# COMMONWEALTH OF VIRGINIA

# Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

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## Tentative Agenda of Full Board Meeting

*September 9, 2014*

**9:00AM**

- Excerpt of 2007 Minutes regarding Board Decision to Allow Use of Stamps for Pharmacists' Initials 78-79
- Concerns for Pharmacy Work Flow Interruptions when Administering Flu Shots 80-81
  - Background materials provided by staff:
    - Excerpt of May 2012 Minutes regarding Pharmacy Working Conditions and "System Induced Errors" 82-84
    - Excerpt of June 2012 Minutes regarding Working Conditions and "System Induced Errors" 85-86
    - Excerpt of 2013 Board E-newsletter regarding Concern for Contemporary Practice 87-88
- Guidance Requested for Security Systems Transitioning from 2G to 4G and if it Necessitates Submission of Remodel Inspection 89-92
- Request from VDH for Guidance for Accessing Alternate Delivery Drugs 93-95
- Set Dates for 2015 Full Board and Tentative Regulation Committee Meetings 96

**Reports:**

- DHP Director's Report - David Brown, DC
- Chairman's Report – Ellen B. Shinaberry
  - Report on Board of Health Professions Handout
- Report on Compounding Workgroup –Jody H. Allen
- Report on Planning of NABP/AACP Districts 1&2 Meeting – Cindy Warriner
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day
- Executive Director's Report –Caroline D. Juran
  - Report on Process to be Used to Schedule Drugs in Consultation with DFS 97-98
  - Report on Recent DEA Action to Schedule tramadol and Reschedule Hydrocodone Combination Products

**Consideration of consent orders, if any, and possible summary suspensions**

**Adjourn**

******The Board will have a working lunch at approximately 12pm ******

******A panel of the Board of Pharmacy will convene at 2pm or immediately following adjournment of the meeting, whichever is later.******

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF INFORMAL CONFERENCE COMMITTEE REVIEW OF INNOVATIVE PILOT APPLICATION

June 3, 2014
Second Floor
Training Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:10PM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT: Jody H. Allen

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager

SENTARA VIRGINIA BEACH GENERAL HOSPITAL: The purpose of the informal conference was to act upon the Application of Sentara Virginia Beach General Hospital for approval of an innovative (pilot) program ("Application") to utilize "Radio Frequency Identification Tagging for Pharmacy Kit Processing." Richard Lee Grasmick, PIC at Sentara Virginia Beach General Hospital; Tegan Williams, Team Coordinator at Sentara Virginia Beach General Hospital; and, Tim Kress-Spatz, CTO with Kitcheck appeared in person at the informal conference.

CLOSED MEETING: Upon a motion by Ms. Allen and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to Section 2.2-3711 (A)(7) of the Code of Virginia for the purpose of briefing by staff members pertaining to probable litigation and to act upon the application for approval of an Innovative (pilot) program for Sentara Virginia Beach General Hospital to utilize "Radio Frequency Identification Tagging for Pharmacy Kit Processing." Additionally, she moved that Caroline D. Juran, J. Samuel Johnson, Jr., and Beth O'Halloran 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 §2.2-3711 of the Code, the Committee re-convened in open meeting and announced the decision.

DECISION: Ms. Shinaberry announced the committee's decision to approve the innovative (pilot) program for a period of one (1) year. The following terms and conditions also apply and were read by Ms. Juran:

1. Pharmacists shall perform and document 100% verification of the accuracy for the kit and drug radio frequency identification (RFID) tagging processes and addition of new drugs into the RFID software tagging system. Documentation of this check shall include the pharmacist's initials for each kit and drug tagged and each new drug added into the RFID software tagging system and

a description of all discrepancies found;

2. Pharmacists shall perform a daily random check for verification of the accuracy of 5.0% of all kits prepared that day utilizing the RFID technology. Documentation of this check shall include the pharmacist's initials for each kit checked and a description of all discrepancies found;
3. The requirement in Regulation 18VAC110-20-490 C for the delivery record to include the initials of the pharmacist checking the drugs to be removed from the pharmacy shall be waived for the kits prepared using RFID technology;
4. The requirement in Regulation 18VAC110-20-460 A for a pharmacist to check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy shall be waived for the kits prepared using RFID technology;
5. The requirement in Regulation 18VAC110-20-355A for a pharmacist to verify the repackaging shall be waived for those kits prepared using RFID technology;
6. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.;
7. The innovative (pilot) program 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. Sentara Virginia Beach General Hospital shall be solely responsible for the payment of an inspection fee of $150.00 to be paid to the Board within thirty days from the date of the statement of monies owed which will be mailed following the inspection;
8. Quarterly reports shall be submitted to the Board identifying the number of kits prepared using the RFID technology, number of kits verified by a pharmacist under the 5% check requirement, duration of any downtime in the use of the technology other than for routine maintenance, and a description of any errors identified in using the RFID technology. Such reports shall be submitted in March, June, September, and December;
9. Errors resulting from the use of the RFID technology to prepare kits shall be immediately reported to the Board;
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 significant errors or other problems, or failure to comply with the terms and conditions described 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: The meeting adjourned at approximately 3:50PM.

Ellen Shinaberry, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

RA

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# PUBLIC HEARING FOR REGULATIONS REGARDING ADMINISTRATIVE FEES FOR DUPLICATE LICENSES AND VERIFICATION

June 4, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:05 AM.

PRESIDING: Jody H. Allen, Chairman

MEMBERS PRESENT:
Crady R. Adam
Ryan K. Logan
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT: Dinny Li

STAFF PRESENT:
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David E. Brown, D.C., Director, DHP
Jamie Hoyle, Deputy Director, DHP
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

STAFF ABSENT: Caroline D. Juran, Executive Director

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

CALL FOR COMMENT: Ms. Allen called for comment on the proposed regulations for administrative fees for duplicate licenses and verification. There was no public comment received at this time.

Ms. Allen stated that written comments may be submitted to Town Hall or to Caroline Juran, Executive Director, Board of Pharmacy, until July 18, 2014. Final regulations will be adopted at the September 9, 2014 full board meeting.

ADJOURN: The public hearing adjourned at 9:10am..

Jody H. Allen, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF BOARD MEETING

June 4, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT:
Crady R. Adams
Dinny Li (arrived at 9:12am)
Ryan K. Logan
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director (arrived at 10:16am)
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
David E. Brown, D.C., Director, DHP
Jamie Hoyle, Deputy Director, DHP.
James Rutkowski, Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

APPROVAL OF AGENDA: Staff presented a final amended agenda which included a set of additional minutes from the May 12, 2014 Regulation committee meeting. The final amended agenda was approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the March 25, 2014 (Informal Conference Committee-Innovative Pilot Application), March 26, 2014 (Full Board Meeting), April 22, 2014 (Panel Formal Hearing), April 24, 2014 (Special Conference Committee), May 6, 2014 (Informal Conference Committee- Innovative Pilot Application and May 12, 2014 (Regulation Committee). A change was made to the April 22, 2014 Panel Formal Hearing, on pages 23-24 to correct the spelling of the name "Shiliessmann" to "Schliessmann". Corrections were also made to page 33A of the May 12, 2014 Regulation committee minutes to change



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"Prince William County" to "Northern Virginia", "county" on line 7 to "region" and "645" to "644".

**MOTION:**

**The Board voted unanimously to approve the minutes as amended. (motion by Warriner, second by Rhodes)**

PUBLIC COMMENTS:

Battalion Chief Jennie Collins with the Prince William County Department of Fire and Rescue thanked the Board for its time and assistance in amending Regulation 18VAC 110-20-500 regarding EMS agencies. She stated that Northern Virginia EMS Council is in favor of the proposed draft regulations and wants the Board to consider fast-tracking. Gill Abernathy, Pharmacy Manager for Inova Health System, stated that they also approve of the changes and would like the regulations to be fast-tracked as well. Tim Musselman, Executive Director, Virginia Pharmacist Association (VPhA), addressed the Board regarding compounding issues and offered the assistance of the VPhA Compounding Workgroup. He also stated that he has recently provided 15 law updates across Virginia. Devin Boerm with Healthcare Distribution Management Association offered comment on the draft legislative proposal in the agenda packet to require wholesale distributors to notify the Board when they cease or restrict distribution of prescription drugs based on suspicious activity. She stated that while they agreed with the process, some of the language may need to be amended and that she was going to work with some members to draft a formal letter to Ms. Juran with some possible changes that could help improve the language.

DHP DIRECTOR'S REPORT:

Dr. Brown introduced to the Board Jamie Hoyle, newly-appointed Chief Deputy Director for the Department of Health Professions (DHP). He stated that agency-wide training for employees was held May 14th and May 15th; new Board member orientation and training will be scheduled for September. Dr. Brown reported that DHP is working with the National Governor's Association (NGA), Veterans Policy Academy regarding a pilot program that will assist veterans in crossing over to civilian jobs and finding ways to utilize the training they previously received in the military. Dr. Brown reported that he was invited to participate in the Medical Examiner's Office Strategic Planning.

REPORTS

- Chairman's report

Ms. Allen reported that the National Association of Boards of Pharmacy (NABP) has elected a new president, Joseph Adams, and reminded members to submit their letter of interest by June 6, 2014 if they wished to participate on an upcoming NABP committee or

taskforce. She reported that the current dean of the VCU School of Pharmacy, Victor Yanchick is retiring on July 1, 2014 and Joseph DiPiro will be taking his place. Ms. Allen expressed her thanks to the board and staff for all of their hard work and dedication during her time as Chairman. This is her last Board meeting serving as chairman and her first term as a board member expires June 30, 2014. She also recognized David Kozera, former board member and Howard Casway, former Assistant Attorney General who served several years as board counsel.

- Report on Board of Health Professions:

Mr. Rhodes gave praise to the Board of Health Professions for the monumental job that they have done with the workforce surveys and the licensee data. He stated that he has completed another year serving on the Board of Health Professions and that it has been a great experience.

- Report on Planning of NABP/AACP Districts I & II Meeting:

Ms. Warriner gave an update on the planning for the NABP/AACP Districts I & II meeting being held in Williamsburg, Virginia. The dates are October 5, 2014 through October 7, 2014. Ms. Warriner stated that all of the speakers have been arranged and confirmed, approval has been received for continuing education credit for several of the topics, and that Ms. Juran, Sean Bates, and she have met with staff of the Williamsburg Lodge to plan the food and entertainment. She stated that the information about the District I & II meeting was well received at the NABP Annual meeting that was held in May in Phoenix, Arizona. Ms. Warriner thanked all of the board members that have been contributing to the planning such as Ms. Munden who has been working on the gift bags to give all of the attendees. There will be at least 13 boards of pharmacy and 40 schools of pharmacy that will be attending the meeting. Ms. Warriner stated that it is hoped that all of our board members will attend. She also extended the invitation to any pharmacy student who is interested in attending.

- Report on Prescription Monitoring Program:

Mr. Orr updated the Board with current information regarding the Prescription Monitoring Program (PMP). In September 2013, the PMP celebrated 10 years of being active in Virginia. Mr. Orr stated that 1.3 million requests were received in the year 2013. He reported that to date, 4,831 of the 7,818 current active pharmacists in Virginia are registered users of the PMP. Data collected just for the month of May showed there had been 142,407 requests alone and the total so far this year is around 700,000. Mr. Orr also stated that new legislation, effective July 1, 2014, will require dispensers to report the dispensing of "drugs of concern" to the PMP. The legislation specifically identified tramadol as a drug of concern which must be reported. There is also legislation, effective July 1,



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2014, that has passed to allow pharmacists to use delegates to make requests to the PMP for prescription histories.

- Report on Licensure Program:

Mr. Johnson reported the board issued 1,159 licenses and registrations for the period of March 1, 2014 through May 31, 2014, including 127 pharmacists, 256 pharmacy interns, and 574 pharmacy technicians. Mr. Johnson updated the Board about that the renewal process for nonresident pharmacies. Of the 554 nonresident pharmacies due to renew by April 30, 2014, 458 were successfully renewed, 45 were not renewed due to missing or incomplete documentation, and 51 have not applied for renewal. Inspectors conducted 495 facility inspections including 245 routine inspections of pharmacies and resulted in the following: 85 (35%) inspections resulted in no deficiency; 72 (29%) inspections resulted in cited deficiencies but no monetary penalty; and, 88 (36%) inspections resulted in cited deficiencies and a consent order. This is the second consecutive quarter where deficiencies and a consent order have been below 40%. This may be attributed to amendments made to Guidance Document 110-9 at the December 12, 2013 Board meeting that modified several major deficiencies and established new minor deficiencies. Mr. Johnson reviewed the summary report of the major & minor inspection deficiencies cited over the last several quarters. A new column has been added to the report to identify when a pharmacy is cited for a "repeat" deficiency. The report identified six major and eleven minor "repeat" deficiencies. Mr. Johnson also introduced a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with a handout and discussed the results from the third quarter of the DHP Patient Care Disciplinary Case Processing Times.

Further, she provided the board with a handout and discussed the board's Open Disciplinary Case Report comparing the case stages between the four report dates of September 9, 2013; December 10, 2013; March 25, 2014; and June 3, 2014. As of June 3, 2014, there are 71 cases at the investigation stage, 74 at the probable cause stage, 13 at the administrative proceedings division stage, 21 at the informal hearing stage, one at the formal hearing stage, and 116 at the pending closure stage.

- Executive Director's Report:

Mr. Johnson gave the Executive Director's Report on behalf of Ms. Juran since she was unable to attend this portion of the meeting. Mr. Johnson stated that Ms. Juran, Ms. Warriner, Mr. Rhodes, and former Board member Leo Ross attended the NABP Annual Meeting in Phoenix, Arizona, May 17th through May 22nd. Program topics included presentations on: Title II of the Drug Quality and Security Act, compounding and outsourcing facilities, medical marijuana, physician dispensing and pharmacist compounding in a physician's office, and medication synchronization. Resolutions that were passed included: collaborating with federal and state agencies regarding policies surrounding the illegal importation of prescription drugs, convening a task force to examine strategies for preventing and reacting to pharmacy robberies and thefts, reaffirming NABP's existing policy to encourage pharmacies to stop selling tobacco products and work towards a smoke-free society, convening a task force to develop standards to ensure regular, consistent and appropriate use of prescription monitoring program (PMP) data as well as facilitating cooperation between state PMPs, NABP PMP InterConnect®, other health care entities, and state health data exchanges, encouraging the development and availability of veterinary pharmacology education to ensure the competence of pharmacists dispensing medication for veterinary patients, and supporting the Food and Drug Administration and appropriate state agencies regarding the regulation of electronic cigarettes and liquid nicotine products. Joe Adams, former Louisiana Board member, took office as the newly elected President of the NABP. The Virginia Pharmacists Association (VPhA) has requested that staff provide a law update and host a question and answer session at the upcoming VPhA annual meeting in Virginia Beach this August. Additionally, approval will be sought in order to take one or two inspectors to the meeting to discuss the routine inspection process with a focus on explaining the type of information that is reviewed during a routine inspection and how compliance or non-compliance is determined. On March 25th, Ms. Juran provided a presentation to the students of Shenandoah College of Pharmacy. She was also recently re-elected vice-chairman of the Forensic Sciences Board. Mr. Johnson stated that he, Ms. Juran and Ms. O'Halloran will be seeking approval to attend a training session on USP chapters <797> and <795> offered by USP at their headquarters in Maryland in July.

**NEW BUSINESS:**

- Summary of Healthcare Workforce Surveys:

Dr. Elizabeth Carter, Executive Director and Justin Crow, Deputy Executive Director for the Board of Health Professions gave a summary to the Board of the recent pharmacist and pharmacy technician healthcare workforce surveys. Dr. Carter stated that the Board of Pharmacy's licensees were a growing population and has a large group of practitioners with a broader insurance coverage. In 2007, the Governor stated that a healthcare workforce needs to be created in order to track the supply and demand of licensure at the state level and determine a way to collect this data and ensure confidentiality of the practitioner. A standard template was created for all boards and the surveys are attached to new applications and renewals to gather practitioner information. Mr. Crow stated that the survey respondents represent 82% of the 12,732 pharmacists who are licensed in the state, 70% of the 14,262 pharmacy technicians registered in the state and 91% of renewing practitioners. Mr. Crow reported that 62% of the pharmacists are female and 71% are under 40 female. Eighty-four percent of pharmacy technicians are female and the median age of all pharmacy technicians is 34. In the data collected, it was also noted that 36% of pharmacists carry educational debt with the median debt between $90,000 and $100,000. There is a high percentage of employment satisfaction and low turnover. It was also determined based off the gathered information a majority of the practice was related to patient care and dispensing with a small portion being administrative. Regarding age of workforce, pharmacists and pharmacy technicians are overall younger than other healthcare professionals. The expected timeframe for retirement for one-half of the pharmacist workforce is estimated by 2038 and for one-half of the pharmacy technicians by 2043. Mr. Crow also discussed the standard survey template that is used for most professions, streamline data process and different data products used to collect information for the reports. Dr. Carter thanked the board and its licensees for participating in their surveys. The board requested adding to the survey a means for discerning if a pharmacy technician is a pharmacy student.

**OLD BUSINESS:**

Dr. Brown discussed with the Board his decision regarding the request from the March 26, 2014 board meeting for inspectors to give pharmacies a 24-hour notice for routine inspections. He acknowledged that this was not a small decision and that he had researched the matter. During his research of several other state agencies, he learned that none conduct announced inspections. Dr. Brown commented that providing notice, even short notice, may compromise the inspector's ability to identify non-compliance with

certain requirements such as unauthorized access to the prescription department or pharmacist to pharmacy technician ratio. Additionally, providing longer notice does not appear to offer a more efficient inspection process as it is unlikely that additional pharmacy staff will be routinely scheduled for the 3 months in which an inspection could randomly be performed. Dr. Brown stated that the goal of an inspection program is not to catch someone doing something they shouldn't, but to create a culture of compliance. He stated that communication is important for ensuring the licensees know what to expect during an inspection and that we may need to create a better system of communication and utilize the assistance of the associations for solutions.

REGULATORY ACTIONS:

- Regulatory Update:

Ms. Yeatts reviewed the update of the board's current regulatory actions found on page 34 of the agenda packet. The public hearing for the proposed regulations for administrative fees for duplicate licenses and verifications was held prior to this morning's board meeting and the comment period ends July 16, 2014. The board will adopt the final regulations on September 9, 2014. Ms. Yeatts stated that final regulations for continuous quality improvement programs are scheduled to be adopted by the board during today's meeting. The proposed regulations for addressing hours of continuous work by pharmacist is currently at the Secretary's office and has been there for 381 days. Fast-tracked regulations regarding floor stock for correctional facilities is at the Department of Planning and Budget and the final regulations governing collaborative practice agreements has a register date of March 24, 2014 with an Errata published on May 19, 2014.

REPORT FROM REGULATORY COMMITTEE:

- Continuous quality improvement programs

The Regulation committee recommended that the board amend the definition for "dispensing error" in Regulation 18VAC110-20-10 by adding "regardless of whether the patient received the drug" following the words "final verification by the pharmacist" and to adopt the proposed emergency regulations for continuous quality improvement programs as amended.

**MOTION:**

**The Board voted unanimously to amend the definition for "dispensing error" in Regulation 18VAC110-20-10 by adding "regardless of whether the patient received the drug" following the words "final verification by the pharmacist" and to adopt the proposed emergency regulations for continuous quality improvement programs as amended.**

- Reconsideration of a fast-track regulation on EMS:

The Regulation Committee recommended that the board adopt the proposed changes to the EMS regulations and requested that they be fast-tracked. The amendments to the regulation would allow for an EMS agency to conduct a 1 for 1 exchange for schedule VI drugs or devices. Ms. Juran suggested a change in the language on page 60 under section 6, line 4, to add the wording "by the pharmacy".

**MOTION:**

**The Board voted unanimously to adopt the change that was suggested by Ms. Juran to add the wording "by the pharmacy" on page 60, section 6, line 4. (motion by Stelly, second by Warriner)**

Battalion Chief Jennie Collins with Prince William County Department of Fire and Rescue and Sam Dahl, Director of the Northern Virginia EMS Council requested that the Board consider suggested language on page 58 under 18VAC 110-20-500, section A, number 2 to add the wording "theft and loss" after "and aid in detection". Also, changes were suggested on page 61 under section B to add at the end of the sentence "provided that the schedule II, III, IV and V drugs are in a separate, sealed container".

**MOTION:**

**The Board voted unanimously to adopt the amended language on page 58 that adds the wording "theft or loss" and on page 60 that adds "provided that the schedule II, III, IV and V drugs are in a separate, sealed container". (motion by Shinaberry, second by Warriner)**

**MOTION:**

**The Board voted unanimously to adopt the proposed regulations for EMS agencies as fast-track regulations as recommended by the Regulation committee and amended by the board. (motion by Stelly, second by Rhodes)**

- Adoption of NOIRA prohibiting the offering of incentives or inducements to transfer prescriptions:

Ms. Yeatts reminded the members of the petition for rule-making that was submitted by Daniel Colpo requesting that the Board amend regulations in order to prohibit the offering of incentives or inducements that would entice patients to transfer their prescriptions. The board had denied the petition for rulemaking at the March 2014 full board meeting, but referred the matter to the Regulation Committee for further consideration.

**MOTION:**

**The Board voted unanimously to adopt a Notice of Intended Regulatory Action (NORIA), as recommended by the Regulation Committee, that would prohibit the offering of incentives or inducements to transfer prescriptions. (motion by**

**Shinaberry, second by Adams)**

DRAFT LEGISLATIVE PROPOSALS:

Ms. Yeatts reviewed the draft legislative proposals for the Board to consider and adopt. Ms. Yeatts stated that the legislative proposals need to be at the Secretary's office by the second week of September from which it will go to the Governor's office. The draft proposed legislation include: the addition of alfaxalone to schedule IV in the Drug Control Act for consistency with federal rule, the authority for the Board to issue permits to facilities for physicians selling drugs, requirements for wholesale distributors to notify the board if they cease distribution to a licensed dispenser for suspicious orders, authority for pharmacists to possess and administer epinephrine and oxygen, and the creation of a new licensing category, "outsourcing facilities", for large sterile compounding operations that predominantly compound for hospitals or medical practices for office administration. The Regulation Committee recommended the board adopt all of the proposed legislative proposals.

**MOTION:** **The Board voted unanimously to approve the draft legislative proposal for placing alfaxalone into Schedule IV of the Drug Control Act and to include any other drug in the proposal which may be scheduled federally prior to the 2015 General Assembly session so to conform state scheduling with federal scheduling. (motion by Warriner, second by Stelly)**

**MOTION:** **The Board voted unanimously to approve the draft legislative proposal for the authority to issue permits to facilities for practitioners of the healing arts to sell controlled substances. (motion by Warriner, second by Li)**

**MOTION:** **The Board voted unanimously to approve the draft legislative proposal that would give pharmacists the authority to possess and administer epinephrine and oxygen. (motion by Warriner, second by Adams)**

The Board discussed the draft legislative proposal for the requirement for wholesale distributors to notify the board if they cease or restrict the distribution to a licensed dispenser for suspicious ordering. Staff shared highlights of its recent discussions with HDMA and a member of the association. Based on some concerns expressed during those discussions, staff suggested that it consider the draft legislative proposal on the handout that was disseminated during the meeting which strikes the requirement to notify the Virginia State Police and the requirement to notify the board of restrictions on distributions.

**MOTION:**

**The Board voted unanimously to adopt the legislative proposal as provided on the handout which would require wholesale distributors to notify the Board of Pharmacy when it ceases distribution of prescription drugs to a dispenser for suspicious activity and directed staff to send the proposal out to stakeholders for further comment. (motion by Warriner, second by Stelly)**

While the Regulation Committee did not take action on whether the board should prohibit compounding human drugs for office administration, the board discussed a presentation provided at the NABP annual meeting in May which confirmed FDA's position that federal law prohibits pharmacies from compounding human drugs for office-use. Ms. Juran and Ms. Warriner indicated that it appears the board should consider prohibiting this activity as it has become clearer that federal law does not allow pharmacies to compound human drugs for office administration. Any organizations disagreeing with the FDA position would likely need to resolve the matter in court.

**MOTION:**

**The Board voted unanimously to adopt the legislative proposal to create new licensing categories for "outsourcing facilities" as recommended by the Regulation Committee and to include language which would prohibit compounding human drugs for office administration. (motion by Stelly, second by Munden)**

LUNCH:

The board had a working lunch at approximately 12:26pm and presented former board member Dave Kozera and former board counsel Howard Casway with plaques of appreciation for their time and service to the Board of Pharmacy.

NEW BUSINESS (continued):

- Compounding Working Group-HB 1035:

Ms. Juran discussed with the board that the enactment clause of HB 1035 requires the Board of Pharmacy to convene a compounding workgroup to explore and clarify issues related to the compounding of drugs for human and animal use. Ms. Allen announced that she has appointed Mr. Adams, Ms. Shinaberry and herself to the workgroup. Ms. Juran stated that the stakeholders identified in the enactment clause will receive information in the near future soliciting their participation on the workgroup.

- Staff request to amend

Ms. Juran reviewed with the board staff's request to amend

Guidance Document 110-38 regarding inspections from non-resident pharmacies:

Guidance Document 110-38 regarding inspections from non-resident pharmacies. The amendments would allow a non-resident pharmacy that may have recently been licensed in their resident state to submit a "new" or "opening" inspection report with their application instead of an "operational" inspection report. This process would mirror the licensing process of in-state pharmacies. However, the non-resident pharmacy would be required to submit an "operational" inspection report during the subsequent renewal period.

**MOTION:**

**The board voted unanimously to amend Guidance Document 110-38 as presented. (motion by Warriner, second by Thornbury)**

- Board member request to amend 18VAC 110-20-200 B to allow Schedule II drugs to be dispersed, securely locked or a combination of them both:

A request was submitted by Mr. Adams to amend 18VAC 110-20-200B to allow Schedule II drugs in a pharmacy to be dispersed with other schedules of drugs on the shelves, maintained within a securely locked cabinet, drawer, or safe, or a combination of the two allowances. It was suggested to provide an interpretation of the regulation by adopting guidance on the subject and to amend the regulation during the next periodic regulatory review period.

**MOTION:**

**The board voted unanimously to direct staff to draft a guidance document indicating the board interprets Regulation 18VAC 110-20-200 B to mean that Schedule II drugs in a pharmacy may be dispersed with other schedules of drugs on the shelves, maintained within a securely locked cabinet, drawer, or safe, or maintained in a manner which combines the two allowances and consider amending the regulation during the next periodic regulatory review period. (motion by Adams, second by Warriner)**

- Staff request to amend 18VAC 110-20-20 to allow staggering renewal of non-resident pharmacies:

To ease the workload associated with the new requirement to review current inspection reports annually during renewal, staff requested the board amend Regulation 18VAC 110-20-20 to stagger the renewal of non-resident pharmacies throughout the calendar year. It was proposed that they renew by the anniversary of their initial registration date.

**MOTION:**

**The Board voted unanimously to amend 18VAC 110-20-20 to require non-resident pharmacies to renew annually by the anniversary of their initial registration date. (motion by Warriner, second Munden)**

- Staff request to amend

Ms. Juran shared observations regarding 3 suspended pharmacists

18VAC 110-20-190 to prohibit suspended or revoked pharmacists, pharmacy interns, and pharmacy technicians from accessing the prescription department and controlled substances:

during the past few years who continued to work in some capacity at the pharmacy such as running the cashier in the prescription department or delivering dispensed drugs. The board discussed whether it should consider amending 18VAC 110-20-190 to prohibit suspended or revoked pharmacists, pharmacy interns, and pharmacy technicians from accessing the prescription department and controlled substances. Concern was expressed for the pharmacist on-duty who may not feel comfortable prohibiting his employer from accessing the prescription department. Concern was also expressed for a suspended pharmacist having the ability to access controlled substances within the prescription department or by delivering controlled substances to patients' residences or alternate delivery sites.

**MOTION:**

**The Board voted unanimously to amend 18VAC 110-20-190 to prohibit suspended or revoked pharmacists, pharmacy interns and pharmacy technicians from accessing the prescription department and controlled substances, to include the delivery of dispensed controlled substances. (motion by Munden, second by Stelly)**

**MOTION:**

**The Board voted unanimously to amend the language on page 113 to read "The PIC or pharmacist on duty shall not permit access to the prescription department or controlled substances". (motion by Adams, second by Rhodes).**

- Board member request to discuss possibility of a "pharmacy assistant":

Mr. Adams stated that the board may want to consider in the future the use of "pharmacy assistants" who would be able to assist the pharmacist by performing some unsupervised duties. He stated that prescription dispensing volume will steadily increase and the pharmacists may not be able to handle it. These "pharmacist assistants" will have more education and less supervision, but still have a checks and balance system in place. Mr. Adams feels that this type of position may be necessary in a clinical setting. The Board felt that it was a good concept, but may be premature as several members believed standardization of pharmacy technician education should occur first.

**ELECTION OF OFFICERS:**

**MOTION:**

**The Board voted unanimously to elect Ms. Shinaberry as Chairman for the term July 1, 2014 through June 30, 2015. (motion by Munden, second by Adams)**

**MOTION:**

**The Board voted unanimously to elect Ms. Munden as Vice Chairman for the term July 1, 2014 through June 30, 2015. (motion by Rhodes, second by Adams)**

Since Ms. Shinaberry's first term expires June 30, 2014, Ms. Allen stated that should Ms. Shinaberry not be reappointed to the board, then Ms. Munden would assume the role as chairman and the board would elect a new vice-chairman at the subsequent meeting.

**SUMMARY SUSPENSIONS**

JESSICA G. BAILEY
Pharmacy Technician
Registration Number:
0230-014580

Cynthia Warriner recused herself from this matter.

Wayne T. 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.

**Closed Meeting:**

**Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Munden, the Board voted 9-0 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 Jessica G. Bailey. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, Heather Hurley, James Rutkowski, and Sammy Johnson, attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.**

Reconvene

The Board voted unanimously that only public business matters lawfully exempt 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.

**MOTION:**

**Upon a motion by Ms. Stelly, and duly seconded by Ms. Munden, the Board voted 9-0 in favor of the motion that, according to the evidence presented, the continued practice by Jessica G. Bailey as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Jessica G. Bailey to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Bailey for the indefinite suspension of her pharmacy technician registration for not less than two years in lieu of a hearing.**

CHANTAL
M. BHOLANATH
Pharmacy Technician

Cindy Warriner recused herself from this matter.

Registration Number:
0230-021934

Wayne T. 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.

**Closed Meeting:**

**Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Munden, the Board voted 9-0 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 Chantel M. Bholanath. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, Heather Hurley, James Rutkowski, and Sammy Johnson, attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.**

Reconvene

The Board voted unanimously, that only public business matters lawfully exempt 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.

**MOTION:**

**Upon a motion by Ms. Stelly, and duly seconded by Ms. Munden, the Board voted 9-0 in favor of the motion that, according to the evidence presented, the continued practice by Chantel M. Bholanath as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Chantel M. Bholanath to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Bholanath for the revocation of her pharmacy technician registration.**

**CONSIDERATION OF A CONSENT ORDER AND ORDER**

**Closed Meeting:**

**Upon a motion by Ms. Shinaberry, and duly seconded by Ms. Stelly, the Board voted 10-0 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 Consent Order and an Order. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, Heather Hurley, James Rutkowski, and Sammy Johnson, attend the closed meeting because their presence in the closed meeting was**

**deemed necessary and would aid the Board in its deliberations.**

Reconvene

The Board voted unanimously that only public business matters lawfully exempt 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.

**MOTION:**

**Upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board voted 10-0 in favor of accepting the Consent Order as presented by Ms. Reiniers-Day in the matter of Casey R. Frick, a pharmacy technician.**

**MOTION:**

**With Ms. Shinaberry abstaining from this matter, and upon a motion by Ms. Warriner and duly seconded by Ms. Li, the Board voted 9-0 in favor of accepting the Order entered on February 12, 2014, as presented by Mr. Rutkowski in the matter of Susan L. Windsor, a pharmacist..**

**REQUEST FOR EXAMINATION REQUESTS:**

**MOTION FOR A CLOSED MEETING:**

**The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711(A)(15) of the Code of Virginia for the purpose of consideration and discussion of medical/mental health records contained in an accommodation request that are excluded from the Freedom of Information Act by Virginia Code Section 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, James Rutkowski, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations.**

**MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:**

**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.**

**MOTION:**

**The Board voted unanimously to approve the following examination requests of Carla Rene Cobbs: extended time by one and a half times the normally allotted time; a desk large enough to accommodate a wheelchair ; and, a separate room for completing the exams with a proctor appropriately monitoring her testing experiences. (motion by Adams, second by Warriner)**

ADJOURN: With all business concluded, the meeting adjourned at 3:22pm.

Jody H. Allen, Chairman

Date:_____

Caroline D. Juran, Executive Director

Date:_____

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF AD HOC INSPECTION COMMITTEE

June 4, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 3:40pm.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Cynthia Warriner
Ryan K. Logan

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Heather W. Hurley, Administrative Assistant

APPROVAL OF AGENDA: An amended agenda was provided to the board. With no further changes made to the agenda, the amended agenda was approved as presented.

PUBLIC COMMENT: The Committee received public comment from Joe Cabaleiro, Pharmacist and Associate Director of Pharmacy for the Accreditation Commission for Health Care (ACHC). Mr. Cabaleiro requested the Committee's consideration to allow the ACHC certification program to be accepted as an alternative to the required inspection report performed by the resident state regulatory or licensing body. It was referenced that the board has agreed within Guidance Document 110-38 to accept the Verified Pharmacy Provider inspection report from the National Association of Boards of Pharmacy (NABP) for non-resident pharmacies. He stated that the ACHC surveyors are trained and that their certification program focuses on USP-NF standards for 795 and 797. Mr. Cabaleiro reviewed the accreditation process with the Committee by presenting a power point program. The presentation consisted of the following; personnel competency interviews, having a scoring system for their surveys, plan of corrective action, and having a review plan of corrective action. If the pharmacy has met all requirements, then an accreditation or certification certificate is issued. Louis S. Diorio, Pharmacist, FAPhA, Principal for LDT Health Solutions, Inc., requested that the Committee give consideration for their gap analysis tool being accepted in lieu of an inspection report as required in Virginia law and outlined in Guidance Document 110-38. Mr. Diorio stated that the audit conducted uses self-assessments and they have used the gap analysis tool thus far in New Jersey, New York and South Carolina.

DISCUSSION: The Committee discussed the requests from ACHC and LDT Health Solutions. While the Committee saw value in the information provided and showed appreciation for their request, the following concerns were expressed: the ACHC certification program is very new and there is little

experience with the program thus far; the ACHC certification program does not review for compliance of general pharmacy practice requirements; NABP appears to be meeting the inspection needs as it recently indicated to the board that it had succeeded at inspecting all the nonresident pharmacies by mid-April that applied for inspection prior to the deadline of January 31, 2014 as noted in the letters sent to all nonresident pharmacies; and, that it may be premature at this time to make other adjustments to this complex subject which requires critical oversight.

**MOTION:**

**The Committee voted unanimously not to take any action at this time on the requests from ACHC and LDT Health Solutions to accept their certification/surveys in lieu of an inspection performed by the resident state regulatory or licensing board and therefore, no recommendation for amending Guidance Document 110-38 was made. (motion by Warriner, second by Logan)**

CONSIDERATION OF AMENDING GUIDANCE DOCUMENT 110-9 TO INCLUDE A DEFICIENCY REGARDING NON-COMPLIANCE WITH GLOVED FINGERTIP SAMPLING:

The Committee discussed the amending of Guidance Document 110-9 to include a deficiency regarding non-compliance with gloved fingertip sampling. There was discussion as to whether there should be a delay in implementing the deficiency. The committee concluded that pharmacists should already be performing gloved finger tip testing as this is not a new requirement of USP chapter <797> and Inspector Tim Reilly confirmed that it is his observation that most pharmacists are performing gloved finger tip testing presently. Staff indicated they would provide information on the subject in the next board e-newsletter to be published in July.

**MOTION:**

**The Committee voted unanimously to recommend to the full board that it amend Guidance Document 110-9 by inserting "or gloved finger tip testing" following the words "media-fill testing" in Major Deficiency 26 and in Major Deficiency 25a. (motion by Warriner, second by Munden)**

ADJOURN:

With all business concluded, the meeting adjourned at 5:04pm.



Ellen Shinaberry, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Thursday, June 5, 2014
Commonwealth Conference Center
Second Floor
Board Room 4

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: | Empsy Munden, Committee Chair |
| MEMBERS PRESENT: | R. Crady Adams, Committee Member |
| STAFF PRESENT: | J. Samuel Johnson, Jr., Deputy Executive Director<br>Beth O'Halloran, Individual Licensing Manager<br>Brittany Taylor, Administrative Assistant<br>Mykl D. Egan, DHP Adjudication Specialist |
| ASHLEY M. ONGKINGCO<br>Pharmacy Technician<br>Registration No.: 0230-016290 | Ashley M. Onkingco appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 9, 2014, Notice. |
| Closed Meeting: | Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Ashley M. Ongkingco. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order. |

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Ongkingco, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Ongkingco 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.

CARRIE E. PRITTS
Pharmacy Technician
Registration No.: 0230-012657

Carrie E. Pritts appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 12, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Carrie E. Pritts. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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.

Decision:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Pritts, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Pritts 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.

YVONNE B. LEE
Pharmacy Technician
Registration No.: 0230-016514

Yvonne B. Lee appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 9, 2014, Notice.

Decision:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Lee, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Lee 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.

MARIO E. LOPEZ
Pharmacy Technician
Registration No.: 0230-020425

Mario E. Lopez failed to appear to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 9, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Mario E. Lopez. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Lopez, unless a written request made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Lopez 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.

CAMERINA Y. YOUNCE
Pharmacy Technician
Registration No.: 0230-017627

Camerina Y. Younce failed to appear to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 9, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Camerina Y. Younce. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Younce, unless a written request

made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Younce 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.

TABATHA T. JOYNER
Pharmacy Technician
Registration No.: 0230-004995

Tabatha T. Joyner failed to appear to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 9, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Tabatha T. Joyner. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to dismiss the case.

KEISHA DAVIS
Pharmacy Technician
Registration No.: 0230-014542

Keisha Davis failed to appear to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 9, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Keisha Davis. Additionally, he moved that Sammy

Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Davis, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Davis 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.

FATIMA R. ABDULHAKIM
Pharmacy Technician
Registration No.: 0230-015132

Fatima R. Abdulhakim failed to appear to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 12, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Fatima R. Abdulhakim. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Abdulhakim, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Abdulhakim 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.

JAMES R. MILES
Pharmacist
Registration No.: 0202-006227

James R. Miles failed to appear to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the May 12, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of James R. Miles. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a

final Order thirty (30) days after service of such Order on Mr. Miles, unless a written request made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Miles 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.

COURTNEY L. ASWELL
Pharmacy Technician
Registration No.: 0230-010136

Courtney L. Aswell appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 12, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Courtney L. Aswell. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Aswell, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Aswell 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.

HILDA A. KYEM
Pharmacy Technician
Registration No.: 0230-018242

Hilda A. Kyem appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 12, 2014, Notice.

Decision:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Kyem, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Kyem 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.

TREVER C. FEATHERS
Pharmacy Technician
Registration No.: 0230-017166

Trever C. Feathers failed to appear to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 12, 2014, Notice.

Closed Meeting;

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Trever C. Feathers. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain

Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order. This Consent Order shall be effective upon endorsement by Mr. Feathers.

WILLIAM Z. BOYD
Pharmacy Technician
Registration No.: 0230-012276

William Z. Boyd failed to appear to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the May 12, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of William Z. Boyd. Additionally, he moved that Sammy Johnson, Beth O'Halloran, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting 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. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Boyd, unless a written request made to the Board requesting a formal hearing on the allegations made against her is received from Mr. Boyd 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.

Adjourn:

With all business concluded, the meeting adjourned at 11:09 a.m.

Empsy Munden
Chair

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, July 9, 2014

Department of Health Professions
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 § 54.1-2408.1(A) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on July 9, 2014, at 10:35 a.m., to consider the summary suspension of the registration of Heather Linelle Young (Lewis) to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Empsy Munden, Chair

MEMBERS PRESENT:
Dinny Li
Ryan Logan
Pratt P. Stelly
Robert Rhodes
Cynthia Warriner

MEMBERS ABSENT:
Jody H. Allen
Rebecca Thornbury
Ellen B. Shinaberry
R. Crady Adams

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
James E. Rutkowski, Assistant Attorney General

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

With six (6) members participating and four (4) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

HEATHER LINELLE YOUNG (LEWIS)
Registration No. 0230-001910

Wayne T. Halbleib presented a summary of the evidence in this case.

Closed Session:

Upon a motion by Mr. Rhodes and duly seconded by Ms. Warriner, the Board voted 6-0 to convene a closed meeting pursuant to § 2.2-3711(A)(7) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter Heather Linelle Young. Additionally, he moved that Cathy M. Reiniers-Day, Caroline D. Juran, Eusebia Joyner and James Rutkowski participate in the closed session because their presence in the closed session was deemed necessary and would aid the Board in its deliberations.

Reconvene:

The quorum of the Board returned to open session and voted unanimously that only public business matters lawfully exempted from open session requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed session were heard, discussed or considered during the closed session.

MOTION:

Upon a motion by Ms. Warriner, and duly seconded by Mr. Rhodes, the Board voted 6-0 in favor of the motion that, according to the evidence presented, the continued practice by Heather Linelle Young as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Heather Linelle Young to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Young for the revocation of her pharmacy technician registration in lieu of a formal hearing.

ADJOURN: With all business concluded, the telephone conference call adjourned at 11:10 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Empsy Munden, Chair

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## MINUTES OF A PANEL OF THE BOARD

Tuesday, July 22, 2014
Commonwealth Conference Center
Second Floor
Board Room 2

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

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| | |
|---|---|
| CALL TO ORDER: | A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 9:30 a.m. |
| PRESIDING: | Empsy Munden, Chair |
| MEMBERS PRESENT: | Dinny Li<br>Ryan K. Logan<br>Robert M. Rhodes<br>Pratt P. Stelly |
| STAFF PRESENT: | Cathy M. Reiniers-Day, Deputy Executive Director<br>Heather W. Hurley, Facility Licensing Specialist<br>James Rutkowski, Assistant Attorney General<br>Wayne T. Halbleib, Senior Assistant Attorney General<br>Mykl Egan, DHP Adjudication Specialist |
| QUORUM: | With five (5) members of the Board present, a panel was established. |
| JESSICA G. BAILEY<br>Registration No. 0230-014580 | A formal hearing was held in the matter of Jessica G. Bailey to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.<br><br>Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist.<br><br>Adam Harrell, Walgreen's District Loss Prevention Manager, and Andrea P. Christian, DHP Senior Investigator, testified on behalf of the Commonwealth.<br><br>Mr. Bailey was not present at the hearing. The Board proceeded with the hearing in Ms. Bailey's absence as the Notice of Hearing dated June 11, 2014, was mailed to her legal address of record, both by regular and certified mail. Ms. Munden ruled that adequate notice was provided to Ms. Bailey. |

| | |
|---|---|
| Closed Meeting: | Upon a motion by Mr. Rhodes, and duly seconded by Ms. Stelly, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Jessica G. Bailey. Additionally, he moved that Cathy Reiniers-Day, Heather W. Hurley and James Rutkowski attend the closed meeting. |
| Reconvene: | Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision. |
| Decision: | Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, the panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and read by Mr. Rutkowski.<br><br>Upon a motion by Ms. Stelly and duly seconded by Mr. Logan, the panel voted 5-0 to revoke Ms. Bailey's registration to practice as a pharmacy technician. |
| Adjourn: | With all business concluded, the meeting adjourned at 10:35 a.m. |

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, July 29, 2014
Commonwealth Conference Center
Second Floor
Board 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 9:30 a.m. |
| PRESIDING: | Empsy Munden, Committee Chair |
| MEMBERS PRESENT: | Robert M. Rhodes, Committee Member |
| STAFF PRESENT: | Cathy M. Reiniers-Day, Deputy Executive Director<br>Mykl D. Egan, DHP Adjudication Specialist |
| MICHAEL TO<br>Pharmacist<br>License No: 0202-011972 | Michael To appeared with his attorney, Michael Gartner, to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 27, 2014, Notice.<br><br>The Committee recessed the meeting from 10:20 a.m. to 10:55 a.m. |
| Closed Meeting: | Upon a motion by Mr. Rhodes, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Michael To. Additionally, he moved that Cathy Reiniers-Day, Beth O'Halloran 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 an open meeting and announced the decision. |
| Decision: | Upon a motion by Mr. Rhodes, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Mr. To and require him to successfully pass the |

Pharmacists Assessment for Remediation Evaluation.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. To, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. To 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.

KYLE DODGE
Pharmacy Technician
Registration No: 0230-021552

Kyle Dodge did not appear at the informal conference. The Committee chose to proceed in his absence as the notice was mailed to Mr. Dodge's legal address of record. The Committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the June 27, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Kyle Dodge. 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. Rhodes, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Mr. Dodge for the voluntary surrender of his pharmacy technician registration with his right to renew said registration suspended. Further, a Notice for a formal administrative proceeding shall be issued.

Jeann Lee Gillespie did not appear at the informal conference. The Committee chose to proceed in her absence as the notice was mailed to Ms. Gillespie's legal address of record. The Committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the June 27, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jeann Lee Gillespie. 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. Rhodes, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Ms. Gillespie for the voluntary surrender of her pharmacist license with her right to renew said license suspended. Further, a Notice for a formal administrative proceeding shall be issued.

ADJOURN:

With all business concluded, the meeting adjourned at 1:25 p.m.

_____
Empsy Munden, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## MINUTES OF TELEPHONE CONFERENCE CALL

Tuesday, July 29, 2014

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 on July 29, 2014, at 10:30 a.m., to consider the summary suspension of the registration of Carolyn Annette Fields to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Ellen B. Shinaberry, Chair

MEMBERS PRESENT:
R. Crady Adams
Ryan K. Logan
Empsy Munden
Robert M. Rhodes
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
James Rutkowski, 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 cases. Ms. Munden and Mr. Rhodes stated that they were at the Board office for a meeting; however, the remaining Board members stated that they would not have been able to attend.

With seven (7) members participating and three (3) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

CAROLYN ANNETTE FIELDS
Registration No. 0230-010118

Wayne T. Halbleib presented a summary of the evidence in this case.

Upon a motion by Ms. Munden and duly seconded by Mr. Rhodes, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Carolyn Annette Fields poses a substantial danger to the public; and therefore, the registration of Ms. Fields shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order for the revocation of her registration shall be offered to Ms. Fields in lieu of a formal hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 10:55 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Ellen B. Shinaberry, Chair

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, August 20, 2014
Commonwealth Conference Center
Second Floor
Board 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 10:00 a.m. |
| PRESIDING: | Ellen Shinaberry, Committee Chair |
| MEMBERS PRESENT: | Ryan Logan, Committee Member |
| STAFF PRESENT: | Cathy M. Reiniers-Day, Deputy Executive Director<br>Mykl D. Egan, DHP Adjudication Specialist |
| CHRISTINE H. HOMMELL<br>Pharmacy Technician<br>Registration No: 0230=011942 | Christine H. Hommell appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 31, 2014, Notice. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Christine H. Hommell. 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 an open meeting and announced the decision. |
| Decision: | Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Ms. Hommell.<br><br>As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Hommell, unless a written request is |

made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Hommell 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.

JAMES L. McCOY, M.D.
Physician Licensed to Sell Controlled Substances
License No: 0213-000966

James L. McCoy, M.D., appeared to review allegations that he may have violated certain laws and regulations governing the practice of physicians licensed to sell controlled substances as stated in the July 31, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of James L. McCoy. 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. Logan, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Dr. McCoy and to require that he provide the Board with an Affidavit that he has read and understands the laws and regulations regarding the practice of physicians licensed to sell controlled substances.

JERRI D. MALLORY
Pharmacy Technician
Registration No: 0230-008907

Jerri D. Mallory appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 31, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the

purpose of deliberation to reach a decision in the matter of Jerri D. Mallory. 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. Logan, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Ms. Mallory for the indefinite suspension of her pharmacy technician registration for not less than six months.

ADJOURN: With all business concluded, the meeting adjourned at 2:20 p.m.

Ellen Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

# (DRAFT/UNAPPROVED)

## VIRGINIA BOARD OF PHARMACY
## SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, August 20, 2014
Commonwealth Conference Center
Second Floor
Board 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 10:00 a.m. |
| PRESIDING: | Ellen Shinaberry, Committee Chair |
| MEMBERS PRESENT: | Ryan Logan, Committee Member |
| STAFF PRESENT: | Cathy M. Reiniers-Day, Deputy Executive Director<br>Mykl D. Egan, DHP Adjudication Specialist |
| CHRISTINE H. HOMMELL<br>Pharmacy Technician<br>Registration No: 0230=011942 | Christine H. Hommell appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 31, 2014, Notice. |
| Closed Meeting: | Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Christine H. Hommell. 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 an open meeting and announced the decision. |
| Decision: | Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Ms. Hommell.<br><br>As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Hommell, unless a written request is |

made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Hommell 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.

JAMES L. McCOY, M.D.
Physician Licensed to Sell Controlled Substances
License No: 0213-000966

James L. McCoy, M.D., appeared to review allegations that he may have violated certain laws and regulations governing the practice of physicians licensed to sell controlled substances as stated in the July 31, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of James L. McCoy. 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. Logan, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Dr. McCoy and to require that he provide the Board with an Affidavit that he has read and understands the laws and regulations regarding the practice of physicians licensed to sell controlled substances.

JERRI D. MALLORY
Pharmacy Technician
Registration No: 0230-008907

Jerri D. Mallory appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the July 31, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Logan, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the

purpose of deliberation to reach a decision in the matter of Jerri D. Mallory. 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. Logan, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Ms. Mallory for the indefinite suspension of her pharmacy technician registration for not less than six months.

ADJOURN: With all business concluded, the meeting adjourned at 2:20 p.m.

_____
Ellen Shinaberry, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

**Agenda Item:** **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board **as of August 29, 2014**

Action: None – provided for information only

| Chapter | | Action / Stage Information |
|---|---|---|
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Prohibition against incentives to transfer prescriptions [Action 4186]<br>NOIRA - *At Secretary's Office for 70 days* |
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Administrative fees for duplicate licenses and verification [Action 3444]<br>Proposed - *Register Date: 5/19/14*<br>*Final to be adopted 9/9/14* |
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Addressing hours of continuous work by pharmacists [Action 3755]<br>Proposed - *At Secretary's Office for 477 days* |
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Maintaining floor stock of certain drugs onsite at correctional facilities [Action 4157]<br>Fast-Track - *At Governor's Office for 17 days* |
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Nonresident pharmacy renewal date and access by suspended pharmacists to prescription department [Action 4215]<br>Fast-Track - *DPB Review in progress* |
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Drugs and emergency medical services agencies [Action 4216]<br>Fast-Track - *DPB Review in progress* |
| [18 VAC 110 - 20] | Virginia Board of Pharmacy Regulations | Continuous quality improvement programs [Action 3496]<br>Final - *At Governor's Office for 26 days*<br>*Emergency regulation expired 9/30/13* |

**Agenda Item: Adoption of Final Regulations**

**Administrative Fees**

**Included in your agenda package are:**

A copy of the Proposed Regulations

**Staff note:**

There was a comment period on the proposed regulations which ended 7/18/14. At the public hearing on 6/4/14, there was no public comment.

**Board action:**

Adoption of proposed amendments as a final action

## Proposed Text

### Administrative fees for duplicate licenses and verification

18VAC110-20-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

| | |
|---|---|
| 1. Pharmacist license | $180 |
| 2. Pharmacy intern registration | $15 |
| 3. Pharmacy technician registration | $25 |
| 4. Pharmacy permit | $270 |
| 5. Permitted physician licensed to dispense drugs | $270 |
| 6. Medical equipment supplier permit | $180 |
| 7. Humane society permit | $20 |
| 8. Nonresident pharmacy | $270 |
| 9. Controlled substances registrations | $90 |
| 10. Innovative program approval.<br><br>If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee. | $250 |
| 11. Approval of a pharmacy technician training program | $150 |
| 12. Approval of a continuing education program | $100 |
| 13. Approval of a repackaging training program | $50 |

D. Annual renewal fees.

| | |
|---|---|
| 1. Pharmacist active license due no later than December 31 | $90 |
| 2. Pharmacist inactive license due no later than December 31 | $45 |
| 3. Pharmacy technician registration due no later than December 31 | $25 |
| 4. Pharmacy permit due no later than April 30 | $270 |
| 5. Physician permit to practice pharmacy due no later than February 28 | $270 |
| 6. Medical equipment supplier permit due no later than February 28 | $180 |
| 7. Humane society permit due no later than February 28 | $20 |

| | |
|---|---|
| 8. Nonresident pharmacy due no later than April 30 | $270 |
| 9. Controlled substances registrations due no later than February 28 | $90 |
| 10. Innovative program continued approval based on board order not to exceed $200 per approval period. | |
| 11. Approval of a pharmacy technician training program | $75 every two years |
| 12. Approval of a repackaging training program | $30 every two years |

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

| | |
|---|---|
| 1. Pharmacist license | $30 |
| 2. Pharmacist inactive license | $15 |
| 3. Pharmacy technician registration | $10 |
| 4. Pharmacy permit | $90 |
| 5. Physician permit to practice pharmacy | $90 |
| 6. Medical equipment supplier permit | $60 |
| 7. Humane society permit | $5 |
| 8. Nonresident pharmacy | $90 |
| 9. Controlled substances registrations | $30 |
| 10. Approval of a pharmacy technician training program | $15 |
| 11. Approval of a repackaging training program | $10 |

F. Reinstatement fees. Any person or entity attempting to renew a license, permit, or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

| | |
|---|---|
| 1. Pharmacist license | $210 |
| 2. Pharmacist license after revocation or suspension | $500 |
| 3. Pharmacy technician registration | $35 |
| 4. Pharmacy technician registration after revocation or suspension | $125 |
| 5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees: | |

| | | |
|---|---|---|
| | a. Pharmacy permit | $240 |
| | b. Physician permit to practice pharmacy | $240 |
| | c. Medical equipment supplier permit | $210 |
| | d. Humane society permit | $30 |
| | e. Nonresident pharmacy | $115 |
| | f. Controlled substances registration | $180 |
| | g. Approval of a pharmacy technician training program | $75 |
| | h. Approval of a repackaging training program | $50 |

G. Application for change or inspection fees for facilities or other entities.

| | | |
|---|---|---|
| | 1. Change of pharmacist-in-charge | $50 |
| | 2. Change of ownership for any facility | $50 |
| | 3. Inspection for remodeling or change of location for any facility | 150 |
| | 4. Reinspection of any facility | $150 |
| | 5. Board-required inspection for a robotic pharmacy system | $150 |
| | 6. Board-required inspection of an innovative program location | $150 |
| | 7. Change of pharmacist responsible for an approved innovative program | $25 |

H. Miscellaneous fees.

| | | |
|---|---|---|
| | 1. Duplicate wall certificate | $25 |
| | 2. Returned check | $35 |
| | 3. Duplicate license or registration | $10 |
| | 4. Verification of licensure or registration | $25 |

18VAC110-50-20. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. Initial application fees.

| | | |
|---|---|---|
| | 1. Nonrestricted manufacturer permit | $270 |
| | 2. Restricted manufacturer permit | $180 |
| | 3. Wholesale distributor license | $270 |
| | 4. Warehouser permit | $270 |
| | 5. Nonresident wholesale distributor | $270 |
| | 6. Controlled substances registration | $90 |

C. Annual renewal fees shall be due on February 28 of each year.

| | | |
|---|---|---|
| | 1. Nonrestricted manufacturer permit | $270 |
| | 2. Restricted manufacturer permit | $180 |
| | 3. Wholesale distributor license | $270 |
| | 4. Warehouser permit | $270 |
| | 5. Nonresident wholesale distributor | $270 |
| | 6. Controlled substances registration | $90 |

D. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date. In addition, engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board.

| | | |
|---|---|---|
| | 1. Nonrestricted manufacturer permit | $90 |
| | 2. Restricted manufacturer permit | $60 |
| | 3. Wholesale distributor license | $90 |
| | 4. Warehouser permit | $90 |
| | 5. Nonresident wholesale distributor | $90 |
| | 6. Controlled substances registration | $30 |

E. Reinstatement fees.

1. Any entity attempting to renew a license, permit, or registration more than one year after the expiration date shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following license revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

2. Engaging in activities requiring a license, permit, or registration after the expiration date of such license, permit, or registration shall be grounds for disciplinary action by the board. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement, but shall apply for a new permit or registration.

3. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:

| | | |
|---|---|---|
| | a. Nonrestricted manufacturer permit | $240 |
| | b. Restricted manufacturer permit | $210 |
| | c. Wholesale distributor license | $240 |
| | d. Warehouser permit | $240 |
| | e. Nonresident wholesale distributor | $240 |
| | f. Controlled substances registration | $180 |

F. Application for change or inspection fees.

| | | |
|---|---|---|
| | 1. Reinspection fee | $150 |
| | 2. Inspection fee for change of location, structural changes, | $150 |

| | | |
|---|---|---|
| | or security system changes | |
| | 3. Change of ownership fee | $50 |
| | 4. Change of responsible party | $50 |

G. The fee for a returned check shall be $35.

~~H. For the annual renewal due on February 28, 2010, the following fees shall be imposed for a license or permit:~~

| | | |
|---|---|---|
| | ~~1. Nonrestricted manufacturer permit~~ | ~~$210~~ |
| | ~~2. Restricted manufacturer permit~~ | ~~$140~~ |
| | ~~3. Wholesale distributor license~~ | ~~$210~~ |
| | ~~4. Warehouser permit~~ | ~~$210~~ |
| | ~~5. Nonresident wholesale distributor~~ | ~~$210~~ |

H. The fee for verification of license or permit shall be $25.

**Agenda Item:** **Legislative Proposals**

**Enclosed:**

- Copy of bill proposing Virginia licensure for "outsourcing facilities," pharmacies that compound human drugs for office administration **to include new provision relating to compounding reasonable amounts of drugs for administration by a doctor in his office to address a critical need for an emergency condition.**
- Copy of bill proposing wholesale distributors notify the Board if they cease distribution of a dispenser located in Virginia for suspicious ordering

**Staff note:**

- Addition to the compounding legislation was recommended by the Ad Hoc Workgroup on Compounding at its meeting on August 26, 2014.
- Change in wholesale distributor legislation was in response to comment from HDMA.

**Board Action:**

Agenda item is included for Board discussion and comment. No board action is required.

**Department of Health Professions**

**2015 Session of the General Assembly**

*A bill to amend and reenact §§ 54.1-3401, 54.1-3406, 54.1-3410.2, 54.1-3434.1, 54.1-3434.4 of the Code of Virginia and to enact §§ 54.1-3434.05 and 54.1-3434.5, relating to a prerequisite for licensure of nonresident pharmacies, compounding of drugs and registration of outsourcing facilities.*

**Be it enacted by the General Assembly of Virginia:**

**1. That *§§ 54.1-3401, 54.1-3406, 54.1-3410.2, 54.1-3434.1, 54.1-3434.4* of the Code of Virginia are amended and reenacted §§ 54.1-3434.05 and 54.1-3434.5 are enacted as follows:**

**§ 54.1-3401. Definitions.**

As used in this chapter, unless the context requires a different meaning:

"Administer" means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a patient or research subject by (i) a practitioner or by his authorized agent and under his direction or (ii) the patient or research subject at the direction and in the presence of the practitioner.

"Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of drugs or devices.

"Agent" means an authorized person who acts on behalf of or at the direction of a manufacturer, distributor, or dispenser. It does not include a common or contract carrier, public warehouseman, or employee of the carrier or warehouseman.

"Anabolic steroid" means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, corticosteroids, and dehydroepiandrosterone.

"Animal" means any nonhuman animate being endowed with the power of voluntary action.

"Automated drug dispensing system" means a mechanical or electronic system that performs operations or activities, other than compounding or administration, relating to pharmacy services, including the storage, dispensing, or distribution of drugs and the collection, control, and maintenance of all transaction information, to provide security and accountability for such drugs.

"Biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein other than a chemically synthesized polypeptide, or analogous product, or arsphenamine or any derivative of arsphenamine or any other trivalent organic arsenic compound, applicable to the prevention, treatment, or cure of a disease or condition of human beings.

"Biosimilar" means a biological product that is highly similar to a specific reference biological product, notwithstanding minor differences in clinically inactive compounds, such that there are no clinically meaningful differences between the reference biological product and the biological product that has been licensed as a biosimilar pursuant to 42 U.S.C. § 262(k) in terms of safety, purity, and potency of the product.

"Board" means the Board of Pharmacy.

"Bulk drug substance" means any substance that is represented for use, and that, when used in the compounding, manufacturing, processing, or packaging of a drug, becomes an active ingredient or a finished dosage form of the drug; however, "bulk drug substance" shall not include intermediates that are used in the synthesis of such substances.

"Change of ownership" of an existing entity permitted, registered, or licensed by the Board means (i) the sale or transfer of all or substantially all of the assets of the entity or of any corporation that owns or controls the entity; (ii) the creation of a partnership by a sole proprietor, the dissolution of a partnership, or change in partnership composition; (iii) the acquisition or disposal of 50 percent or more of the outstanding shares of voting stock of a corporation owning the entity or of the parent corporation of a wholly owned subsidiary owning the entity, except that this shall not apply to any corporation the voting stock of which is actively traded on any securities exchange or in any over-the-counter market; (iv) the merger of a corporation owning the entity or of the parent corporation of a wholly-owned subsidiary owning the entity with another business or corporation; or (v) the expiration or forfeiture of a corporation's charter.

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by a pharmacist, or within a permitted pharmacy, pursuant to a valid prescription issued for a medicinal or therapeutic purpose in the context of a bona fide practitioner-patient-pharmacist relationship, or in expectation of receiving a valid prescription based on observed historical patterns of prescribing and dispensing; (ii) by a practitioner of medicine, osteopathy, podiatry, dentistry, or veterinary medicine as an incident to his administering or dispensing, if authorized to dispense, a controlled substance in the course of his professional practice; or (iii) for the purpose of, or as incident to, research, teaching, or chemical analysis and not for sale or for dispensing. The mixing, diluting, or reconstituting of a manufacturer's product drugs for the purpose of administration to a patient, when performed by a practitioner of medicine or osteopathy licensed under Chapter 29 (§ 54.1-2900 et seq.), a person supervised by such practitioner pursuant to subdivision A 6 or A 19 of § 54.1-2901, or a person supervised by such practitioner or a licensed nurse practitioner or physician assistant pursuant to subdivision A 4 of § 54.1-2901 shall not be considered compounding.



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"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1.

"DEA" means the Drug Enforcement Administration, U.S. Department of Justice, or its successor agency.

"Deliver" or "delivery" means the actual, constructive, or attempted transfer of any item regulated by this chapter, whether or not there exists an agency relationship.

"Device" means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals or to affect the structure or any function of the body of man or animals.

"Dialysis care technician" or "dialysis patient care technician" means an individual who is certified by an organization approved by the Board of Health Professions pursuant to Chapter 27.01 (§ 54.1-2729.1 et seq.) and who, under the supervision of a licensed physician, nurse practitioner, physician assistant, or a registered nurse, assists in the care of patients undergoing renal dialysis treatments in a Medicare-certified renal dialysis facility.

"Dialysis solution" means either the commercially available, unopened, sterile solutions whose purpose is to be instilled into the peritoneal cavity during the medical procedure known as peritoneal dialysis, or commercially available solutions whose purpose is to be used in the performance of hemodialysis not to include any solutions administered to the patient intravenously.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for that delivery. However, dispensing shall not include the transportation of drugs mixed, diluted, or reconstituted in accordance with this chapter to other sites operated by such practitioner or that practitioner's medical practice for the purpose of administration of such drugs to patients of the practitioner or that practitioner's medical practice at such other sites. For practitioners of medicine or osteopathy, "dispense" shall only include the provision of drugs by a practitioner to patients to take with them away from the practitioner's place of practice.

"Dispenser" means a practitioner who dispenses.

"Distribute" means to deliver other than by administering or dispensing a controlled substance.

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure,

mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

"Drug product" means a specific drug in dosage form from a known source of manufacture, whether by brand or therapeutically equivalent drug product name.

"Electronic transmission prescription" means any prescription, other than an oral or written prescription or a prescription transmitted by facsimile machine, that is electronically transmitted directly to a pharmacy without interception or intervention from a third party from a practitioner authorized to prescribe or from one pharmacy to another pharmacy.

"Facsimile (FAX) prescription" means a written prescription or order that is transmitted by an electronic device over telephone lines that sends the exact image to the receiving pharmacy in hard copy form.

"FDA" means the U.S. Food and Drug Administration.

"Hashish oil" means any oily extract containing one or more cannabinoids, but shall not include any such extract with a tetrahydrocannabinol content of less than 12 percent by weight.

"Immediate precursor" means a substance which the Board of Pharmacy has found to be and by regulation designates as being the principal compound commonly used or produced primarily for use, and which is an immediate chemical intermediary used or likely to be used in the manufacture of a controlled substance, the control of which is necessary to prevent, curtail, or limit manufacture.

"Interchangeable" means a biosimilar that meets safety standards for determining interchangeability pursuant to 42 U.S.C. § 262(k)(4).

"Label" means a display of written, printed, or graphic matter upon the immediate container of any article. A requirement made by or under authority of this chapter that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such article or is easily legible through the outside container or wrapper.

"Labeling" means all labels and other written, printed, or graphic matter on an article or any of its containers or wrappers, or accompanying such article.

"Manufacture" means the production, preparation, propagation, conversion, or processing of any item regulated by this chapter, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging or repackaging of the substance or labeling or relabeling of its container. This term does not include compounding.

"Manufacturer" means every person who manufactures.

"Marijuana" means any part of a plant of the genus Cannabis whether growing or not, its seeds, or its resin; and every compound, manufacture, salt, derivative, mixture, or preparation of such plant, its seeds, or its resin. Marijuana shall not include any oily extract containing one or more cannabinoids unless such extract contains less than 12 percent of tetrahydrocannabinol by weight, nor shall marijuana include the mature stalks of such plant, fiber produced from such stalk, or oil or cake made from the seeds of such plant, unless such stalks, fiber, oil, or cake is combined with other parts of plants of the genus Cannabis.

"Medical equipment supplier" means any person, as defined in § 1-230, engaged in the delivery to the ultimate consumer, pursuant to the lawful order of a practitioner, of hypodermic syringes and needles, medicinal oxygen, Schedule VI controlled devices, those Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment, solutions for peritoneal dialysis, and sterile water or saline for irrigation.

"Narcotic drug" means any of the following, whether produced directly or indirectly by extraction from substances of vegetable origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis: (i) opium, opiates, and any salt, compound, derivative, or preparation of opium or opiates; (ii) any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of the substances referred to in clause (i), but not including the isoquinoline alkaloids of opium; (iii) opium poppy and poppy straw; (iv) coca leaves and any salt, compound, derivative, or preparation of coca leaves, and any salt, compound, isomer, derivative, or preparation thereof which is chemically equivalent or identical with any of these substances, but not including decocainized coca leaves or extraction of coca leaves which do not contain cocaine or ecgonine.

"New drug" means (i) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this chapter it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

"Nuclear medicine technologist" means an individual who holds a current certification with the American Registry of Radiological Technologists or the Nuclear Medicine Technology Certification Board.

"Official compendium" means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them.

"Official written order" means an order written on a form provided for that purpose by the U.S. Drug Enforcement Administration, under any laws of the United States making provision therefor, if such order forms are authorized and required by federal law, and if no such order form is provided then on an official form provided for that purpose by the Board of Pharmacy.

"Opiate" means any substance having an addiction-forming or addiction-sustaining liability similar to morphine or being capable of conversion into a drug having such addiction-forming or addiction-sustaining liability. It does not include, unless specifically designated as controlled under Article 4 (§ 54.1-3437 et seq.), the dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan). It does include its racemic and levorotatory forms.

"Opium poppy" means the plant of the species Papaver somniferum L., except the seeds thereof.

"Original package" means the unbroken container or wrapping in which any drug or medicine is enclosed together with label and labeling, put up by or for the manufacturer, wholesaler, or distributor for use in the delivery or display of such article.

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs, currently registered as an outsourcing facility with the Secretary of Health and Human Services, and complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

"Person" means both the plural and singular, as the case demands, and includes an individual, partnership, corporation, association, governmental agency, trust, or other institution or entity.

"Pharmacist-in-charge" means the person who, being licensed as a pharmacist, signs the application for a pharmacy permit and assumes full legal responsibility for the operation of the relevant pharmacy in a manner complying with the laws and regulations for the practice of pharmacy and the sale and dispensing of controlled substances; the "pharmacist-in-charge" shall personally supervise the pharmacy and the pharmacy's personnel as required by § 54.1-3432.

"Poppy straw" means all parts, except the seeds, of the opium poppy, after mowing.

"Practitioner" means a physician, dentist, licensed nurse practitioner pursuant to § 54.1-2957.01, licensed physician assistant pursuant to § 54.1-2952.1, pharmacist pursuant to § 54.1-3300, TPA-certified optometrist pursuant to Article 5 (§ 54.1-3222 et seq.) of Chapter 32, veterinarian, scientific investigator, or other person licensed, registered, or otherwise permitted to distribute, dispense, prescribe and administer, or conduct research with respect to a controlled substance in the course of professional practice or research in the Commonwealth.

"Prescriber" means a practitioner who is authorized pursuant to §§ 54.1-3303 and 54.1-3408 to issue a prescription.

"Prescription" means an order for drugs or medical supplies, written or signed or transmitted by word of mouth, telephone, telegraph, or other means of communication to a pharmacist by a duly licensed physician, dentist, veterinarian, or other practitioner authorized by law to prescribe and administer such drugs or medical supplies.

"Prescription drug" means any drug required by federal law or regulation to be dispensed only pursuant to a prescription, including finished dosage forms and active ingredients subject to § 503(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 353(b)).

"Production" or "produce" includes the manufacture, planting, cultivation, growing, or harvesting of a controlled substance or marijuana.

"Proprietary medicine" means a completely compounded nonprescription drug in its unbroken, original package which does not contain any controlled substance or marijuana as defined in this chapter and is not in itself poisonous, and which is sold, offered, promoted, or advertised directly to the general public by or under the authority of the manufacturer or primary distributor, under a trademark, trade name, or other trade symbol privately owned, and the labeling of which conforms to the requirements of this chapter and applicable federal law. However, this definition shall not include a drug that is only advertised or promoted professionally to licensed practitioners, a narcotic or drug containing a narcotic, a drug that may be dispensed only upon prescription or the label of which bears substantially the statement "Warning - may be habit-forming," or a drug intended for injection.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

"Reference biological product" means the single biological product licensed pursuant to 42 U.S.C. § 262(a) against which a biological product is evaluated in an application submitted to the U.S. Food and Drug Administration for licensure of biological products as biosimilar or interchangeable pursuant to 42 U.S.C. § 262(k).

"Sale" includes barter, exchange, or gift, or offer therefor, and each such transaction made by any person, whether as an individual, proprietor, agent, servant, or employee.

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the U.S. Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

"USP-NF" means the current edition of the United States Pharmacopeia-National Formulary.

"Warehouser" means any person, other than a wholesale distributor, engaged in the business of selling or otherwise distributing prescription drugs or devices to any person who is not the ultimate user or consumer. No person shall be subject to any state or local tax by reason of this definition.

"Wholesale distribution" means distribution of prescription drugs to persons other than consumers or patients, subject to the exceptions set forth in § 54.1-3401.1.

"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs including, but not limited to, manufacturers; repackers; own-label distributors; private-label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses conducting wholesale distributions, and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies conducting wholesale distributions. No person shall be subject to any state or local tax as a wholesale merchant by reason of this definition.

The words "drugs" and "devices" as used in Chapter 33 (§ 54.1-3300 et seq.) and in this chapter shall not include surgical or dental instruments, physical therapy equipment, X-ray apparatus, or glasses or lenses for the eyes.

The terms "pharmacist," "pharmacy," and "practice of pharmacy" as used in this chapter shall be defined as provided in Chapter 33 (§ 54.1-3300 et seq.) unless the context requires a different meaning.

**§ 54.1-3406. Records confidential; provision of information to the Secretary of Health and Human Services.**

A. No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

B. Notwithstanding the provisions of §54.1-2400.2, the Board shall submit to the Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulation.

**§ 54.1-3410.2. Compounding; pharmacists' authority to compound under certain conditions; labeling and record maintenance requirements.**

A. A pharmacist may engage in compounding of drug products when the dispensing of such compounded products is (i) pursuant to valid prescriptions for specific patients and (ii) consistent with the provisions of § 54.1-3303 relating to the issuance of prescriptions and the dispensing of drugs.

Pharmacists shall label all compounded drug products that are dispensed pursuant to a prescription in accordance with this chapter and the Board's regulations, and shall include on the labeling an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding.

B. A pharmacist may also engage in compounding of drug products in anticipation of receipt of prescriptions based on a routine, regularly observed prescribing pattern.

Pharmacists shall label all products compounded prior to dispensing with (i) the name and strength of the compounded medication or a list of the active ingredients and strengths; (ii) the pharmacy's assigned control number that corresponds with the compounding record; (iii) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; and (iv) the quantity.

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

A pharmacist may, however, deliver compounded products dispensed pursuant to valid prescriptions to alternate delivery locations pursuant to § 54.1-3420.2.

A pharmacist may ~~also~~ provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry~~, or veterinary medicine~~ to administer to their patients ~~in the course of their professional practice~~, either personally or under their direct and immediate supervision, if there is a critical need to treat an emergency condition. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office administration to their patients.

~~Pharmacists shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.~~

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

D. Pharmacists shall personally perform or personally supervise the compounding process, which shall include a final check for accuracy and conformity to the formula of the product being prepared, correct ingredients and calculations, accurate and precise measurements, appropriate conditions and procedures, and appearance of the final product.

E. Pharmacists shall ensure compliance with USP-NF standards for both sterile and non-sterile compounding.

F. Pharmacists may use bulk drug substances in compounding when such bulk drug substances:

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

2. Are manufactured by an establishment that is registered by the FDA; or

3. Are distributed by a licensed wholesale distributor or registered nonresident wholesale distributor, or are distributed by a supplier otherwise approved by the FDA to distribute bulk drug substances if the pharmacist can establish purity and safety by reasonable means, such as lot analysis, manufacturer reputation, or reliability of the source.

G. Pharmacists may compound using ingredients that are not considered drug products in accordance with the USP-NF standards and guidance on pharmacy compounding.

H. Pharmacists shall not engage in the following:

1. The compounding for human use of a drug product that has been withdrawn or removed from the market by the FDA because such drug product or a component of such drug product has been found to be unsafe. However, this prohibition shall be limited to the scope of the FDA withdrawal;

2. The regular compounding or the compounding of inordinate amounts of any drug products that are essentially copies of commercially available drug products. However, this prohibition shall not include (i) the compounding of any commercially available product when there is a change in the product ordered by the prescriber for an individual patient, (ii) the compounding of a commercially manufactured drug only during times when the product is not available from the manufacturer or supplier, (iii) the compounding of a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage, (iv) the compounding of a commercially manufactured drug when the prescriber has indicated in the oral or written prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary, or (v) the mixing of two or more commercially available products regardless of whether the end product is a commercially available product; or

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

I. Pharmacists shall maintain records of all compounded drug products as part of the prescription, formula record, formula book, or other log or record. Records may be maintained electronically, manually, in a combination of both, or by any other readily retrievable method.

1. In addition to other requirements for prescription records, records for products compounded pursuant to a prescription order for a single patient where only manufacturers' finished products are used as components shall include the name and quantity of all components, the date of compounding and dispensing, the prescription number or other identifier of the prescription order, the total quantity of finished product, the signature or initials of the pharmacist or pharmacy technician performing the compounding, and the signature or initials of the pharmacist responsible for supervising the pharmacy technician and verifying the accuracy and integrity of compounded products.

2. In addition to the requirements of subdivision I 1, records for products compounded in bulk or batch in advance of dispensing or when bulk drug substances are used shall include: the generic name and the name of the manufacturer of each component or the brand name of each component; the manufacturer's lot number and expiration date for each component or when the original manufacturer's lot number and expiration date are unknown, the source of acquisition of the component; the assigned lot number if subdivided, the unit or package size and the number of units or packages prepared; and the beyond-use date. The criteria for establishing the beyond-use date shall be available for inspection by the Board.

3. A complete compounding formula listing all procedures, necessary equipment, necessary environmental considerations, and other factors in detail shall be maintained where such instructions are necessary to replicate a compounded product or where the compounding is difficult or complex and must be done by a certain process in order to ensure the integrity of the finished product.

4. A formal written quality assurance plan shall be maintained that describes specific monitoring and evaluation of compounding activities in accordance with USP-NF standards. Records shall be maintained showing compliance with monitoring and evaluation requirements of the plan to include training and initial and periodic competence assessment of personnel involved in compounding, monitoring of environmental controls and equipment calibration, and any end-product testing, if applicable.

J. Practitioners who may lawfully compound drugs for administering or dispensing to their own patients pursuant to §§ 54.1-3301, 54.1-3304, and 54.1-3304.1 shall comply with all provisions of this section and the relevant Board regulations.

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

**§ 54.1-3434.05. Permit to act as an outsourcing facility.**

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board. Prior to obtaining a permit, an outsourcing facility is required to register as an outsourcing facility with the Secretary of Health and Human Services.

B. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall submit a copy of a current inspection report resulting from an inspection conducted by the FDA that indicates compliance with the requirements of state and federal law and Board regulation, including compliance with compounding in compliance with current Good Manufacturing Practices for outsourcing facilities. The inspection report shall be deemed current for the purpose of this subsection if the inspection was conducted (i) no more than one year prior to the date of submission of an application for the permit with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of the permit with the Board. However, if the outsourcing facility has not been inspected by the FDA within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

1. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application.

2. An application for an outsourcing facility permit shall be accompanied by a fee determined by the Board. All permits shall expire annually on a date determined by the Board in regulation.

3. No permit shall be issued or continued for an outsourcing facility until or unless there is compliance with the provisions of state and federal law and regulations promulgated by the Board.

C. An outsourcing facility shall compound in compliance with current Good Manufacturing Practices for outsourcing facilities and comply with state and federal law and Board regulation. Prior to an outsourcing facility compounding a drug pursuant to a patient-specific prescription a pharmacy permit shall also be obtained. The pharmacy shall comply with state and federal requirements and board regulations, except for §54.1-3410.2 of the Drug Control Act.

**§ 54.1-3434.1. Nonresident pharmacies to register with Board.**

A. Any pharmacy located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth shall be considered a nonresident pharmacy, shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia and is responsible for the pharmacy's compliance with this chapter, and shall disclose to the Board all of the following:

1. The location, names, and titles of all principal corporate officers and the name and Virginia license number of the designated pharmacist in charge, if applicable. A report containing this information shall be made on an annual basis and within 30 days after any change of office, corporate officer, or pharmacist in charge.

2. That it maintains, at all times, a current unrestricted license, permit, certificate, or registration to conduct the pharmacy in compliance with the laws of the jurisdiction, within the United States or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States, in which it is a resident. The pharmacy shall also certify that it complies with all lawful directions and requests for information from the regulatory or licensing agency of the jurisdiction in which it is licensed as well as with all requests for information made by the Board pursuant to this section.

3. As a prerequisite to registering or renewing a registration with the Board, the nonresident pharmacy shall submit a copy of a current inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than ~~six months~~ one year prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the required period, the Board may accept an inspection report or other documentation from

another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

4. For a nonresident pharmacy that dispenses more than 50 percent of its total prescription volume pursuant to an original prescription order received as a result of solicitation on the Internet, including the solicitation by electronic mail, that it is credentialed and has been inspected and that it has received certification from the National Association of Boards of Pharmacy that it is a Verified Internet Pharmacy Practice Site, or has received certification from a substantially similar program approved by the Board. The Board may, in its discretion, waive the requirements of this subdivision for a nonresident pharmacy that only does business within the Commonwealth in limited transactions.

5. That it maintains its records of prescription drugs or dangerous drugs or devices dispensed to patients in the Commonwealth so that the records are readily retrievable from the records of other drugs dispensed and provides a copy or report of such dispensing records to the Board, its authorized agents, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of a request.

6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a prescription that he knows or should have known was not written pursuant to a bona fide practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of § 18.2-248.

7. That it maintains a continuous quality improvement program as required of resident pharmacies, pursuant to § 54.1-3434.03.

The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.

B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each container of drugs dispensed to patients in the Commonwealth.

C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription Monitoring Program as set forth in § 54.1-2521.

D. The registration fee shall be the fee specified for pharmacies within Virginia.

E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in Virginia pursuant to regulations of the Board.

F. Pharmacies subject to this section shall comply with the requirements set forth in § 54.1-3408.04 relating to dispensing of an interchangeable biosimilar in the place of a prescribed biological product.

**§ 54.1-3434.4. Prohibited acts.**

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy or compounding services of an outsourcing facility which has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy or outsourcing facility to obtain controlled substances.

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of Pharmacy.

**§ 54.1-3434.5. Nonresident outsourcing facilities to register with Board.**

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices into the Commonwealth shall be registered with the Board, shall designate a pharmacist in charge who is licensed as a pharmacist in Virginia, is in full and actual charge of the outsourcing facility and fully engaged in the compounding performed at the location designated on the application, and is responsible for compliance with state and federal law and Board regulation. The application for such permit shall be made on a form provided by the Board and shall be accompanied by a fee determined by the Board.

B. An nonresident outsourcing facility shall register with the Secretary of Health and Human Services prior to obtaining a nonresident outsourcing registration.

C. As a prerequisite to registering or renewing a registration with the Board, the nonresident outsourcing facility shall submit a copy of a current inspection report resulting from an inspection conducted by the FDA that indicates compliance with the requirements of state and federal law and Board regulation, including compliance with compounding in compliance with current Good Manufacturing Practices for outsourcing facilities. The inspection report shall be deemed current for the purpose of this subdivision if the inspection was conducted (i) no more than one year prior to the date of submission of an application for registration with the Board or (ii) no more than two years prior to the date of submission of an application for renewal of a registration with the Board. However, if the nonresident outsourcing facility has not been inspected by the FDA within the required period, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause

an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

D. A nonresident outsourcing facility that also compounds a drug pursuant to a patient-specific prescription shall obtain a nonresident pharmacy permit prior to shipping drug into the Commonwealth. The nonresident pharmacy shall comply with state and federal requirements and board regulations, except for §54.1-3410.2 of the Drug Control Act.

**Department of Health Professions**
**2015 Session of the General Assembly**

*A bill to amend and reenact §§ 54.1-3435 and 54.1-3435.01 of the Code of Virginia to require notification to the Board of Pharmacy and the State Police if a wholesale distributor ceases or restricts distribution to a licensed dispenser for reason of suspicious ordering.*

**Be it enacted by the General Assembly of Virginia:**

1. **That §§ 54.1-3435 and 54.1-3535.01 of the Code of Virginia are amended and reenacted as follows:**

**§ 54.1-3435. License to act as wholesale distributor; renewal; fee.**

A. It shall be unlawful for any person to engage in the wholesale distribution of prescription drugs in this Commonwealth without a valid unrevoked license issued by the Board. The applicant for licensure as a wholesale distributor, as defined in § 54.1-3401, in this Commonwealth shall apply to the Board for a license, using such forms as the Board may furnish; renew such license using such forms as the Board may furnish, if granted, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information reported on the application form previously submitted to the Board; and remit a fee as determined by the Board.

B. A wholesale distributor that ceases distribution of controlled substances to a licensed or permitted dispenser located in this Commonwealth due to suspicious ordering shall notify the Board of Pharmacy within five days of notification to the DEA. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. A wholesale distributor making a report regarding cessation of distribution shall be immune from any civil liability resulting therefrom unless it acted in bad faith or with malicious intent.

C. The Board may promulgate such regulations relating to the storage, handling, and distribution of prescription drugs by wholesale distributors as it deems necessary to implement this section, to prevent diversion of prescription drugs, and to protect the public.

**§ 54.1-3435.01. Registration of nonresident wholesale distributors; renewal; fee.**

A. Any person located outside this Commonwealth who engages in the wholesale distribution of prescription drugs into this Commonwealth shall be registered with the Board. The applicant for registration as a nonresident wholesale distributor shall apply to the Board using such forms as the Board may furnish; renew such registration, if granted, using such forms as the Board may furnish, annually on a date determined by the Board in regulation; notify the Board within thirty days of any substantive change in the information previously submitted to the Board; and remit a

fee, which shall be the fee specified for wholesale distributors located within the Commonwealth.

B. The nonresident wholesale distributor shall at all times maintain a valid, unexpired license, permit, or registration in the state in which it is located and shall furnish proof of such upon application and at each renewal.

C. Records of prescription drugs distributed into this Commonwealth shall be maintained in such a manner that they are readily retrievable from records of distributions into other jurisdictions and shall be provided to the Board, its authorized agent, or any agent designated by the Superintendent of the Department of State Police upon request within seven days of receipt of such request.

D. A nonresident wholesale distributor that ceases distribution of controlled substances to a licensed or permitted dispenser located in this Commonwealth due to suspicious ordering shall notify the Board of Pharmacy within five days of notification to the DEA. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency. A nonresident wholesale distributor making a report regarding cessation of distribution shall be immune from any civil liability resulting therefrom unless it acted in bad faith or with malicious intent.

~~D.~~E. This section shall not apply to persons who distribute prescription drugs directly to a licensed wholesale distributor located within this Commonwealth.

-----Original Message-----
**From:** Shubhro Pal [spal@westwoodpharmacy.com]
**Sent:** Thursday, July 03, 2014 03:34 PM Eastern Standard Time
**To:** Juran, Caroline (DHP)
**Cc:** Mark Oley; shannon.dowdy@westwoodpharmacy.com; Board of Pharmacy
**Subject:** Petition for including us in the upcoming agenda meeting

Ms. Juran,
As instructed by Sammy Johnson, I am petitioning for including us in your upcoming agenda meeting to discuss the use of numbered rubber stamps (which are cross referenced to pharmacist initials) in lieu of hand written pharmacist initials. I understand that a previous ruling has been made on the use of rubber stamped initials.

Regards,

Shubhro Pal, RPh, PhD
Director of Pharmacy Services
Westwood Pharmacy Clinical Services
5823 Patterson Avenue Suite A
Richmond, VA 23226
Ph: (804)288-3620
Fax:(804)288-1510

**Excerpts of current regulations requiring initials:**

**18VAC110-20-320. Refilling of Schedule III through VI prescriptions.**

A. A prescription for a drug listed in Schedule III, IV, or V shall not be dispensed or refilled more than six months after the date on which such prescription was issued, and no such prescription authorized to be filled may be refilled more than five times.

1. Each refilling of a prescription shall be entered on the back of the prescription or on another record in accordance with §54.1-3412 and 18VAC110-20-255, initialed and dated by the pharmacist as of the date of dispensing. If the pharmacist merely initials and dates the prescription, it shall be presumed that the entire quantity ordered was dispensed.

**18VAC110-20-355. Pharmacy repackaging of drug; records required; labeling requirements.**

A. Pharmacies in which bulk reconstitution of injectable, bulk compounding or the repackaging or prepackaging of drugs is performed shall maintain adequate control records for a period of one year or until the expiration, whichever is greater. The records shall show the name of the drug(s) used; strength, if any; date repackaged; quantity prepared; initials of the pharmacist verifying the process; the assigned lot or control number; the manufacturer's or distributor's name and lot or control number; and an expiration date.

B. The drug name; strength, if any; the assigned lot or control number or the manufacturer's or distributor's name and lot or control number; and an appropriate expiration determined by the pharmacist in accordance with USP guidelines shall appear on any subsequently repackaged or reconstituted units.

C. Pharmacies using automated counting devices or dispensers in which drugs are removed from manufacturer's original packaging and placed in bulk bins shall comply with the following requirements:

1. A bin filling record shall be maintained, manually or in a computerized record for a period of one year from the date of filling from which information can be readily retrieved, for each bin including:

a. The drug name and strength, if any;

b. The name of the manufacturer or distributor;

c. Manufacturer's control or lot number(s) and expiration date for all lots placed into the bin at the time of filling;

d. Any assigned lot number;

e. An expiration date determined according to USP guidelines for repackaging;

f. The date of filling; and

g. The pharmacist's initials verifying the accuracy of the process.

**18VAC110-20-420. Unit dose dispensing system.**

A. A unit dose drug dispensing system may be utilized for the dispensing of drugs to patients in a hospital or long-term care facility. The following requirements shall apply regardless of whether licensed or unlicensed persons administer medications:

8. A record shall be made and maintained within the pharmacy for a period of one year showing:

a. The date of filling of the drug cart;

b. The location of the drug cart;

c. The initials of the person who filled the drug cart; and

d. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18VAC110-20-270 C.

**18VAC110-20-425. Robotic pharmacy systems.**

Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in bar-coded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply:

5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.

**18VAC110-20-490. Automated devices for dispensing and administration of drugs.**

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

2. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedule II through V distribution and delivery records may also be stored offsite or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

**18VAC110-20-760. Procedures for collecting eligible donated drugs.**

A. A pharmacist or a pharmacy technician under the personal supervision of a pharmacist shall receive and conduct the initial screening for eligibility of donated drugs.

B. At the time of accepting donated drugs, the drug donation site shall ensure that a donor form is completed. The drug donation site shall give a copy of the donor form to the person donating the drug at the time of the donation and shall maintain the original donor form. A donor form is not required for drugs donated by a patient residing in a long-term care facility or other facility where drugs are administered to that patient if the drugs are donated directly to the provider pharmacy for that facility and such provider pharmacy is registered as a drug donation site.

C. A donor form shall include the following information:

9. The initials of the receiving pharmacist, or the initials of the receiving pharmacy technician and supervising pharmacist.

PRESCRIPTIONS AND TWO PRESCRIPTION NUMBERS:

dispensing of a Schedule II prescription in which a patient wants a portion billed to a third party and to pay cash for the remainder when the pharmacy computer system will not then indicate the dispensing of the total amount under the same prescription number. Some pharmacies have a method for working around the problem by giving the one prescription two different prescription numbers and dispensing each partial amount under the two numbers. There was significant discussion as to whether this is allowed; on the side of allowing this practice, there is the fact that a prescription number is not required by law, the hard copy record would show that the prescription was really only one prescription and not partially dispensed, a lot of dispensing software could not accommodate a split billing transaction or pharmacists did not know how to do it. On the side of not allowing this practice, the data submitted to the Prescription Monitoring Program (PMP) is not correct, the hard copy is not really the official dispensing record any longer, and the label may show the incorrect quantity if all the drug is put in one vial or, if using two labels, it will look as though two prescriptions were filled. The Board responded that the official dispensing record for the pharmacy would have to accurately reflect one prescription and the total quantity dispensed on that date for that one prescription and must otherwise meet any requirements of law to include accuracy of reporting to the PMP.

DROP BOXES:

Ms. Russell stated that staff has received requests from pharmacies that want to install a drop box for patients to leave new prescriptions after pharmacy hours. There was significant discussion related to security, location and access. The consensus of the Board was to allow this practice with some guidelines to ensure the security of the prescriptions and that patients would not be able to leave containers which contain drugs to be refilled. Ms. Russell offered to draft a guidance document to be considered at the December meeting and the Board agreed.

STAMPS FOR INITIALS:

Ms. Abernathy requested that the Board determine if initial stamps could be used for records requiring the initials of the "checking" pharmacist rather than handwritten initials which are frequently illegible. She stated that at her hospital, they had a policy in which pharmacist had stamps containing all three initials, so that the checking pharmacist could be more easily identified. She stated she found with hand initials, usually the pharmacist only used two initials, she has pharmacists with the same two initials, and after someone has to initial a hundred items in a day the checking pharmacist could often not be determined. She stated the stamp

system worked well. It was discussed that stamps could be stolen and used by someone else or the pharmacist could give a pharmacy technician his stamp and not really check. These concerns were countered with the fact that a pharmacy technician could easily copy the hand initials of the pharmacist, and that this was not so different than a pharmacist's initials in a computer system being used by someone else.

**Motion:**

**A motion was made and passed, to allow the use of stamps by pharmacists on records requiring the pharmacists' initials. (Motion by Beckner, second by Ross)**

NEWSLETTER TOPICS:

Staff asked if the Board members had any ideas for the upcoming Board newsletter. The Board stated that some of the decisions made at this meeting should be included such as the increase sanction for not registering pharmacy technicians, pharmacy technicians being held jointly accountable for dispensing errors, the use of stamps for initials, reminders about upcoming renewals and CE requirements particularly for pharmacy technicians.

BOARD OF HEALTH PROFESSIONS REPORT:

Ms. Edwards stated that she will attend her first Board of Health Professions meeting on September 25, 2007, and will have a report for the December meeting.

EXECUTIVE DIRECTOR'S REPORT:

- NAPLEX SUSPENSION UPDATE

Ms. Russell gave an update on the NAPLEX suspension, stated that NABP is working diligently to have the examination back online by November 1, and is hopeful it will meet that date. She stated that at the time of suspension of the NAPLEX, Virginia had 65 applicants who had not yet taken it.

- NEW EMPLOYEES

Ms. Russell stated that the Board has two new part-time employees assisting with various functions. Ms. Russell introduced Sharon Davenport who will be handling Board meeting matters including contacting Board members related to meeting schedules and travel vouchers. Virginia Davis is assisting the Board with a special project involving preparing the Board's files to be scanned for record retention.

- UPCOMING MEETINGS

Ms. Russell stated that she will be attending the NABP Fall conference next week in Arlington, VA, and the District II meeting in October in Wilmington, DE, as part of her NABP responsibilities. Mr. Ross and Mr. Yi will also be attending the Fall Conference. Due to travel restrictions and because there had been no requests, no Board members are attending the District II

NANCY FRYE

10683 Old Stillhouse Road
Boston, VA 22713

June 29, 2014

Board Of Pharmacy
Department of Health Professions
Perimeter Center
9960 Maryland Drive., Suite 300
Henrico, VA 23233-1463

Dear Board Members:

I am writing concerning the administration of flu shots and other vaccines in the retail pharmacy setting. Though I realize this greatly increases the ease in which the public can get a shot, I don't think anyone realizes how much added stress this has created on the pharmacy staff. I feel that the added work load and stress during peak times could hamper the pharmacists' ability to concentrate and interrupts the work flow immensely.

Retail pharmacy has widely advertised the policy that the customer can walk in any time and get a flu shot with no appointment and no waiting. How have we belittled ourselves so? According to this policy, the pharmacist and staff must interrupt everything else to assure that the patient receiving the flu shot does not have to wait unlike the patients who are there for prescriptions. Many times we are rushed to check prescriptions so we can go administer a flu shot, or prescriptions pile up while the pharmacist is detained giving vaccines.

We also need to consider the increase in the amount of time the pharmacist is not in the pharmacy, supervising technicians, answering doctor calls, and consulting with patients. How have we let flu shots become more important than all other pharmacist duties? Some days a store may give twenty or more shots to make its quota. If each shot takes even just five minutes, that is one to two hours the pharmacist is outside the pharmacy. What is the pharmacist to technician ratio then? With the pilferage that occurs today, how can the Board justify this?

I feel that pharmacies need to go back to offering flu shots the way we did in the past. We had clinics when an extra tech and extra pharmacist were scheduled. Patients did not have to have an appointment, but did have to come when sufficient staff was available. The purpose of a pharmacy is to fill prescriptions as efficiently as possible with the least chance of error. This can best be accomplished without the ongoing interruption of giving flu shots and/or other vaccines.

Thank you for your consideration of this matter.

Sincerely,

Nancy L. Frye, PIC

# COMMONWEALTH of VIRGINIA

Dianne L. Reynolds-Cane, M.D.
Director

*Department of Health Professions*
Perimeter Center
9960 Mayland Drive, Suite 300
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**Board of Pharmacy**
*tel* (804) 367-4456
*fax* (804) 527-4472

January 14, 2014

Dear Pharmacist-in-Charge:

In an effort to further educate pharmacists-in-charge of their responsibilities and address concerns regarding diversion of controlled substances, the Board is mailing the enclosed Guidance Document 110-27 to all pharmacists-in-charge. On December 12, 2013, the Board revised the document by adding the language beginning on page 3 which highlights required safeguards against diversion and provides suggested best practices to prevent diversion of all controlled substances. Please review this document, ensure you are compliant with current laws and regulations, and consider implementing the suggested best practices as necessary.

Please contact the Board office at (804) 367-4456 or pharmbd@dhp.virginia.gov should you have any questions.

Thank you.

Virginia Board of Pharmacy

Enclosure

I believe best practices would include having the pharmacist in the pharmacy as much as possible.

FINAL/APPROVED

# VIRGINIA BOARD OF PHARMACY
# MINUTES OF REGULATION COMMITTEE REGARDING PHARMACY WORKING CONDITIONS

May 2, 2012
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:05PM.

PRESIDING: Jody H. Allen, Committee Chairman

MEMBERS PRESENT:
Gill B. Abernathy
David C. Kozera
Empsy Munden
Robert M. Rhodes
Crady Adams

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Elaine J. Yeatts, Senior Policy Analyst, DHP

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented.

The Regulation Committee met to discuss the specific mandates requested by The Pharmacy Alliance and referred to committee for further consideration during the March 13, 2012 full board meeting. Those mandates were: prohibition of any guarantee or advertisement that promotes how fast prescriptions will be dispensed; requirement that drive-thru windows be closed when there is no pharmacy technician support in the prescription department; prohibition against mandatory corporate production metrics or quotas regarding prescription dispensing or immunization administration; requirement that other timed metrics regarding the phone, drive-thru, or cash register may only be imposed on pharmacy technicians and not pharmacists; and prohibition of any non-pharmacy employ of the permit holder influencing the professional decision of the pharmacist. Additionally, the Committee discussed a recent petition for rulemaking received on February 22, 2012 regarding working conditions. Specifically it requested regulations similar to West Virginia and North Carolina which require breaks for pharmacists working more than 6 continuous hours and a prohibition against pharmacists working more than 12 continuous hours per day.

PETITION FOR RULEMAKING REGARDING PHARMACY WORKING CONDITIONS - REQUIRED BREAKS AND NUMBER OF CONTINUOUS HOURS PHARMACIST MAY WORK:

The Committee first discussed the petition for rulemaking. The public comment period had closed on April 15, 2012. Ms. Yeatts provided a summary of the approximate twenty public comments received. All, but one were completely supportive of the petition.

MOTION:

**The Committee voted unanimously to recommend to the full Board in June to accept the petition for rulemaking and publish a NOIRA to address pharmacy working conditions such as a requirement that no pharmacist may work more than 12 continuous hours in any 24-hour period or more than 60 hours in any 5-day period and an allowance for pharmacists working more than 6 continuous hours to take a 30-minute uninterrupted break and one additional uninterrupted 15-minute break, with emergency provisions for addressing immediate needs of patients.**

REQUEST FROM *THE PHARMACY ALLIANCE* TO IMPLEMENT MANDATES TO ADDRESS "SYSTEM INDUCED ERRORS"

The Committee then discussed the specific mandate requests received from *The Pharmacy Alliance* and referred to committee for further consideration. Public comment was received from Mr. Bob Garland, pharmacist, who believes Regulation 18VAC110-20-110 addresses the concerns raised by The Pharmacy Alliance. The regulation states that the pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy and that any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit. He stated that the corporations may not clearly understand this regulation. Comment was also received by Ms. Kristen Barratt, pharmacist, who supported the concern for a drive-thru operating when there is only one pharmacist on-duty and no pharmacy technicians. Pursuant to §54.1-100, Board counsel indicated that the promulgation of regulation may require proof that an unregulated practice can harm or endanger the health, safety or welfare of the public; without such proof, the Board may be overreaching in its authority. Through lengthy discussions, concerns were expressed by various members for the current business practices, along with concerns for the Board's ability to lawfully regulate the practices.

MOTION:

**The Committee voted unanimously to recommend the following to the full Board in June: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and pharmacists to provide evidence to the Board that the identified practices referred to the Committee can or have created patient harm; and, publish an article in an upcoming Board e-newsletter expressing concern for contemporary practices and restating the relevant sections §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary**

**action against the pharmacy permit.**

ADJOURN: With all business concluded, the meeting adjourned at 4:40PM.

Jody H. Allen, Committee Chairman

6/12/2012
Date

Caroline D. Juran, Executive Director

June 12, 2012
Date

be submitted to the Secretary's Office by August. She also reported that she has been conducting a weekly progress check of the regulations that are currently at the Governor's Office. Arne Owens, Chief Deputy Director, DHP, and Ralph Orr, Director, Prescription Monitoring Program (PMP), visited the Department of Health and Human Resources in Washington, DC to discuss the PMP with regards to interoperability between states (interstate data sharing between PMP programs). Dr. Cane also spoke on new policies being set forth by the agency that will help decrease traveling expenses.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated that the comment period for the changes to the "run-dry" requirement for automated dispensing devices is now closed. Emergency regulations for Continuous Quality Improvement Programs (CQI) are at the Governor's Office. The proposed amendments to address on-hold prescriptions and the final regulations for repackaging in the Community Service Boards and Behavioral Health Authorities are also at the Governor's Office (emergency regulations for CSB's and BHA's expire 6/18/12). The proposed regulation for administrative fees for duplicate licenses and verification are at the Secretary's Office.

- Re-adoption of the proposed regulations for automated dispensing devices:

Ms. Yeatts indicated that staff did not make any substantive changes, but did reorganize the proposed regulations for automated dispensing devices to improve readability. Therefore, she requested that the Board review the changes. Ms. Yeatts stated that the Board would need to re-adopt the proposed regulations.

**MOTION:**

**The Board voted unanimously to adopt the proposed regulations as presented for automated dispensing devices.**
**(motion by Yi, second by Allen)**

REGULATORY COMMITTEE REPORT:

- Recommendation on Petition for Rulemaking, Kristen Barratt, Pharmacist

Ms. Yeatts presented to the Board Ms. Barratt's Petition for Rulemaking concerning professional work environment. Ms. Yeatts stated that the Board could either deny the petitioner's request for amendments and state the reason why the request was denied, or accept the request and initiate rulemaking by adopting a Notice of Intended Regulatory Action (NOIRA). Ms. Juran discussed the research that staff conducted and provided to the Regulation Committee. The Regulation Committee's motion was for the Board to accept the request and adopt a NOIRA.

**MOTION:**

**The Board voted unanimously to approve the Regulation Committee's recommendation to accept the petition for rulemaking and adopt a Notice of Intended Regulation Action regarding the number of continuous hours a pharmacist may work and required breaks.**

- Recommendation regarding request from *The Pharmacy Alliance* on pharmacy working conditions

Ms. Allen discussed with the Board the request from The Pharmacy Alliance concerning pharmacy working conditions and the Regulation Committee's recommendation. The Committee recommended the following: continue discussions on pharmacy working conditions as needed; encourage *The Pharmacy Alliance* and other pharmacists to submit evidence to the Board that the identified practices referred to the Committee can or have created patient harm; publish an article in the Board's e-newsletter expressing concerns for contemporary practices and restating the relevant sections of §54.1-3434 and Regulation 18VAC110-20-110 B which indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, and that the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

**MOTION:**

**The Board voted unanimously to approve the Regulation Committee's recommendation regarding *The Pharmacy Alliance's* request concerning pharmacy working conditions.**

MISCELLANEOUS:

- Request to discuss length of time associated with and access to final orders:

Mr. Adams presented to the Board his concerns regarding pharmacists who have past disciplinary actions on their licenses and are having a difficult time getting employment as a result. Notices and Orders are public information and kept on record for eighty-five years. Mr. Casway explained that changes would necessitate the General Assembly amending the Administrative Process Act, Freedom of Information Act, title 54.1 and possibly other sections of law. Additionally, changes to the state record retention requirements and agency policy would be necessary. Mr. Kozera commented that many violations are also reportable to the National Practitioner Databank and therefore, a violation would also exist in its records.

**MOTION:**

**A motion was presented and subsequently withdrawn by Mr. Adams for the Board to consider a process to expunge certain case violations from a pharmacist's license.**

**MOTION:**

**A new motion was made that the Department of Health Professions reconsider how it displays public information on its website with a focus of discussion on violations occurring in excess of twenty years. (motion by Adams, died for lack of a second)**

- Define "annual" and "semiannual" in guidance document 110-36

To further clarify the Board's expectations regarding when media fill testing must be performed, Ms. Juran requested that the Board review staff's suggested changes to Guidance Document 110-36 concerning the definitions of "annual" and "semiannual". It was suggested the terms

February 2013

# Virginia Board of Pharmacy News

*Published to promote compliance of pharmacy and drug law*

Perimeter Center • 9960 Mayland Dr, Suite 300 • Henrico, VA 23233
Phone: 804/367-4456 • *www.dhp.virginia.gov/pharmacy*

## Compounding Sterile Preparations

Virginia Board of Pharmacy Regulation 18VAC110-20-321 states compounding of both sterile and nonsterile drug products shall be performed in accordance with United States Pharmacopeia-National Formulary (USP-NF) compounding standards and §54.1-3410.2 of the Code of Virginia. While pharmacists often associate sterile compounding requirements with USP Chapter <797> *Pharmaceutical Compounding: Sterile Preparations*, it is important not to overlook the requirements in USP Chapters <1> *Injections*, <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Test*, and <85> *Bacterial Endotoxin Testing*.

At the December 12, 2012 Board meeting, the Board addressed several issues in Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide*, related to compliance with USP-NF standards regarding the compounding of sterile preparations. Modifications, including changes for when an inspector should cite a deficiency, were made to Major Deficiencies 20, 21, 22, 24, 25, 26, and 33, and Minor Deficiencies 30, 31, and 32. To access Guidance Document 110-9, visit *www.dhp.virginia.gov/Pharmacy/pharmacy_guidelines.htm*.

## Deficiencies Associated With Compounding Sterile Preparations

Certification of the direct compounding area, buffer or clean room, and ante room is to be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed (refer to Major Deficiencies 22 and 23). Every six months is interpreted to be six months from the date of the last certification. For example, a direct compounding area certified as ISO Class 5 on January 17, 2013, requires certification on or before July 17, 2013. The inspector will ask for documentation of at least the two most recent certifications to ensure that the areas comply with the appropriate ISO class.

Individuals preparing compounded sterile preparations (CSP) must complete media-fill testing annually when preparing low and medium-risk CSPs and semiannually when preparing high-risk level CSPs (refer to Major Deficiencies 25a and 26). The terms "annually" and "semiannually" as used in USP Chapter <797> are defined to mean every 12 months and every six months, respectively. In the event an individual fails a media-fill test, that individual may not perform high-risk level compounding prior to retraining and receipt of a passing media-fill test (refer to Major Deficiency 25c). Individuals preparing low or medium-risk level CSPs must provide documentation of passing the media-fill test within 45 days of the failed test (refer to Major Deficiency 26a). Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. The records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection. The inspector will ask for documentation that each individual who prepares CSPs has completed the required media-fill testing and retesting if required.

Compounded sterile preparations must be assigned an appropriate beyond-use date (BUD) in compliance with USP-NF standards (Major Deficiencies 25 and 33). In the absence of sterility testing, the BUD for low, medium, and high-risk CSPs are:

| | Low Risk | Medium Risk | High Risk |
|---|---|---|---|
| Controlled Room Temperature | 48 hours | 30 hours | 24 hours |
| 2° to 8°C (36° and 46°F) | 14 days | 9 days | 3 days |
| -25° to -10°C (-4° and 14°F) or colder | 45 days | 45 days | 45 days |

If performed, sterility and endotoxin testing must comply with USP Chapters <51> *Antimicrobial Effectiveness Testing*, <71> *Sterility Test*, or <85> *Bacterial Endotoxin Testing* in addition to USP Chapter <797> *Pharmaceutical Compounding: Sterile Preparations*. The inspector will ask for documentation for sterility or endotoxin testing.

## Concern for Contemporary Practice: Evidence Requested

During the June 2012 full Board meeting, the Board expressed concern for several identified contemporary practices such as the advertising of a guarantee for how quickly prescriptions will be dispensed, or corporate production quotas regarding prescription dispensing or immunization administration. However, the Board determined that there was insufficient evidence proving that the identified practices can or have created patient harm. Such evidence is legally necessary for the promulgation of regulation. Therefore, the Board voted to encourage pharmacists to submit evidence to the Board when contemporary pharmacy practices can or have created patient harm and remind everyone of the following relevant sections of 54.1-3434 and Regulation 18VAC110-20-110 B:

- The pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy.

*continued on page 4*



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*continued from page 1*

- If the owner is not a pharmacist, he or she shall not abridge the authority of the pharmacist-in-charge (PIC) to exercise professional judgment relating to the dispensing of drugs.
- The PIC or pharmacist on duty shall control all aspects of the practice of pharmacy, and any decision overriding such control shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

Evidence of possible patient harm resulting from contemporary pharmacy practice or any violation of law, to include 54.1-3434 and Regulation 18VAC110-20-110 B, may be submitted to the Virginia Department of Health Professions, Enforcement Division by following the directions for "How to file a Complaint" found at *www.dhp.virginia.gov/Enforcement/complaints.htm.*

## Regulations for Continuous Quality Improvement Programs

On October 1, 2012, emergency regulations for continuous quality improvement (CQI) programs became effective. As emergency regulations, they will remain in effect for one year with an option for the Board to request a six-month extension, if permanent replacement regulations have not been approved by the governor at that time. Regulations were promulgated pursuant to §54.1-3434.03 of the Code of Virginia. This law requires each pharmacy to implement a program for CQI in compliance with Board regulations or actively report to a patient safety organization (PSO) that has as its primary mission CQI under the Patient Safety and Quality Improvement Act of 2005 (Public Law 109-41). To provide sufficient time for pharmacies to come into compliance, the Board instructed staff to not cite a deficiency during a routine inspection for the first six months from the date the regulations became effective. Thus, through March 31, 2013, if the pharmacy is not in compliance with CQI requirements, the inspector will simply note this as a comment on the inspection report rather than citing a deficiency. As of April 1, 2013, the inspector will cite a deficiency for noncompliance.

In a pharmacy that chooses to comply with CQI requirements by actively reporting to a PSO, the inspector will look for a record indicating the date a report was submitted to the PSO. If no dispensing errors occurred within the past 30 days, the record must indicate a zero report with date. The record is to be maintained for 12 months from the date of reporting. In a pharmacy that chooses to implement its own CQI program in compliance with Board regulations, the inspector will look for a record that includes the following general information: (1) dates the analysis was initiated and completed; (2) names of the participants in the analysis; and (3) general description of remedial action taken to prevent or reduce future errors. A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days. The record is to be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors. The report is not intended to be punitive by revealing patient-specific information associated with dispensing errors, but is intended to demonstrate to the inspector the pharmacy's compliance with CQI requirements.

For more information, the emergency CQI regulations may be accessed at *www.dhp.virginia.gov/Pharmacy/leg/EmergencyRegs_QualityImprovementPrograms.doc.*

## Pre-Populating Refill Authorization Forms for Prescribers

Drug Enforcement Administration (DEA) has recently indicated that a pharmacy, to include community and long-term care pharmacies, may not send a refill request to a prescriber that contains partially or fully pre-populated information within the "prescription" portion of the refill reminder. DEA does not characterize the pharmacy as acting as the prescriber's agent for the purposes of preparing the prescription since federal regulations require the prescriber to direct the agent as to the required elements of a valid prescription and not vice-versa. Refill reminders for drugs in Schedules III through V should instruct the prescriber to prepare and transmit a prescription to the pharmacy if the prescriber wishes to issue a new prescription for the patient. Please remember when a prescriber faxes a written prescription to a pharmacy it must bear the prescriber's manual signature. A faxed prescription containing an electronic or computer-generated signature is not a valid prescription.

## Interoperability of the Virginia Prescription Monitoring Program With Other States

A report from the Virginia Prescription Monitoring Program (VPMP) reveals only those drugs in Schedules II through IV that a specific patient was dispensed by a pharmacy located in Virginia. If the patient resides in another state but is using a Virginia pharmacy to obtain a prescription drug, a query to the VPMP may not reveal a complete dispensing history assuming the patient also receives prescriptions from pharmacies in his or her home state. However, the VPMP is becoming increasingly more interoperable with other states. By sharing dispensing information across the borders, prescribers and pharmacists are able to receive a more comprehensive patient dispensing history and make more meaningful decisions regarding the appropriateness for prescribing or dispensing a controlled substance. Currently, Virginia is interoperable with nine states: Ohio, Indiana, Connecticut, Michigan, North Dakota, Kansas, Arizona, Kentucky, and South Carolina. To request PMP information from these states, a registered user of the VPMP selects the corresponding box for the state from which information is desired when submitting the request to the VPMP. The request for information is sent to the selected states. Dispensing information, if available, reported by that state(s) is provided to the requestor along with information from the VPMP.

Because other states such as West Virginia, Tennessee, and North Carolina are not currently interoperable with the VPMP, a Virginia pharmacist must directly register as a user with the other state's PMP program in order to access a patient's dispensing history within that state. It is hoped that these states will be able to implement interoperability in the near future. Information for becoming a registered user of these surrounding states' PMP programs may be accessed at:

- West Virginia: *https://65.78.228.163*
- Tennessee: *https://prescriptionmonitoring.state.tn.us*
- North Carolina: *www.ncdhhs.gov/mhddsas/controlledsubstance/index.htm*

Maryland and Washington DC do not have operational PMPs at this time. For more information, see the "Prescriptions from Out-of-State Prescribers and Patients" article, in the July 2012 Board *Newsletter,* available at *www.dhp.virginia.gov/Pharmacy/newsletters/VA072012.pdf.*



The *Virginia Board of Pharmacy News* is published by the Virginia Board of Pharmacy and the National Association of Boards of Pharmacy Foundation, Inc, to promote compliance of pharmacy and drug law. The opinions and views expressed in this publication do not necessarily reflect the official views, opinions, or policies of the Foundation or the Board unless expressly so stated.

Caroline Juran, Executive Director - State News Editor
Carmen A. Catizone, MS, RPh, DPh - National News Editor & Executive Editor
Larissa Doucette - Communications Manager

**Juran, Caroline (DHP)**

**Subject:** FW: FYI 2G

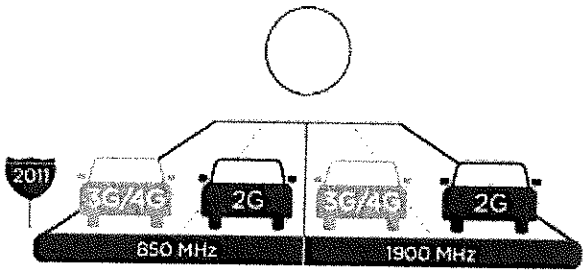
**From:** khodges@gloucesterpharmacy.com [mailto:khodges@gloucesterpharmacy.com]
**Sent:** Friday, August 08, 2014 12:52 PM
**To:** Johnson, Sammy (DHP)
**Subject:** Fw: FYI 2G

Sent from Windows Mail

**From:** Rich Redd
**Sent:** Thursday, April 10, 2014 11:40 AM
**To:** Keith Hodges RPh

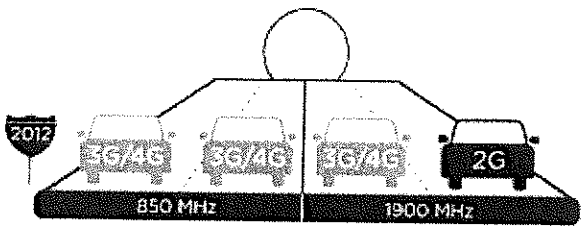
# Finally, after December 31, 2016, when the 2G Sunset is complete, it will be just like the Analog Sunset. Anything using 2G will stop working overnight.

## Roadmap of the 2G Sunset




**Before the Sunset:**

You'll recall that cellular carriers deploy their networks in two frequency bands: a preferred band with deep building penetration (850 MHz) and another band with shallow building penetration (1900 MHz). Prior to 2011, cellular carriers equally spread 2G and 3G/4G across both bands like a highway that allows all cars to drive in all lanes.




**During the Sunset:**

Starting in 2011, in an effort to increase service levels to their consumer cell phone customers, cellular carriers will start to make their preferred frequencies 3G/4G only. The process is called *spectrum harvesting.* Similar to how semis must stay in the highway's far right lanes because of their slower speeds, 2G devices will not be allowed on the best frequencies.

For 2G devices this will be a noticeable shift. If they were



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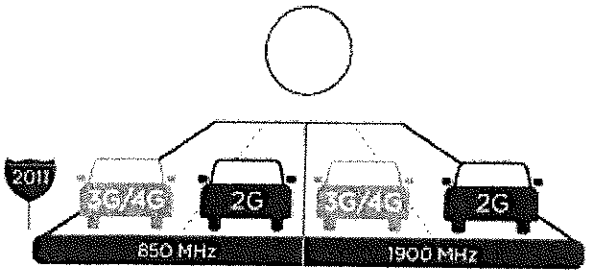
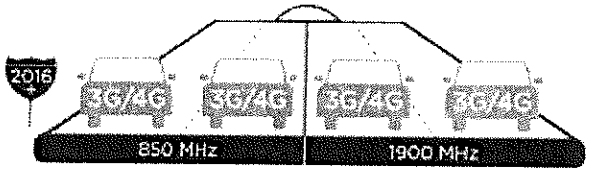



**Before the Sunset**:

You'll recall that cellular carriers deploy their networks in two frequency bands: a preferred band with deep building penetration (850 MHz) and another band with shallow building penetration (1900 MHz). Prior to 2011, cellular carriers equally spread 2G and 3G/4G across both bands like a highway that allows all cars to drive in all lanes.

installed based on the coverage provided by the preferred frequencies, their signal levels will drop as they are forced onto the inferior, shallow penetrating frequencies still supporting 2G. This restriction will not occur all at once. It will appear sporadically across the country and when it does, only 3G/4G devices will be oblivious to the change.




**After the Sunset**:

Finally, after December 31, 2016, when the 2G Sunset is complete, it will be just like the Analog Sunset. Anything using 2G will stop working overnight. Only 3G/4G will work from that day forward.

Jim Yopp
Central Station Mgr
Sonitrol of Greater Richmond



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**18VAC110-20-140. New pharmacies, acquisitions and changes to existing pharmacies.**

A. Any person wishing to open a new pharmacy, engage in the acquisition of an existing pharmacy, change the location of an existing pharmacy, move the location or make structural changes to an existing prescription department, or make changes to a previously approved security system shall file an application with the board.

B. In the acquisition of an existing pharmacy, if prescription records are to be accessible to anyone for purposes other than for continuity of pharmacy services at substantially the same level offered by the previous owner or for the necessary transfer of prescription records, the owner of the pharmacy acquiring the records shall disclose such information in writing to each patient 14 days prior to the acquisition. Such release of prescription records shall be allowed only to the extent authorized by §32.1-127.1:03 of the Code of Virginia.

C. The proposed location or structural changes shall be inspected by an authorized agent of the board prior to issuance of a permit.

1. Pharmacy permit applications which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

2. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

3. At the time of the inspection, the dispensing area shall comply with 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180, and 18VAC110-20-190.

4. If an applicant substantially fails to meet the requirements for issuance of a permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18 VAC 110-20-20 prior to a reinspection being conducted.

D. Drugs shall not be stocked within the proposed pharmacy or moved to a new location until approval is granted by the inspector or board staff.

E. Once the permit is issued, prescription drugs may not be stocked earlier than two weeks prior to the designated opening date. Once prescription drugs have been placed in the pharmacy, a pharmacist shall be present on a daily basis to ensure the safety and integrity of the drugs. If there is a change in the designated opening date, the pharmacy shall notify the board office, and a pharmacist shall continue to be on site on a daily basis.

**18VAC110-20-180. Security system.**

A. A device for the detection of breaking shall be installed in each prescription department of each pharmacy. The installation and the device shall be based on accepted alarm industry standards, and shall be subject to the following conditions:

1. The device shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device.

2. The device shall be 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.

3. The device shall fully protect the prescription department and shall be capable of detecting breaking by any means when activated.

4. Access to the alarm system for the prescription department area of the pharmacy shall be restricted to the pharmacists working at the pharmacy, except for access by other persons in accordance with 18VAC110-20-190 B 2, and the system shall be activated whenever the prescription department is closed for business.

B. Exceptions to provisions in this section:

1. Alarm systems approved prior to November 4, 1993, will be deemed to meet the requirements of subdivisions A 1, 2, and 3 of this section, provided that no structural changes are made in the prescription department, that no changes are made in the security system, that the prescription department is not closed while the rest of the business remains open, and that a breaking and loss of drugs does not occur. If a breaking with a loss of drugs occurs, the pharmacy shall upgrade the alarm to meet the current standards and shall file an application with the board in accordance with 18VAC110-20-140 A within 14 days of the breaking.

2. If the prescription department was located in a business with extended hours prior to November 4, 1993, and had met the special security requirements by having a floor to ceiling enclosure, a separately activated alarm system shall not be required.

3. This section shall not apply to pharmacies which are open and staffed by pharmacists 24 hours a day. If the pharmacy changes its hours or if it must be closed for any reason, the PIC or owner must immediately notify the board, file an application in accordance with 18VAC110-20-140 A, and have installed prior to closing, a security system that meets the requirements of subdivisions A 1 through 4 of this section.

Guidance Document: 110-3

Adopted: December 8, 2005
Reviewed: August 1, 2013
Revised September 9, 2014

**Virginia Board of Pharmacy**

ALTERNATE DELIVERY OF PRESCRIPTIONS IN VIRGINIA
Pharmacy to Physician or Controlled Substances Registration Type of Delivery

Reference: §54.1-3420.2 of the Code of Virginia, 18VAC 110-20-275 of the Regulations of the Virginia Board of Pharmacy

The following is an example of some of the requirements for a Pilot Program approved by the Board to deliver prescriptions to an alternate location which was a physician licensed to practice pharmacy. These requirements formed the basis for the Regulations.

***18 VAC 110-20-275. Delivery of dispensed prescriptions.***

*C. Delivery to a practitioner of the healing arts licensed by the board to practice pharmacy or to sell controlled substances or other authorized person or entity holding a controlled substances registration authorized for this purpose.*

*1. A prescription may be delivered by a pharmacy to the office of such a practitioner or other authorized person provided there is written contract or agreement between the two parties describing the procedures for such a delivery system and the responsibilities of each party.*

*2. Each pharmacy using this delivery system shall maintain a policy and procedure manual that includes the following information:*

*a. Procedure for tracking and assuring security, accountability, integrity, and accuracy of delivery for the dispensed prescription from the time it leaves the pharmacy until it is handed to the patient or agent of the patient;*

Example:

- The pharmacy will prepare a log of all the prescriptions. The employee delivering the prescriptions will sign this log. All of the prescriptions prepared for delivery and the signed log will be placed in a sealed tote/container prior to the employee leaving the pharmacy.

- The agent at the receiving location will sign for receipt of the sealed container, then open the sealed container and check the prescriptions against the delivery log to insure that all prescriptions have been received and sign the log as being complete. The delivered prescriptions shall be stored in accordance with law and regulations.



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- Patients picking up their prescription(s) will sign the log indicating receipt of the prescription.

*b. Procedure for providing counseling;*

Example: The prescriptions for a patient will be placed in a tamper-resistant bag with the Medi-Span Patient Information Leaflet for each prescription and a written offer for counseling by a pharmacist available by a toll free phone number to include the hours of operation for the pharmacy when counseling may be obtained. A label identifying the patient will be placed on the outside of the bag.

*c. Procedure and recordkeeping for return of any prescription medications not delivered to the patient;*

Example: Completed logs are to be returned to the originating pharmacy within 14 days, and maintained in chronological order for a period of 2 years. Any prescriptions not picked up within 14 days are to be returned to the originating pharmacy in a sealed tote/container.

*d. The procedure for assuring confidentiality of patient information; and*

Example: The only personnel handling the prescriptions will be employees of the pharmacy or employees of the permitted physician who already have access to these patients' medical records.

*e. The procedure for informing the patient and obtaining consent if required by law for using such a delivery process.*

Example: A form explaining the service and explicitly requesting the patient's consent to participate in the service. (Not in pilot)

*3. ~~Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in accordance with 18 VAC 110-20-710.~~* Prescriptions waiting to be picked up by a patient at the alternate site shall be stored in a lockable room or lockable cabinet, cart, or other device which cannot be easily moved and which shall be locked at all times when not in use. Access shall be restricted to the licensed practitioner of the healing arts or the responsible party listed on the application for the controlled substances registration, or either person's designee.

Other notes:
- Copies of forms to be utilized should be included in the policy and procedure manual.
- Description of supplies used to deliver prescriptions should be included in the policy and procedure manual.

- Designation of other persons who may access the dispensed drugs shall be in writing and available for review by an agent of the board.
- Access by a designee shall occur at a time when a prescriber or pharmacist is present at all times with the exception of those qualifying facilities pursuant to 18VAC110-20-275 (E).

> *E. A controlled substances registration as an alternate delivery site shall only be issued to an entity without a prescriber or pharmacist present at all times the site is open if there is a valid patient health or safety reason not to deliver dispensed prescriptions directly to the patient and if compliance with all requirements for security, policies, and procedures can be reasonably assured.*

Example: A Virginia Department of Health department has been issued a controlled substances registration as an alternate delivery site without a prescriber or pharmacist present at all times the site is open because of the unique needs of the patients receiving services and the medical conditions being treated.

## Options for 2015 Meeting Dates

March Full Board Meeting

- 3/23 Board room 4
- 3/24 -1st choice Board room 4
- 3/27 Board room 2
- 3/31- 2nd choice Board room 2

Tentative Regulation Committee Meeting

- 5/5-2nd choice Board room 4
- 5/11-1st choice Board room 2

June Full Board Meeting

- 6/16 Board room 2
- 6/17-1st choice Board room 4
- 6/24-2nd choice Board room 2
- 6/25 Board room 2

September Full Board Meeting

- 9/3 – 1st choice Board room 2
- 9/23-9/24 Board room 2
- 9/29 Board room 2
- 9/30 - 2nd choice Board room 2

Tentative Regulation Committee Meeting

- 10/27-10/29 Board room 2
- 11/3-2nd choice Board room 2
- 11/4 - 1st choice Board room 2
- 11/5 Board room 2

December Full Board Meeting

- 12/1 Board room 2
- 12/16 -1st choice Board room 4
- 12/18 Board room 2

**§ 54.1-3443. Board to administer article.**

A. The Board shall administer this article and may add substances to or deschedule or reschedule all substances enumerated in the schedules in this article pursuant to the procedures of the Administrative Process Act (§ 2.2-4000 et seq.). In making a determination regarding a substance, the Board shall consider the following:

1. The actual or relative potential for abuse;

2. The scientific evidence of its pharmacological effect, if known;

3. The state of current scientific knowledge regarding the substance;

4. The history and current pattern of abuse;

5. The scope, duration, and significance of abuse;

6. The risk to the public health;

7. The potential of the substance to produce psychic or physical dependence; and

8. Whether the substance is an immediate precursor of a substance already controlled under this article.

B. After considering the factors enumerated in subsection A, the Board shall make findings and issue a regulation controlling the substance if it finds the substance has a potential for abuse.

C. If the Board designates a substance as an immediate precursor, substances which are precursors of the controlled precursor shall not be subject to control solely because they are precursors of the controlled precursor.

D. If the Board, in consultation with the Department of Forensic Science, determines the substance shall be placed into Schedule I or II pursuant to § 54.1-3445 or 54.1-3447, the Board may amend its regulations pursuant to Article 2 (§ 2.2-4006 et seq.) of the Administrative Process Act. Prior to making such amendments, the Board shall conduct a public hearing. At least 30 days prior to conducting such hearing, it shall post notice of the hearing on the Virginia Regulatory Town Hall and shall send notice of the hearing to any persons requesting to be notified of a regulatory action. In the notice, the Board shall include a list of all substances it intends to schedule by regulation. The Board shall notify the House Courts of Justice and Senate Courts of Justice Committees of any new substance added to Schedule I or II pursuant to this subsection. Any substance added to Schedule I or II pursuant to this subsection shall remain on Schedule I or II for a period of 18 months. Upon expiration of such 18-month period, such substance shall be descheduled unless a general law is enacted adding such substance to Schedule I or II. Nothing in this subsection shall preclude the Board from adding substances to or descheduling or rescheduling all substances enumerated in the schedules pursuant to the provisions of subsections A, B, and E.

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 120 days from publication in the Federal Register of the final order

designating a substance as a controlled substance or rescheduling or descheduling a substance without following the provisions specified in subsections A and B.

F. Authority to control under this section does not extend to distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 4.1.

G. The Board shall exempt any nonnarcotic substance from a schedule if such substance may, under the provisions of the federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.) or state law, be lawfully sold over the counter without a prescription.