To access functionality that requires re-entering the prescription with a new date, increases the risk of order-entry errors. Similar rationale exists for prescriptions that are not electronically received, such as Controlled substances.

Our computerized pharmacy information management system presents a clear picture of the prescription history, no matter whether the prescription was dispensed or filed for later dispensing. Our pharmacists and technicians can determine whether the prescription was actually dispensed or not. The date the prescription was originally entered is also viewable in the system. Additionally, the pharmacist can view the original copy of the prescription sent electronically by the physician.

Electronic capabilities offer convenient, safe, efficient and accurate storage of prescriptions for filling when our patients need them. We can think of no valuable reason to require that prescriptions be filed solely by the date of dispensing, as long as that date can be determined.

Thank you, again, for the chance to offer comments on the petition for rulemaking concerning 18VAC110-20 Regulations Governing the Practice of Pharmacy. Please feel free to contact me should you have questions.

Sincerely,



Alan S. Friedman, RPh
Regulatory, Quality and Professional Affairs Manager
Department of Pharmacy Services

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Logged in: DHP

Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]

All comments for this forum

Commenter: Nichole Lawson CPhT, Safeway Pharmacy *

6/30/10

Petition for Rulemaking

14150

Hello..

I am a CPhT for Safeway in VA. I agree with Mr. Haas. I think that deactivating an Rx and holding it for a further fill date is not good business at all. Not only can prescriptions be lost if not given back to the patient it can create clutter in the pharmacy which creates confusion and anxiety. When an Rx is put into the system on hold, at least it's known where it is by the staff and to floater pharmacists and technicians that might be filling in at that pharmacy. Holding them for their actual fill date to put them in the system to get a paid claim is not the way to go. The pharmacist that puts the Rx on hold should be the one that is responsible for the Rx going out the right way. If it's put in the system correctly to begin with there will be no errors. I understand that it's only human to make errors but not so much for our business practice. We have to be perfect 100% of the time and it's not going to help if we are searching through 100 or more Rx's for "Mrs. Jones" that dropped off an original Rx at the beginning of the month. She gets aggravated because we are taking longer than normal to retrieve her Rx because we have to sift through the 100 or more Rx's that we are holding to be filled and that creates a longer wait time, chaos and anxiety. The most simple way I have found is to just put everything on hold in the computer and if the patient wants it filled, deactivate the Rx, make a copy of it to put in the file and then fill it as new. It's easier than holding onto prescriptions that may or may not ever be filled. But that takes more time too. Isn't there a simpler way to do this?

Commenter: Linh Burgi, CPhT, Safeway Pharmacy *

7/5/10

Petition for Rulemaking

14155

I, too, agree with Mr. E. Hass. Currently, pharmacies are made to enter an "on hold" prescription twice. The first time entered is when the patient drops it off and the second time is when the patient or insurance allows us to fill the script, at which time we are made to deactivate the "on hold" prescription and reprocess THE SAME PRESCRIPTION for the fill date. This allows for double the chance of errors and in our field of work that is not okay. It is also double the work which means more time and money wasted. If this process of entering and filling the prescription on the actual fill date was mandated to better research/audit pharmacy records, couldn't you just look back at the patient's profile, pick an "on hold" prescription and see that nothing was dispensed when it was originally put on hold and that the first fill date was the next entry on the patients profile?

I don't understand this change and to be frank, it seems to be a bit redundant. There must be an alternative.

Commenter: Tim LaDonna, Walmart Pharmacist *

7/9/10

14167

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Rule Amendment

This amendment is a good idea - with the computer systems used in pharmacies today, a 'Held' prescription should be treated just like an original new prescription. Having to search for the Held prescription and reprocess it, with a different RX number, just opens the door for potential errors and misfiled prescriptions. This amendment would make the process much more logical

Back to List Comments

* Nonregistered public user

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NOV 13 2009

Pharmacy Coupons Pose Unnecessary Health Risks for Patients and Place
Undue Burden on Pharmacists

DHP

November 10, 2009

Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Board Members,

My name is Jonathan Carter and I am a student pharmacist at the Medical College of Virginia Campus of Virginia Commonwealth University. I am writing today to express my concern with the widespread use and abuse of pharmacy coupons. Such coupons, which promise gift cards of varying amounts with the filling of a new or transferred prescription, not only demean our great profession of pharmacy, but more importantly, pose a health risk to the patients who use them.

While working as an intern at CVS and Kmart pharmacies, I have frequently been disappointed to hear a patient explain to me that he or she does not know where his or her prescription is on file. In fact, in one instance, a previously-loyal patient whom we had not seen in months called our pharmacy in tears, exclaiming that she had no idea where any of her prescriptions were on file. She proceeded to beg my head pharmacist to call every pharmacy in a 10-mile radius to request any and all prescriptions for her and her family members so that she could have the safety and security that comes with filling all of her prescriptions with one pharmacist at one pharmacy.

My fear is that unfortunate occurrences similar to this one will continue to transpire as long as patients have access to these pharmacy coupons. This particular incident not only cost the patient unimaginable stress, but also resulted in the patient and her family members missing multiple days of necessary drug therapy for chronic disease states.

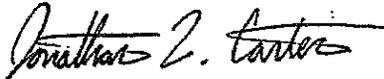
Another concern I have with the widespread use of these coupons is one that could jeopardize my future licensure as a pharmacist. As patients utilize more and more pharmacies, spreading their medications around, it becomes increasingly more difficult for pharmacists to perform duties outlined under the OBRA act of 1990. A satisfactory prospective and/or retrospective DUR process becomes impossible, especially if the patient is a cash customer (which a large portion of those using the coupons are). Because I may be liable for any negative health outcome that may result from me dispensing a medication to a patient, I will be forced to dispense every prescription with the fear that I may not have access to a serious drug interaction that may be present. While I can and

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will take the time to question the patient about any concerns I have, it is most often the case that the patient cannot recall his or her other medications. As a student pharmacist in my final year of a PharmD program, this health risk to the patient is extremely concerning to me.

I understand that in economic situations such as the current one, it is advantageous for patients to find ways to save money and lower expenses, but I do not believe that these savings should come at the cost of their health. Because, in the end, complications from unfavorable drug therapy outcomes will cost the patient and the health care system much more than any gift card could ever cover. As a student pharmacist and pharmacy intern, and on behalf of every student pharmacist, pharmacist, and district pharmacy supervisor that I have spoken with regarding this issue, I implore you to take action to ensure that the use of these pharmacy coupons is prohibited in our great Commonwealth.

Sincerely,

A handwritten signature in cursive script that reads "Jonathan Carter".

Jonathan Carter
PharmD Candidate, 2010
Virginia Commonwealth University School of Pharmacy



COMMONWEALTH OF VIRGINIA

Board of Pharmacy

9960 Mayland Drive, Suite 300
Richmond, Virginia 23233
www.dhp.virginia.gov/pharmacy

(804) 367-4456 (Tel)
(804) 527-4472 (Fax)
pharmbd@dhp.virginia.gov (email)

APPLICATION FOR A PHARMACY PERMIT

Check Appropriate Box(es):

- | | | | |
|---|----------|--|----------|
| <input type="checkbox"/> New ³ | \$270.00 | <input type="checkbox"/> Change of Pharmacist-In-Charge ² | \$50.00 |
| <input type="checkbox"/> Change of Ownership ² | \$50.00 | <input type="checkbox"/> Change of Location ³ | \$150.00 |
| <input type="checkbox"/> Change of Pharmacy Name ² | No Fee | <input type="checkbox"/> Remodeling of Prescription Dept. ³ | \$150.00 |
| <input type="checkbox"/> Reinstatement ^{1, possibly 3} | | | |

¹ If reinstatement, due to: Lapse of Permit or Suspension or Revocation of a Permit

The required fees must accompany the application. Make check payable to "Treasurer of Virginia".

Applicant—Please provide the information requested below. (Print or Type) Use full name not initials

Name of Pharmacy		Area Code and Telephone Number	
Street Address		Area Code and Fax Number	
City		State	Zip Code
If a current pharmacy permit is held, indicate the permit number 0201-		Area Code and Telephone Number (currently working number)	
(Print) Name of the Pharmacist-In-Charge (PIC) (if change of PIC, list incoming)		License Number of the PIC 0202-	
Signature of the Pharmacist-In-Charge (PIC) (if change of PIC, incoming signature)- By affixing my signature I acknowledge that I have read and understood guidance document 110-27 and associated information regarding the inspection process.		Effective Date of Change (if change of PIC, date assuming role as PIC) ²	
		Date	
Expected Hours of Operation	Expected Opening, Moving, or Completion Date	Requested Inspection Date ³	

³ A 14-day notice is required for scheduling an opening or change of location inspection. Drugs may not be stocked prior to inspection and approval. An inspector will call prior to the requested date to confirm readiness for inspection. If the inspector does not call to confirm the date, the responsible party should call the Enforcement Division at 804-367-4691 to verify the inspection date with the inspector.

FOR BOARD USE ONLY: Acknowledgement of Inspection Request			
Date Processed: _____		Assigned Inspection Date ³ : _____	
Application Number Assigned	Date Inspected	Permit Number	Date Issued
0201-		0201-	

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OWNERSHIP TYPE—check one: Corporation Partnership Individual Other

Name of ownership entity if different from name of application:

Street Address:

Phone No.

City:

State:

Zip Code:

State(s) of incorporation:

List all other trade or business names used by this facility

Name: _____

Name: _____

Name: _____

Name: _____

LIST OF OWNERS/OFFICERS AND RESIDENCE ADDRESSES, OR LIST IS ATTACHED

Name: _____

Title: _____

Residence Address: _____

Name: _____

Title: _____

Residence Address: _____

Name: _____

Title: _____

Residence Address: _____

LIST OF PHARMACISTS PRACTICING AT THIS PHARMACY OTHER THAN PIC OR LIST IS ATTACHED

Name: _____

License No. 0202-

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Virginia Board of Pharmacy PIC Responsibilities

This document is intended to assist a new pharmacist-in-charge (PIC) as a reminder of some of the responsibilities, and some "do's" and "don'ts". It is not intended to be a comprehensive list of all responsibilities and is not intended to negate individual responsibility of any other pharmacist practicing at the location. **Pharmacists should not be fearful that, by merely being the PIC of a pharmacy, they will be the subject of Board action for circumstances which are beyond their control.**

New Pharmacies:

- It is your responsibility to ensure that your pharmacy is ready to be inspected on the date assigned. At least 24 hours prior to a scheduled opening make sure that the pharmacy is ready, i.e. all enclosures to the prescription department are in place with appropriate locks on entrances, all counters and shelving are in place, hot and cold running water, refrigerator/freezer is working and at proper temperature with monitoring thermometer if drugs requiring storage at these temperatures plan to be stored, all minimum equipment is in place, and the alarm system is functional and fully protects the prescription department. Please note that Regulation 18 VAC 110-20-180 requires that the alarm device must be capable of detecting breaking by any means when activated, monitored in accordance with accepted industry standards, maintained in operating order, have an auxiliary source of power, and be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. The system must be approved prior to stocking drugs. On the opening inspection, the inspector will "walk test" the system to ensure that there are no areas within the prescription department uncovered by the alarm. For example, if an inspector can stand in a corner of a bay and move his arms without setting off the alarm, the alarm will not pass. In most cases, more than one sensor is necessary to provide complete coverage. The inspector will also want assurances of monitoring and the ability to alert the monitoring company if the alarm system is breached even when the communication line is cut. Although not required, some PICs find it very helpful to have an alarm technician present at the time of the inspection to answer any questions the inspector may have or to make any adjustments or additions necessary to bring the system into compliance which may negate the need for a reinspection.
- If the new pharmacy will not be ready, you or the owner should notify the inspector as soon as it is known to prevent the inspector from making an unnecessary trip. If the inspector is not notified and the pharmacy cannot reasonably be inspected, a \$150 reinspection fee will be assessed in order to schedule and conduct the reinspection.
- As PIC of a new pharmacy, you should be present at the opening inspection of the pharmacy. If you are not able to be present at the opening, you need to notify the Board prior to the date of the inspection with the reason why you are not able to be present. Additionally, you must ensure that another Virginia licensed pharmacist is present if you are absent. If deficiencies are noted on the opening inspection, drugs may not be stocked and the permit will not be issued until you assure the Board in writing that the deficiencies have been corrected and the Board gives approval.
- If any deficiencies are noted on the opening inspection, as the PIC, you must personally notify the Board of corrections made prior to a permit being issued. Therefore, you should personally inspect any corrections to be sure they have been made properly before contacting the Board.

Upon taking over responsibility as PIC:

- You are not a PIC until the Board approves your signed application. Make sure when you sign an application to be a PIC that you are not still on record with the Board as being a PIC for more than one other pharmacy. Once you are approved as PIC, the Board will issue a pharmacy permit in your name. This is your permit. It must be displayed where the public can read it. If you do not receive the permit

within two weeks of sending in the application call the Board and check on the status (804)-367-4456. All pharmacy permits expire on 4/30 annually. Be sure that the permit is renewed each year.

- A PIC is required to be in "full and actual charge of the pharmacy" and "fully engaged in the practice of pharmacy at the location designated on the application". Never agree to sign a pharmacy permit application as PIC unless you intend to meet the requirement of being fully engaged in practice at that pharmacy. There is no minimum number of hours established to define "fully engaged etc."
- Take an incoming change of PIC inventory of all Schedule II – V controlled substances on the date you first engage in business as the PIC. Sign and date the inventory and indicate whether the inventory was taken prior to the opening of business or after close of business that day. For a 24-hour pharmacy with no opening or closing of business, you must clearly document whether the receipt or distribution of drugs on the inventory date occurred before or after the inventory was taken. If the pharmacy is a new pharmacy and you have no drugs on hand on opening date, you still "take" an inventory, and record a zero balance.
- Verify that every pharmacist working at your pharmacy holds a current license to practice pharmacy. Licensure can be verified by using the "license lookup" function on the Board's website at www.dhp.virginia.gov/pharmacy, calling the Board at (804) 367-4456, or if you know the license number or social security number of the individual, you may call (804) 270-6836 for automated verification.
- Verify via the methods listed in the previous item that every pharmacy technician working at your pharmacy holds a current registration, or that there is documentation on site showing enrollment in a Board approved training program for not more than 9 months.
- You are responsible for ensuring that the practice of pharmacy is in overall compliance with laws and regulations. You are not responsible for individual actions of practicing pharmacists. It is **strongly** recommended that you perform a routine self-inspection of the pharmacy using the most current pharmacy inspection report which may be downloaded from http://www.dhp.virginia.gov/Enforcement/enf_guidelines.htm. You should review pharmacy security equipment and procedures to ensure that they meet requirements, such as functional locks on enclosures, functional alarm systems, and access to keys and alarm restricted to pharmacists practicing at the location, including any emergency key kept in compliance with current regulations. Routinely check the refrigerator and freezer to ensure that there is a working thermometer placed within and that they are maintained at the required temperatures- between 36° and 46°F for refrigerators and between -4° and 14°F for freezers. Also review record keeping systems to make sure they meet current requirements and that staff pharmacists are aware of their responsibilities. Additionally, you should review the list of deficiencies that may result in a monetary penalty identified in guidance document 110-9 found at http://www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm. You may choose to create a folder or notebook containing all required inventories, along with information indicating the location of all required documents for an inspector to review. This will ensure that all staff, even floater staff who may be on duty at the time of an unannounced inspection, know where to locate the required documents. Performing a self-inspection and staying organized will assist in identifying areas of non-compliance for which you should correct and will prevent the unnecessary citing of deficiencies.
- Notify the Board of any theft or unusual losses of drugs as soon as discovered. Within 30 days after the discovery of such theft or loss, furnish the Board with a listing of the kind, quantity and strength of such drugs lost. Maintain this listing for two years from the date of the transaction recorded.
- Notify the Board of any known violation of law or regulation on the part of another individual in your pharmacy or of any inability to have known deficiencies corrected.

Upon leaving as PIC:

- Although not required by law or regulation, you have the right to take an outgoing change of pharmacist-in-charge inventory of all Schedule II-V controlled substances unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed. If you so take one, you should take a copy with you. Once you leave, you cannot ensure that the pharmacy will maintain it, and this inventory is your documentation of what drugs were on hand when you left if there is a subsequent diversion. If you request but are denied an opportunity to take this inventory, you should immediately report this to the Board.
- As you terminate your position as PIC, remove the pharmacy permit and return it directly to the Board office indicating the effective date of the termination of the PIC position. Do not leave it on the wall. Do not return it to a corporate or district office or a district manager. It is your permit and your responsibility to return it to the Board immediately. For your protection, we would suggest that you return it by certified mail, return receipt requested.



W. Scott Johnson
Ext. 416
sjohnson@hdjn.com

JUL 30 2010
DHP

Caroline D. Juran
Deputy Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

RE: September 8 Board of Pharmacy Meeting

Dear Caroline:

I very much appreciate you and Scotti meeting with us on behalf of Allergan on July 12 to discuss the issues surrounding physician dispensing of topical drugs prescribed for aesthetic purposes.

In follow up to our meeting we would ask that this issue be included on the agenda for the September 8th Board meeting. I plan to attend, along with representatives from Allergan. If you or the Board have any questions or require any additional information in advance of the meeting, please do not hesitate to contact me.

I look forward to working with you and the Board on this matter.

Very truly yours,

W. Scott Johnson

WSJ/tsc

cc: Pat Cannon, RN, Allergan, Inc.
Tyler Cox, Hancock, Daniel, Johnson & Nagle, PC

DM#287240

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§ 54.1-2400. General powers and duties of health regulatory boards.

The general powers and duties of health regulatory boards shall be:

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.
2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.
3. To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.
4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.
5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.
6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title.
7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license or multistate licensure privilege which such board has authority to issue for causes enumerated in applicable law and regulations.
8. To appoint designees from their membership or immediate staff to coordinate with the Director and the Health Practitioners' Monitoring Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.
9. To take appropriate disciplinary action for violations of applicable law and regulations, and to accept, in their discretion, the surrender of a license, certificate, registration or multistate licensure privilege in lieu of disciplinary action.
10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, or, when required for special conference committees of the Board of Nursing, not less than one member of the Board and one member of the relevant advisory board, to act in accordance with § 2.2-4019 upon receipt of information that a practitioner of the appropriate board may be subject to disciplinary action. The special conference committee may (i) exonerate the practitioner; (ii) reinstate the practitioner; (iii) place the practitioner on probation with such terms as it may deem appropriate; (iv) reprimand the practitioner; (v) modify a previous order; and (vi) impose a monetary penalty pursuant to § 54.1-2401. The order of the special conference committee shall become final 30 days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 2.2-4020, and the action of the committee shall be vacated. This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in

accordance with § 2.2-4019, upon receipt of information that a practitioner may be subject to a disciplinary action. The recommendation of such subordinate may be considered by a panel consisting of at least five board members, or, if a quorum of the board is less than five members, consisting of a quorum of the members, convened for the purpose of issuing a case decision. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.

11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 2.2-4020, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 2.2-4019 shall serve on a panel conducting formal proceedings pursuant to § 2.2-4020 to consider the same matter.

12. To issue inactive licenses or certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of licenses or certificates.

13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.

14. To request and accept from a certified, registered or licensed practitioner or person holding a multistate licensure privilege to practice nursing, in lieu of disciplinary action, a confidential consent agreement. A confidential consent agreement shall be subject to the confidentiality provisions of § 54.1-2400.2 and shall not be disclosed by a practitioner. A confidential consent agreement shall include findings of fact and may include an admission or a finding of a violation. A confidential consent agreement shall not be considered either a notice or order of any health regulatory board, but it may be considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the practitioner. A board shall not enter into a confidential consent agreement if there is probable cause to believe the practitioner has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public. A certified, registered or licensed practitioner who has entered into two confidential consent agreements involving a standard of care violation, within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered, shall receive public discipline for any subsequent violation within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public.

15. When a board has probable cause to believe a practitioner is unable to practice with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the board, after preliminary investigation by an informal fact-finding proceeding, may direct that the practitioner submit to a mental or physical examination. Failure to submit to the examination shall constitute grounds for disciplinary action. Any practitioner affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice with reasonable skill and safety to patients. For the purposes of this subdivision, "practitioner" shall include any person holding a multistate licensure privilege to practice nursing.

(1988, c. 765; 1992, cc. 659, 890; 1997, cc. 439, 564; 1998, c. 469; 2002, cc. 455, 698; 2003, cc. 753, 762; 2004, cc. 49, 64; 2009, cc. 472, 534; 2010, c. 414.)

18 VAC 110-20-15. Criteria for delegation of informal fact-finding proceedings to an agency subordinate.

A. Decision to delegate. In accordance with § 54.1-2400 (10) of the Code of Virginia, the board may delegate an informal fact-finding proceeding to an agency subordinate upon determination that probable cause exists that a practitioner may be subject to a disciplinary action.

B. Criteria for delegation. Cases that may not be delegated to an agency subordinate, except as may be approved by a committee of the board, include those that involve:

1. Intentional or negligent conduct that causes or is likely to cause injury to a patient;
2. Drug diversion;
3. Impairment with an inability to practice with skill and safety;
4. Indiscriminate dispensing; and
5. Medication error in administration or dispensing.

C. Criteria for an agency subordinate.

1. An agency subordinate authorized by the board to conduct an informal fact-finding proceeding may include board members and professional staff or other persons deemed knowledgeable by virtue of their training and experience in administrative proceedings involving the regulation and discipline of health professionals.
2. The executive director shall maintain a list of appropriately qualified persons to whom an informal fact-finding proceeding may be delegated.
3. The board may delegate to the executive director the selection of the agency subordinate who is deemed appropriately qualified to conduct a proceeding based on the qualifications of the subordinate and the type of case being heard.

Juran, Caroline (DHP)

From: Juran, Caroline (DHP)
Sent: Monday, August 23, 2010 2:15 PM
To: Parrish, Roland (VDH)
Subject: RE: Proposed VDH legislation re: EPT

Craig,

The Department does not have a position on the bill, but the Executive Directors of both the Board of Pharmacy and the Board of Medicine strongly suggest that the attached language be used rather than the language in the draft.

Please let me know if you wish to discuss this issue.

PROPOSED LANGUAGE:

§ 54.1-3303 (subsection C)

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) *when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, serious disability, or the transmission of chlamydia or gonorrhea.*

Caroline D. Juran
Acting Executive Director
Virginia Board of Pharmacy
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

(804) 367-4456
(804) 527-4472 FAX
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From: Parrish, Roland (VDH)
Sent: Friday, August 20, 2010 1:21 PM
To: Juran, Caroline (DHP)
Cc: Henry, Theresa (VDH); Hafford, Kathryn (VDH)
Subject: Proposed VDH legislation re: EPT

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Caroline,

Below is proposed legislation that VDH intends on introducing in this years GA. Scottie and I talked about this over a year ago and she indicated that she did not think the BOP would oppose such legislation if worded appropriately. Please take a look at this and I will call you next week to discuss. Have a nice weekend!

Thanks,
Craig

Expedited Partner Therapy

BACKGROUND: In 2006, the Centers for Disease Control and Prevention (CDC) recommended Expedited Partner Therapy (EPT) as a viable option for partner management of sexually transmitted diseases. The CDC defines EPT as “the practice of treating the sex partners of persons with sexually transmitted disease (STD) without an intervening medical evaluation or professional prevention counseling”. Although EPT is not the “gold standard of care”, it is an innovative treatment option that can be utilized. EPT has been shown to decrease costs, prevent re-infection, and reduce disease transmission. The American Medical Association (AMA) has supported the CDC’s stance on EPT and has worked with them in developing tools for local health departments and health care professionals to implement this type of therapy. EPT is legal in 22 states. The Virginia Board of Pharmacy will likely support the Bill, as will a few STD Clinic Medical Directors that have already indicated a willingness to implement EPT. We have not approached the Medical Society of Virginia because we wanted to know first whether the agency was interested in pursuing this legislation.

PROPOSED LANGUAGE:

§ 54.1-3303 (subsection C)

C. Notwithstanding any provision of law to the contrary and consistent with recommendations of the Centers for Disease Control and Prevention or the Department of Health, a practitioner may prescribe Schedule VI antibiotics and antiviral agents to other persons in close contact with a diagnosed patient when (i) the practitioner meets all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, with the diagnosed patient; (ii) in the practitioner's professional judgment, the practitioner deems there is urgency to begin treatment to prevent the transmission of a communicable disease; (iii) the practitioner has met all requirements of a bona fide practitioner-patient relationship, as defined in subsection A, for the close contact except for the physical examination required in clause (iii) of subsection A; and (iv) when such emergency treatment is necessary to prevent imminent risk of death, life-threatening illness, or serious disability. *Clause (iv) of this subsection will not apply if the practitioner prescribes Schedule VI antibiotics for contacts of patients diagnosed with chlamydia or gonorrhoea.*

§ 54.1-2507. Board of Health Professions; membership, appointments, and terms of office.

The Board of Health Professions shall consist of one member from each health regulatory board appointed by the Governor, and five members to be appointed by the Governor from the Commonwealth at large. No member of the Board of Health Professions who represents a health regulatory board shall serve as such after he ceases to be a member of a board. The members appointed by the Governor shall be subject to confirmation by the General Assembly and shall serve for four-year terms.

(1977, c. 579, § 54-951; 1985, c. 448; 1986, c. 564; 1988, c. 765.)

§ 54.1-2508. Chairman; meetings of Board; quorum.

The chairman of the Board of Health Professions shall be elected by the Board from its members. The Board shall meet at least once quarterly and may hold additional meetings as necessary to perform its duties. A majority of the Board shall constitute a quorum for the conduct of business.

(1977, c. 579, § 54-953; 1980, c. 678; 1986, c. 564; 1988, c. 765.)

§ 54.1-2509. Reimbursement of Board members for expenses.

All members of the Board shall be compensated in accordance with § 2.2-2813 from the funds of the Department.

(1977, c. 579, § 54-954; 1980, cc. 678, 728; 1986, c. 564; 1988, c. 765.)

§ 54.1-2510. Powers and duties of Board of Health Professions.

The Board of Health Professions shall have the following powers and duties:

1. To evaluate the need for coordination among the health regulatory boards and their staffs and report its findings and recommendations to the Director and the boards;
2. To evaluate all health care professions and occupations in the Commonwealth, including those regulated and those not regulated by other provisions of this title, to consider whether each such profession or occupation should be regulated and the degree of regulation to be imposed. Whenever the Board determines that the public interest requires that a health care profession or occupation which is not regulated by law should be regulated, the Board shall recommend to the General Assembly a regulatory system to establish the appropriate degree of regulation;
3. To review and comment on the budget for the Department;
4. To provide a means of citizen access to the Department;
5. To provide a means of publicizing the policies and programs of the Department in order to educate the public and elicit public support for Department activities;
6. To monitor the policies and activities of the Department, serve as a forum for resolving conflicts among the health regulatory boards and between the health regulatory boards and the Department and have access to departmental information;
7. To advise the Governor, the General Assembly and the Director on matters relating to the regulation or deregulation of health care professions and occupations;

8. To make bylaws for the government of the Board of Health Professions and the proper fulfillment of its duties under this chapter;
9. To promote the development of standards to evaluate the competency of the professions and occupations represented on the Board;
10. To review and comment, as it deems appropriate, on all regulations promulgated or proposed for issuance by the health regulatory boards under the auspices of the Department. At least one member of the relevant board shall be invited to be present during any comments by the Board on proposed board regulations;
11. To review periodically the investigatory, disciplinary and enforcement processes of the Department and the individual boards to ensure the protection of the public and the fair and equitable treatment of health professionals;
12. To examine scope of practice conflicts involving regulated and unregulated professions and advise the health regulatory boards and the General Assembly of the nature and degree of such conflicts;
13. To receive, review, and forward to the appropriate health regulatory board any departmental investigative reports relating to complaints of violations by practitioners of Chapter 24.1 (§ 54.1-2410 et seq.) of this subtitle;
14. To determine compliance with and violations of and grant exceptions to the prohibitions set forth in Chapter 24.1 of this subtitle; and
15. To take appropriate actions against entities, other than practitioners, for violations of Chapter 24.1 of this subtitle.

(1977, c. 579, § 54-955.1; 1980, c. 678; 1984, cc. 447, 720, 734; 1986, c. 564; 1988, c. 765; 1993, c. 869.)