COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor (804) 367-4456 (Tel)
Henrico, Virginia 23233 (804) 527-4472(Fax)

Tentative Agenda of Meeting

March 13, 2012

9:00AM

TOPIC	PAGE(S)
Call to Order: Gill Abernathy, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	
· December 14, 2011, Public Hearing	1-2
· December 14, 2011, Full Board Meeting	3-12
· December 14, 2011, Panel of the Board, Formal Hearing	13-15
· January 10, 2012, Special Conference Committee and Informal Conference Committee	16-20
· February 14, 2012, Special Conference Committee and Informal Conference Committee	21-24
· February 16, 2012, Regulation Committee for Pharmacist to Pharmacy Technician Ratio	25-27
· February 16, 2012, Informal Conference Committee – Pilot Program	Handout
· March 6, 2012, Special Conference Committee and Informal Conference Committee	Handout

Call for public comment: The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters. The Board will receive comments on specific topics on this agenda at the time the matter is taken up by the Board.

DHP Director's Report: Diane Reynolds-Cane, M.D.

Legislation Update: Elaine Yeatts	28-32
Regulatory Actions: Elaine Yeatts	
• Regulatory Update	33
• Adoption of final regulations for repackaging in community service boards and behavioral health authorities	34-54
• Adoption of proposed regulations regarding requirements for automated dispensing devices	55-61
• Petition for rulemaking to allow transfer of prescriptions between medical equipment suppliers	62-65

Update on Action Items: Jody H. Allen, Committee Chairman

- Regulation Committee's recommendation regarding request to amend pharmacy technician to pharmacist ratio in 18VAC110-20-270 — 66

Miscellaneous: Caroline D. Juran

- Review for compliance Walgreens' mechanisms for transferring prescriptions — 67-78
- Presentation and request from Walgreens for approval, in concept, of new store layout in Virginia locations — 79-81
- Request from Crady Adams to discuss length of time associated with and access to final orders — 82
- Request from *The Pharmacy Alliance* to discuss implementing mandates to address "system induced errors" — 83-85

Reports:

- Report on Board of Health Professions – Robert M. Rhodes
- Report on Licensure Program – J. Samuel Johnson, Jr. — Handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day — Handout
- Executive Director's Report - Caroline D. Juran

New Business

Consideration of consent orders (if any)

Adjourn

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR REGULATIONS TO POSSESS AND REPACKAGE DRUGS IN CERTAIN MENTAL HEALTH AGENCIES

December 14, 2011
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 9:15 AM.

PRESIDING: Gill B. Abernathy, Chairman

MEMBERS PRESENT:
Crady R. Adams
Jody H. Allen
Gerard Dabney
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Brandon K. Yi

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

CALL FOR COMMENT: Ms. Abernathy called for comment on the proposed regulations for possession and repackaging of drugs in certain mental health facilities. There was no public comment received at this time.

Ms. Abernathy stated that written comments may be submitted to Town Hall and or to Caroline Juran, Executive Director, Board of Pharmacy, until January 20, 2012. Final regulations will be adopted at the March 13, 2012 Board Meeting.

ADJOURN: The public hearing adjourned at 9:22 am.

Gill Abernathy, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
DRAFT/ MINUTES OF BOARD MEETING

December 14, 2011
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:22 AM.

PRESIDING: Gill B. Abernathy, Chairman

MEMBERS PRESENT:
Crady R. Adams
Jody H. Allen
Gerard Dabney
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Brandon K. Yi

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne Reynolds-Cane, M.D., Director, DHP
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant

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

INTRODUCTION OF NEW BOARD MEMBER: Ms. Abernathy welcomed Dinny Li, new citizen member, to the Board of Pharmacy.

APPROVAL OF AGENDA: An amended agenda was distributed to the Board members that corrected the page numbering and added under the miscellaneous section "Consider amending Guidance Document 110-41". Additionally, staff requested for approval the inclusion of minutes from the Special Conference Committee and Informal Conference Committee meeting held on December 6, 2011. With these changes, the agenda was approved as amended.

APPROVAL OF MINUTES: The Board reviewed draft minutes for September 20, 2011 (Board Meeting); September 27, 2011 (Special Conference Committee and Informal Conference Committee); October 6, 2011 (Telephone Conference Call); October 13, 2011 (Telephone Conference Call), October 19, 2011 (Special Conference Committee and Informal Conference Committee), November 22, 2011 (Special Conference Committee and Informal Conference Committee), and November 29, 2011, (Regulation Committee for Automated Counting Devices,

Automated Dispensing Devices, and Definition of "Low Volume"). Ms. Abernathy recommended adding a statement in the November 29, 2011 Regulation Committee minutes to explain the purpose of the meeting.

MOTION:

The Board voted unanimously to approve the minutes as amended. (motion by Kozera, second by Stelly)

PUBLIC COMMENTS:

Ms. Abernathy called for public comment. Alan Friedman, Kaiser Permanente, stated he would be taking on additional responsibilities. Mr. Friedman introduced Dr. Soumi Saha as the new Government Relations and Government Affairs Officer for Kaiser. Mr. Friedman extended appreciation to Board staff for past assistance and the expeditious manner in which it is generally provided.

DHP DIRECTOR'S REPORT:

Dr. Cane reported the agency continues its work with agency efficiency measures and that the interoperability of the Prescription Monitoring Program (PMP) to Indiana and Ohio has been extended to all registered users of the PMP. The Virginia Health Workforce Development Authority held a meeting in November and has hired a new executive director who will begin January 15, 2012. Dr. Cane also reported that the legislative proposal approved by the Board of Pharmacy to place tramadol and carisoprodol into Schedule IV was submitted to the Secretary's Office, but was not included in the Governor's package. However, she did comment that the DEA is federally placing carisoprodol into Schedule IV effective January 11, 2012. Dr. Cane also spoke on the Agency Head Summit she attended here in Richmond where Jim Collins, author of "Good to Great" was the keynote speaker. She summarized some of the key points that Mr. Collins believes is characteristic of a good leader.

REGULATIONS:

Ms. Yeatts provided a status update of the Board's current regulatory packages. The public comment period for the proposed regulations for the community service boards, behavioral health authorities, and crisis stabilization units ends January 20, 2012. The CQI emergency regulations were signed by the Secretary on December 14th and have been forwarded to the Governor's office for review. The proposed rules for administrative fees are at the Secretary's Office. The regulation eliminating an alarm system in emergency services under specific circumstances will become effective December 22, 2011. Additionally, she reported that the public comment period for automated dispensing devices will end on December 21, 2011. She also indicated that there may be legislative proposal regarding the Prescription Monitoring Program that would require a method of payment data field and expand access authority to a federal entity such as the FBI.

AUTOMATED COUNTING DEVICES:

Ms. Abernathy indicated that the Regulation Committee met on November 29, 2011 to consider Delegate Chris Jones' request to make the run dry requirement in Regulation 18 VAC 110-20-355 less burdensome. The Committee recommended that the full board consider adopting a Notice of Intended Regulatory Action (NOIRA) to amend Regulation 18 VAC 110-20-355 regarding automated counting devices.

Specifically, the committee recommended striking the "run dry" requirement and including the statement, "In the event of a drug recall involving one of multiple lots placed in a cell of an automated counting device in the last four months, all drug shall be removed from the cell and not used for patient care." The full board received public comment from Alan Friedman, Kaiser Permanente. He indicated that the run dry requirement should be eliminated based on data that he has collected from the vendor, Innovation. Mr. Friedman stated that he is still currently gathering information, however, 3 months may be more reasonable than the 4 month requirement recommended by the Regulation Committee. His concerns with the Committees' recommendation included: the possibility of unnecessary wasting of drugs; not taking into consideration if a run dry happened to have been performed within the last four months; and lack of exemption if the pharmacy could prove that the recalled drug no longer remains in the cell. He recommended the Board consider broader language and receive public comment. Staff stated that the Board may wish to consider a requirement for routinely cleaning the device per manufacturer's recommendations to ensure a potential buildup of drug residue does not have negative implications or affect the accuracy of the counting device.

MOTION:

The Board voted unanimously to adopt a NOIRA to amend 18 VAC 110-20-355 regarding automated counting devices to ensure the regulation appropriately addresses public safety concerns, to include the possible dispensing of recalled or expired drugs, and the routine cleaning of the device to prevent drug contamination and ensure counting accuracy. (motion by Allen, second by Yi)

REMOVAL OF "LOW VOLUME" FROM GUIDANCE DOCUMENT 110-9

Ms. Abernathy reported that the Regulation Committee also considered on November 29, 2011 the received request to expand the Board's definition of "low volume" in Guidance Document 110-9. The term is referenced in USP Chapter 797 regarding allowances for performing sterile compounding of hazardous drugs in an area not physically separated from other preparation areas. Ms. Juran indicated that Board counsel recently advised that the Board may not define the term in guidance since USP standards are simply adopted by reference in statute. It could, however, define the term in regulation after convening an expert panel to determine an appropriate number of hazardous drugs which may be compounded. Additionally, Ms. Juran stated that the USP expert panel previously convened to revise Chapter 797 could not agree on an appropriate number, but that she was informed by USP staff that a newly formed expert panel intends to revisit this issue. The Regulation Committee recommended to the full board to not define "low volume" since USP has indicated its newly formed expert panel will revisit this issue.

MOTION:

The Board voted unanimously to remove the definition of "low volume" from Major Deficiency 24 found in Guidance Document 110-9 and take no further action at this time. (motion by Kozera, second by Allen)

PETITION FOR RULEMAKING TO PLACE TETRAHYDROCANNIBOL INTO SCHEDULE II:

The Board discussed a petition for rulemaking requesting the rescheduling of tetrahydrocannibol from Schedule I into Schedule II for medical use. Ms. Yeatts indicated that the Board had received two public comments in opposition of the petition and that the DEA had denied a petition for rulemaking in June 2011 to reschedule marijuana federally. Ms. Juran explained that technically tetrahydrocannibol is not currently scheduled in the Drug Control Act, but is placed in Schedule I federally. Mr. Casway explained that even if tetrahydrocannibol was placed into Schedule II, the federal rule is more restrictive and practitioners must comply with the more restrictive rule. Alan Friedman, Kaiser Permanente, commented that the federal and state governments are not on the same page and there has been a lot of debate and resistance between the two. Ms. Abernathy stated that she also questioned the efficacy of tetrahydrocannibol for treating bipolar disorder and was not aware of information to support the claim.

MOTION:

The Board voted unanimously to deny the petition for rulemaking to reschedule tetrahydrocannibol from a Schedule I drug to a Schedule II drug based on concerns expressed by DEA for why it should not be rescheduled federally. (motion by Munden, second by Rhodes)

REQUEST FOR ONE-TIME MANDATORY CE ON EMERGENCY AND DISASTER PREPAREDNESS:

Karen Mulharen, pharmacist with INOVA Systems, addressed the Board to support her request for the Board to mandate pharmacists obtaining two hours of continuing education, as permitted in § 54.1-3314.1 J, in the subject area of emergency and disaster preparedness. Ms. Mulharen stated that pharmacists in Virginia could benefit from the CE since Virginians have experienced several recent environmental disasters, the state has several military instillations, and massive distribution of drugs requires additional training beyond a pharmacist's educational training. Ms. Munden noticed that Ms. Mulharen recommended participation in the Medical Reserve Corp, but that the training is not considered formal CE. Discussion ensued regarding the need to encourage pharmacists to participate in the Medical Reserve Corp and Ms. Mulharen had hoped a mandatory CE requirement may lead to increased participation. Ms. Allen recommended the Board could increase awareness by including an article in the next e-newsletter. Additionally, Mr. Owens recommended that a member or staff could contact the Virginia Department of Health, Office of Emergency Preparedness, to learn of its needs regarding the Medical Reserve Corp and how the Board could raise awareness of the program. Mr. Rhodes moved that the Board deny the request to mandate CE on disaster and emergency preparedness, but instructed the Board to review other subject areas needing mandatory CE and to increase awareness of the Medical Reserve Corp. Ms. Munden seconded the motion, but the motion was subsequently withdrawn by Ms. Rhodes and Ms. Munden.

MOTION:

In a second motion, the Board voted unanimously to deny the request for a one-time mandatory CE requirement in the subject area of emergency and disaster preparedness, but to direct staff to contact the Virginia Department of Health to assess its needs for educating pharmacists and pharmacy technicians to the Medical Reserve Corp and take appropriate actions to increase awareness.

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(motion by Stelly, second by Yi)

APPROVAL OF DISCIPLINARY MINUTES:

The Board's attention was brought to handouts of the minutes from the November 30, 2011 meeting (Panel of the Board, Formal Hearing) and December 6, 2011 meeting (Special Conference Committee and Informal Conference Committee).

MOTION:

The Board voted unanimously to approve the minutes of the November 30, 2011 meeting (Panel of the Board, Formal Hearing) and December 6, 2011 meeting (Special Conference Committee and Informal Conference Committee) as presented. (motion by Kozera, second by Rhodes)

REQUEST TO DISCUSS CONCERN REGARDING DIVERSIONS OF HYDROCODONE DRUG PRODUCTS:

Mr. Adams brought to the Board's attention his concerns regarding the diversion of hydrocodone drug products from pharmacies within the recent years. Based on his research, he stated that hydrocodone is the most diverted drug and believed that every state shared concerns on how best to prevent diversion.

MOTION:

A motion was made to reschedule hydrocodone containing drug products from a Schedule III to a Schedule II. (motion by Adams, second by Shinaberry)

DISCUSSION:

Mr. Rhodes stated that placing hydrocodone containing drug products into Schedule II may deny nursing home patients legitimate use of the drug based on the more stringent requirements associated with the issuance of a Schedule II prescription. Mr. Rhodes suggested that pharmacists should voluntarily monitor the inventory of hydrocodone containing drug products as good practice.

MOTION WITHDRAWN:

The motion made to reschedule hydrocodone containing drug products from a Schedule III to a Schedule II was withdrawn. (withdrew by Adams, second by Shinaberry)

MOTION:

A new motion was made requiring a pharmacy to inventory 1/3 of the hydrocodone containing drug products on-hand every 30 days such that all hydrocodone containing drug products are inventoried within 90 days. (motion died for a lack of a second)

Mr. Yi stated that the Board needed to discuss the prevention of diversion in general, not just hydrocodone containing drug products. Mr. Kozera stated that monthly inventories of hydrocodone containing drug products would be too onerous given the volume of hydrocodone containing drug products. Mr. Rhodes suggested the pharmacist-in-charge could be required to sign and date invoices of drugs being received as a means of increasing awareness of drug movement. Ms. Stelly stated that the Board could consider increasing disciplinary action against the pharmacist-in-charge, when diversions occur, for not properly securing drug inventory. Vicki Garrison, Pharmacy Inspector, informed the Board that the number of cases received may be a result of effective loss prevention efforts. The Board decided after further discussion to

take no action on the subject at this time.

PHARMACIST TO PHARMACY TECHNICIAN RATIO:

Mr. Kozera explained that the § 54.1-3320 was amended in 2010 to remove the 4:1 pharmacy technician to pharmacist ratio and require pharmacists to supervise no more pharmacy technicians than allowed by Board regulation. He requested the Board consider eliminating the 4:1 ratio in Board regulation and allow a pharmacist to exercise professional judgment as to how many pharmacy technicians he may safely supervise at any given time. Ms. Juran explained that the Board attempted to remove the ratio from regulation in 2007 during the periodic review of regulations, but realized that it was also required in statute and would require an amendment of the statute. She clarified that the Board was not responsible for the 2010 legislative proposal for amending the statute. Concern was expressed that a corporation may attempt to decide the number of pharmacy technicians which may be supervised by a pharmacist.

MOTION/ ACTION ITEM:

The Board voted unanimously to refer the topic of amending the pharmacist to pharmacy technician ratio in Regulation 110-20-270 to the Regulation Committee for further review. (motion by Kozera, second by Yi)

REQUEST TO EXTEND DELEGATION OF AUTHORITY FOR DISCIPLINARY MATTERS:

Ms. Juran requested that the Board consider extending the delegation of authority to the executive director for the handling of certain disciplinary matters as outlined in guidance document 110-15. She explained that staff was able to resolve approximately 15 cases during the last 6 months using this delegation which improved the efficiency of handling disciplinary matters.

MOTION:

The Board voted unanimously to extend the delegation of authority to the executive director for the handling of certain disciplinary matters as outlined in guidance document 110-15. (motion by Rhodes, second by Adams)

GUIDANCE DOCUMENT 110-41: "CHANGES A PHARMACIST MAY MAKE TO A SCHEDULE II PRESCRIPTION"

Ms. Juran explained that in correspondence received by the National Association of Boards of Pharmacy on August 24, 2011 from DEA, DEA clarified that pharmacists should use their professional judgment and knowledge of state and federal laws and policies when deciding if it's appropriate to make changes to a prescription such as adding the practitioner's DEA number to a Schedule II prescription or correcting the patient's name or address since this may vary on a case-by-case basis depending on the facts present. Therefore, Ms. Juran requested that the Board consider amending Guidance Document 110-41 to include an allowance to correct the patient's name and address upon verification, or add the prescriber's DEA registration number to the Schedule II prescription.

MOTION:

The Board voted unanimously to amend Guidance Document 110-41 to include an allowance to correct the patient's name and address upon verification, or add the prescriber's DEA registration number

to a Schedule II prescription. (motion by Ms. Munden, second by Ms. Allen)

REVIEW AGENCY'S CONSIDERATION OF PAPERLESS LICENSING:

Ms. Juran reported that the agency is considering moving toward a paperless licensing system, with current focus on individuals not facilities, wherein an initial paper license would continue to be issued, but no expiration date would be printed on the license. Additionally, an annual paper license would not be provided upon renewal of the license. Because there have cases of individuals fraudulently manipulating their paper licenses and the information contained on a paper license really only reflects licensing information at the time it was printed, other states have moved toward encouraging verifications through primary source verification. Ms. Munden stated that North Carolina has implemented a paperless licensing system and is not aware of problems associated with it. Additionally, Ms. Juran stated that Board counsel agreed that the posting requirement in §§ 54.1-3314 and 54.1-3430 could potentially be met by posting the initial license. She reminded members that this issue is still under review by the agency, but that she will report any decisions made on the subject in the future.

REPORT ON BOARD OF HEALTH PROFESSIONS:

Mr. Rhodes stated that currently the Board of Health Professions is still forming committees and intends to continue its review of scope of practice issues for nurse practitioners. He reported that they were still in the process of placing new members on the Board of Health Professions. Ms. Juran indicated that the executive director for the Board of Health Professions informed her that a review of pharmacists' scope of practice may begin in February 2012.

REPORT ON LICENSURE PROGRAM:

Mr. Johnson reported that the Board issued 933 licenses and registrations for the period of September 1, 2011 through November 30, 2011, including 130 pharmacists, 305 pharmacy interns, and 377 pharmacy technicians. Inspectors performed 266 facility inspections including 134 routine inspections of pharmacies. Thirty-two resulted in no deficiency, 35 with deficiencies, and 67 with deficiencies and a pre-hearing consent order. No new pilot programs were approved. Key Performance Measures for the quarter ending September 30, 2011, identified a 96% customer satisfaction rating and that 100% of applicants were licensed within 30 days of the Board receiving a complete application.

ACTION ITEM:

The Board requested staff to include, somewhat regularly, information regarding common deficiencies in future e-newsletters.

ACTION ITEM:

The Board requested staff to send a blast e-mail in the near future regarding the need to inventory carisoprodol prior to January 11, 2012 as a result of it being placed into Schedule IV federally.

REPORT ON DISCIPLINARY PROGRAM:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between September 19, 2011, and December 12, 2011. Current open cases are 51 at the investigation stage; 79 at the probable cause stage; 16 at the administrative proceedings

division stage; eight at the informal stage; five at the formal stage; and 157 at the pending closure stage.

Further, Ms. Reiniers-Day reviewed the department's Quarterly Performance Report for the first quarter (July 1, 2011 through September 30, 2011) that indicates a clearance rate of 124%, pending caseload greater than 250 business days of 6% and a 93% closure rate of patient care cases within 250 business days.

EXECUTIVE DIRECTOR'S REPORT:

Ms. Juran updated the Board on two bills referred to study by the Joint Commission for Healthcare, HB 1966 and HB 1961. The Joint Commission recommended no action at this time. Additionally, she reported that SB 878 that was referred to study by JCHC resulted in a recommendation to introduce legislation requiring the National Precursor Log Exchange for the sale of ephedrine and pseudoephedrine and a recommendation that the Crime Commission review several other options involving amendments to criminal law.

Ms. Juran reported that Ralph Orr, Program Director, Prescription Monitoring Program, reports that PMP has 2600 new registered users which include 550 new pharmacists. There has been a 27% growth in registered user in the past year and 21% growth in prescribers. PMP will be processing 600,000 requests this year compared to 433,000 last year. Statewide access for interoperability will be accessible this week for Indiana and Ohio, and will soon be implementing Michigan, West Virginia and Connecticut. In the summer of 2012, North Carolina and Tennessee are anticipated in participating in the interoperability.

Ms. Juran stated that the US Census report indicated a 13% population growth between 2000 and 2010. Specifically, those individuals age 65 and older increased by 23.3% and age 85 and older increased by 40.3%. This was a higher relative increase than that for the US overall. Ms. Juran requested that the Board take this into consideration when promulgating regulations.

There will be several staffing vacancies in the near future for the Board. Gloria Williams, Licensing Specialist, will retire December 31, 2011. Additionally, Susan Beasecker, Compliance Case Manager, will assume another agency role outside of the Board of Pharmacy as of December 27, 2011. Also, the Board intends to hire a new part-time employee to assist with certain inspection and continuing education matters. Recruitment is ongoing for filling these three positions.

Ms. Juran informed the Board that she was invited to participate as a NABP taskforce member to review and recommend revisions to the Controlled Substance Act. The taskforce will convene January 24-25, 2012 at the NABP Headquarters in Mount Prospect, IL. Expenses are being covered by NABP.

Ms. Juran reported that she is still currently serving as Chairman for the Board of Forensic Science. Staff for the Department of Forensic Science has been providing technical assistance on possible upcoming legislation

regarding bath salts and synthetic cannabinoids.

Ms. Juran stated that she continues to serve on the Rx Partnership Board as an ex-officio member. Additionally, she provided a presentation to the Virginia Association of Free Clinics in Staunton, Virginia last month and provided a webinar to the affiliate clinics who are members of Rx Partnership. She reminded the members that Rx Partnership provides free patient assistance medications to indigent patients using free clinic pharmacies that are primarily staffed with volunteer pharmacists.

Ms. Juran also reported that after the last full board meeting, she attended the NABP Executive Director Interactive Forum which was extremely informative. Panel discussions were held to share information and debate appropriate strategies for addressing difficult topics being confronted by all the boards currently. Additionally, she was invited to participate as a panel member in the discussion regarding the licensing of physicians to dispense drugs. Expenses were paid by NABP.

In October, Ms. Juran attended the Joint AACP/NABP District I and II meeting in Boston, MA. Leo Ross (former Board member), Crady Adams, Empsy Munden, Jody Allen, and Ellen Shinaberry also attended the meeting. The presentations were informative and relevant to current practice issues. Two resolutions were voted on and approved by District I and II to be submitted to NABP for consideration at its annual meeting in May where Ms. Juran will be representing District I and II on the NABP Resolutions Committee. No expenses were paid by the Board.

NEW BUSINESS: There was no new business at this time.

CONSIDERATION OF CONSENT ORDER:

MOTION FOR 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 a consent order that is excluded from the Freedom of Information Act by Virginia Code § 2.2-3705(A)(5) and that Caroline Juran, Sammy Johnson, Cathy Reiniers-Day, Howard Casway, and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberations. (motion by Kozera, second by Munden).**

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING: **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 executive meeting were heard, discussed, or considered during the closed session just concluded. (Motion by Kozera, second by Rhodes).**

MOTION: **The Board voted unanimously to accept the consent order with amendments for Meredith Disney, pharmacy technician. (Motion by Kozera, 2nd by Allen)**

ADJOURN: With all business concluded, the meeting adjourned at 2:10pm.

Gill Abernathy, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
FORMAL HEARING MINUTES

Wednesday, December 14, 2011
Commonwealth Conference Center
Second Floor
Board Room 2

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

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

CALL TO ORDER: A meeting of a panel of the Board of Pharmacy ("Board") was called to order at 2:15 p.m.

PRESIDING: Gill B. Abernathy

MEMBERS PRESENT:
Crady Adams
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen Shinaberry
Pratt P. Stelly
Brandon K. Yi

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

QUORUM: With eight members of the Board present, a panel was established.

TAMMY H. IRBY
Pharmacy Technician
Registration No. 0230-003661

A formal hearing was held in the matter of Tammy H. Irby following the summary suspension of her pharmacy technician registration on December 14, 2011, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Irby was not present at the hearing. The panel proceeded in Ms. Irby's absence as the Notice of Formal Hearing dated December 14, 2011, was sent

by first class mail to the legal address or record on file with the Board of Pharmacy, and by UPS overnight mail and first class mail to a secondary address provided to the Board. Ms. Abernathy ruled that adequate notice was provided to Ms. Irby and the hearing proceeded in her absence.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Mitch Fletcher, Loss Prevention Manager, CVS/pharmacy, (by telephone); and Jennifer Challis, DHP Senior Investigator, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Yi and duly seconded by Mr. Dabney, the panel voted 8-0, 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 Tammy H. Irby. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner and Howard Casway 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 Mr. Yi and duly seconded by Ms. Stelly, the panel voted 8-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib and amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Yi and duly seconded by Ms. Shinaberry, the panel voted 8-0 that Ms. Irby's pharmacy technician registration be revoked.

Adjourn: With all business concluded, the meeting adjourned at 3:20 p.m.

Gill B. Abernathy, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, January 10, 2012
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	Brandon K. Yi, Committee Chair
MEMBERS PRESENT:	Pratt P. Stelly, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
SUSAN M. FREEMAN License No. 0202-012548	Susan M. Freeman appeared with Hunter W. Jamerson, her attorney, to discuss allegations that she may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the November 15, 2011, Notice.
Closed Meeting:	Upon a motion by Ms. Stelly, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Susan M. Freeman. Additionally, she 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 Ms. Stelly, and duly seconded by Mr. Yi, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Freeman an Order with a reprimand.

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

JOHN A. BEDNARZ
License No. 0202-011655

John A. Bednarz appeared to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the October 18, 2011, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of John A. Bednarz. Additionally, she 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 Ms. Stelly, and duly seconded by Mr. Yi, the Committee closed this case as no violation.

SHADAI A. MERRITT
Registration No. 0230-011054

Shadai A. Merritt did not appear at the special conference. The committee chose to proceed in her absence as the notice was mailed to Ms. Merritt's legal address of record. The committee discussed that she may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the November 15, 2011, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Shadai A. Merritt. Additionally, she 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 Ms. Stelly, and duly seconded by Mr. Yi, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Merritt a Consent Order to revoke her right to renew her pharmacy technician registration due to a drug diversion.

MARY B. TOOMBS
Registration No. 0230-000459

Mary B. Toombs did not appear at the special conference. The committee chose to proceed in her absence as then notice was mailed to Ms. Toombs' legal address of record. The committee discussed that she may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the November 15, 2011, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Mary B. Toombs. Additionally, she 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 Ms. Stelly, and duly seconded by Mr. Yi, the Committee closed this case as undetermined.

PRATISH R. PATEL
License No. 0202-204729

Pratish R. Patel appeared with Johnny Moore, one of his sponsors; and Greg Alouf, Maurice Fisher, Doug Martin and Katherine Dillon, some of his peers in recovery, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the December 14, 2011, Notice.

Closed Meeting: Upon a motion by Ms. Stelly, and duly seconded by Mr. Yi, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Pratish R. Patel. Additionally, she 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 Ms. Stelly, and duly seconded by Mr. Yi, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Patel an Order that requires him to comply with his contract with the Health Practitioners' Monitoring Program.

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

made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Patel 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 3:40 p.m.

Brandon K. Yi, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, February 14, 2012
Commonwealth Conference Center
Second Floor
Board Room 1

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:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Brandon K. Yi, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
JOSEPH A. OLEY License No. 0202-012292	Joseph A. Oley appeared to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the January 4, 2012, Notice.
Closed Meeting:	Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, 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 Joseph A. Oley. 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. Yi, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Oley an Order with a reprimand. In addition, he is to complete a specific eight (8) hour course on medication errors.

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

BRIAN L. BURNS
Registration No. 0230-010692

Brian L. Burns appeared to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy technicians as stated in the January 4, 2012, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, 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 Brian L. Burns. 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. Yi, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to offer Mr. Burns a Consent Order to suspend his pharmacy technician registration.

FRANK A. ODEH
License No. 0202-013020

Frank A. Odeh appeared with Kenneth D. McArthur and Buckley Warden, his attorneys, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the November 3, 2011, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, 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 Frank A. Odeh. 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. Yi, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Odeh an Order with a reprimand for dispensing prescriptions not in accordance with the physician's instructions.

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

VINOD B. PATEL
License No. 0202-207340

Vinod B. Patel appeared with Kenneth D. McArthur and Buckley Warden, his attorneys, to discuss allegations that he may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the July 21, 2011, Notice.

Closed Meeting:

Upon a motion by Mr. Yi, and duly seconded by Mr. Kozera, 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 Vinod B. Patel. 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. Yi, and duly seconded by Mr. Kozera, the Committee adopts the Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Patel an Order with a reprimand for dispensing prescriptions not in accordance with the physician's instructions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Patel, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Patel 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 5:45 p.m.

_____
David C. Kozera, Chair

_____
Cathy M. Reiniers-Day
Deputy Executive Director

_____
Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE REGARDING PHARMACY TECHNICIAN TO PHARMACIST RATIO

February 16, 2012
Second Floor
Board Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Jody H. Allen, Committee Chairman

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

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP

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

PHARMACY TECHNICIAN TO PHARMACIST RATIO: The Regulation Committee met to consider a request to amend Regulation 18VAC110-20-270 B to eliminate the restriction of a pharmacist not being permitted to supervise more than four persons acting as pharmacy technicians at one time. The request was originally discussed at the December 14, 2011 full board meeting and subsequently referred to the Regulation Committee for further review. The Committees' recommendation resulting from this meeting will be reported to and considered by the full Board at the March 13, 2012 full board meeting.

Written and verbal comment was received and heard for approximately two hours by the committee. Comments in opposition of eliminating the current ratio were provided by pharmacists Michael Stone, Earl Hines, Robert Garland, Tim Musselman, Executive Director, Virginia Pharmacists Association (VPhA), and Dave Creasy, President of VPhA and pharmacy owner. The following general arguments were made for opposing the elimination of the current ratio: individual pharmacists, particularly in chain retail/community pharmacies, do not have sole authority in determining the maximum number of pharmacy technicians that can be supervised, because the decision to hire or staff pharmacy technicians is not made by the individual pharmacist; economics is driving this request; the current 4:1 ratio provides safeguards; and, it is premature to eliminate the ratio prior to the upcoming Board of Health Professions' scope of practice review for pharmacists and pharmacy technicians. Additionally, Mr. Musselman commented that of the 117 VPhA pharmacist members who completed a recent survey regarding whether the ratio should be eliminated, 82% indicated the ratio should

remain 4:1, and of the 158 VPhA members (pharmacists, pharmacy technicians, and students) who completed the survey, 77% indicated the ratio should remain 4:1.

Comments in support of eliminating the ratio were provided by Sandra Guckian, Vice President, State Government Affairs at National Association of Chain Drug Stores, Rusty Maney, President, Virginia Association of Chain Drug Stores, John Beckner, Regional Manager of Martins Pharmacy, Lauren Raleigh with CVS Caremark, and Rick Baxter with Medco. The following general arguments were made for supporting the elimination of the current ratio: pharmacists should be allowed to determine the appropriate number of pharmacy technicians that can be safely supervised; the Board had previously attempted to eliminate the ratio in regulation in 2009 and a subsequent statutory change in 2010 allows the Board to eliminate the ratio; the appropriate number of pharmacy technicians that can be safely supervised will vary based on the practice setting; the delegating of nonjudgmental tasks to additional pharmacy technicians would allow a pharmacist to perform more clinical duties, e.g., focusing on patient outcomes and adherence; ratios are antiquated and restrictive; and, pharmacists currently spend 60% of their time performing administrative duties. Additionally, several comments regarding a possible need to increase or standardize the educational requirements of pharmacy technicians were made. Victor Yanchick, Dean, Virginia Commonwealth University, School of Pharmacy, commented that pharmacists need to be released from technical aspects which would increase opportunities to focus on patient care. He supported the elimination of the ratio with properly educated pharmacy technicians in place.

Comments offered by the Committee and staff during its discussions included: concerns for the possible negative impact on patient safety and security of drugs if no ratio; the importance of the information which could result from the upcoming Board of Health Profession's scope of practice review for pharmacists and pharmacy technicians; and, clarification that the current 4:1 ratio was established in concert with the requirement to register pharmacy technicians which specified minimum educational requirements.

MOTION: **The Board voted unanimously to recommend the following to the full Board: that it not amend Regulation 18VAC110-20-270 B to eliminate the restriction of a pharmacist not being permitted to supervise more than four persons acting as pharmacy technicians at one time; that the ratio remain the same until further information is received from the upcoming Board of Health Profession's scope of practice review; and, that staff continue to gather information from other states on their efforts to evaluate ratios. (motion by Rhodes, second by Munden)**

ADJOURN: With all business concluded, the meeting adjourned at 11:10AM.

Jody H. Allen, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

Report of 2012 General Assembly (as of 2/28/12)
Board of Pharmacy

HB 265 Health Professions, Board of; required to meet annually rather than quarterly.

Chief patron: Peace

Summary as introduced:
Board of Health Professions; meetings. Requires the Board of Health Professions to meet at least annually, rather than quarterly.

02/23/12 Senate: Reported from Education and Health (15-Y 0-N)
02/23/12 Senate: Passed by for the day
02/24/12 Senate: Constitutional reading dispensed (38-Y 0-N)
02/27/12 Senate: Read third time
02/27/12 Senate: Passed Senate (40-Y 0-N)

HB 266 Surgery; definition and who may perform.

Chief patron: Peace

Summary as passed House:

Definition of surgery. Defines "surgery" and provides that no person shall perform surgery unless he is (i) licensed by the Board of Medicine as a doctor of medicine, osteopathy, or podiatry; (ii) licensed by the Board of Dentistry as a doctor of dentistry; (iii) jointly licensed by the Boards of Medicine and Nursing as a nurse practitioner; (iv) a physician assistant acting under the supervision of a doctor of medicine, osteopathy, or podiatry; (iv) a midwife performing episiotomies during childbirth; or (vi) acting pursuant to the orders and under the appropriate supervision of a licensed doctor of medicine, osteopathy, podiatry, or dentistry. The bill is identical to SB 543.

02/15/12 House: Enrolled
02/15/12 House: Bill text as passed House and Senate (HB266ER)
02/15/12 House: Impact statement from DPB (HB266ER)
02/15/12 House: Signed by Speaker
02/16/12 Senate: Signed by President

HB 337 Professions and occupations; unlawful procurement of certificate, license, or permit.

Chief patron: Wilt

Summary as introduced:
Professions and occupations; unlawful procurement of certificate, license, or permit. Clarifies language prohibiting the use, disclosure, or release of questions and answers for examinations for certification or licensure.

02/22/12 Senate: Constitutional reading dispensed (39-Y 0-N)
02/23/12 Senate: Read third time
02/23/12 Senate: Passed Senate (40-Y 0-N)
02/28/12 House: Enrolled
02/28/12 House: Bill text as passed House and Senate (HB337ER)

HB 346 Nurse practitioners; practice as part of patient care teams.

Chief patron: O'Bannon

Summary as passed House:

Practice of nurse practitioners; patient care teams. Amends provisions governing the practice of nurse practitioners. The bill provides that nurse practitioners shall only practice as part of a patient care team and shall maintain appropriate collaboration and consultation, as evidenced in a written or electronic practice agreement, with at least one patient care team physician licensed to practice medicine in the Commonwealth. The bill also establishes requirements for written or electronic practice agreements for nurse practitioners, provides that physicians practicing as part of a patient care team may require nurse practitioners practicing as part of that patient care team to be covered by professional malpractice insurance, and amends requirements related to the prescriptive authority of nurse practitioners practicing as part of a patient care team.

02/24/12 Senate: Constitutional reading dispensed (38-Y 0-N)
02/27/12 Senate: Read third time
02/27/12 Senate: Passed by for the day
02/28/12 Senate: Read third time
02/28/12 Senate: Passed Senate (40-Y 0-N)

HB 347 Prescription Monitoring Program; disclosures.

Chief patron: Miller

Summary as introduced:

Prescription Monitoring Program; disclosures. Modifies the Prescription Monitoring Program to (i) require dispensers of covered substances to report the method of payment for the prescription, (ii) require the Director of the Department of Health Professions to report information relevant to an investigation of a prescription recipient, in addition to a prescriber or dispenser, to any federal law-enforcement agency with authority to conduct drug diversion investigations, (iii) allow the Director to disclose information indicating potential misuse of a prescription by a recipient to the State Police for the purpose of investigation into possible drug diversion, and (iv) allow prescribers to delegate authority to access the Program to an unlimited number, rather than the current limit of two, of regulated health care professionals under their direct supervision. This bill is identical to SB 321.

02/15/12 House: Enrolled
02/15/12 House: Bill text as passed House and Senate (HB347ER)
02/15/12 House: Impact statement from DPB (HB347ER)
02/15/12 House: Signed by Speaker
02/16/12 Senate: Signed by President

HB 508 Cannabinoids, synthetic; amends provisions regarding criminalization.

Chief patron: Garrett

Summary as introduced:
Synthetic cannabinoids; bath salts; penalties. Amends provisions added to the Code last year regarding the criminalization of synthetic cannabinoids and chemicals known as "bath salts" to add newly identified chemical combinations. The bill adds a more generic chemical description of synthetic cannabinoids so that new combinations will be illegal without the precise chemical combination being added to the Code.

02/15/12 Senate: Constitutional reading dispensed
02/15/12 Senate: Referred to Committee for Courts of Justice
02/22/12 Senate: Reported from Courts of Justice (14-Y 0-N)
02/22/12 Senate: Rereferred to Finance
02/28/12 Senate: Reported from Finance (15-Y 0-N)

HB 733 Pharmacists; compounding authority.

Chief patron: Jones

Summary as passed House:

Pharmacists; compounding authority. Increases pharmacists' authority to compound to allow the compounding of (i) a commercially manufactured drug whose manufacturer has notified the FDA that the drug is unavailable due to a current drug shortage or (ii) a commercially manufactured drug when the prescriber has indicated in the written or oral prescription for an individual patient that there is an emergent need for a drug that is not readily available within the time medically necessary.

02/23/12 House: Enrolled
02/23/12 House: Bill text as passed House and Senate (HB733ER)
02/23/12 House: Impact statement from DPB (HB733ER)
02/23/12 House: Signed by Speaker
02/23/12 Senate: Signed by President

HB 937 Spouses of military service members; expediting issuance of business licenses, etc.

Chief patron: Lingamfelter

Summary as passed House:

Professions and occupations; expediting the issuance of licenses for spouses of military service members. Requires a regulatory board within the Department of Professional and Occupational Regulation, the Department of Health Professions, or any board named in Title 54.1 to establish procedures to expedite the issuance of a license, permit, certificate, or other document, however styled or denominated, required for the practice of any business, profession, or occupation in the Commonwealth, of an applicant (i) holding the same or similar license, permit, certificate, or other document required for the practice of any business, profession, or occupation issued by another jurisdiction, (ii) whose spouse is the subject of a military transfer to the Commonwealth, and (iii) who left employment to accompany the applicant's spouse to Virginia, if, in the opinion of the board, the requirements for the issuance of the license, permit, certificate, or other document in such other jurisdiction are substantially equivalent to those required in the Commonwealth. The bill provides for the issuance of a temporary permit under certain circumstances and limits to six months the duration of a temporary permit issued.

02/09/12 Senate: Constitutional reading dispensed
02/09/12 Senate: Referred to Committee on General Laws and Technology
02/15/12 House: Impact statement from DPB (HB937H1)
02/27/12 Senate: Committee substitute printed 12105669D-S1
02/27/12 Senate: Reported from General Laws and Technology with substitute (14-Y 0-N)

HB 938 Military training, etc.; regulatory boards to accept as equivalent to requirements for licensures.

Chief patron: Lingamfelter

Summary as passed House:

Professions and occupations; qualifications for licensure; substantially equivalent military training and education. Except for the Board of Medicine and the Board of Dentistry, requires the regulatory boards within the Department of Professional and Occupational Regulation, the Department of Health Professions, or any board named in Title 54.1 to accept the military training, education, or experience of a service member returning from active military service in the armed forces of the United States, to the extent that such training, education, or experience is substantially equivalent to the requirements established by law and regulations of the respective board for the issuance of any license, permit, certificate, or other document, however styled or denominated, required for the practice of any business, profession, or

calling in the Commonwealth. The bill provides that to the extent that the service member's military training, education or experience, or portion thereof, is not deemed substantially equivalent, the respective board shall credit whatever portion of the military training, education, or experience that is substantially equivalent toward meeting the requirements for the issuance of the license, permit, certificate, or other document. The bill authorizes a regulatory board to require the service member to provide such documentation of his training, education, or experience as deemed necessary to determine substantial equivalency. The bill defines the term "active military service."

02/15/12 House: Impact statement from DPB (HB938H1)
02/20/12 Senate: Reported from General Laws and Technology (15-Y 0-N)
02/22/12 Senate: Constitutional reading dispensed (39-Y 0-N)
02/23/12 Senate: Read third time
02/23/12 Senate: Passed Senate (40-Y 0-N)

HB 1107 Public schools; administration of auto-injectable epinephrine.

Chief patron: Greason

Summary as passed House:

Public schools; possession and administration of epinephrine. Requires local school boards to adopt and implement policies for the possession and administration of epinephrine in every school. The school nurse, a school board employee, or an authorized and trained volunteer may adminster the epinephrine to any student believed to be having an anaphylactic reaction. The bill also requires the Department of Health, in conjunction the Department of Education and the Department of Health Professionals to develop and implement policies for the recognition and treatment of anaphylaxis in the school setting. This bill is identical to SB 656.

02/27/12 Senate: Reading of amendments waived
02/27/12 Senate: Committee amendments agreed to
02/27/12 Senate: Engrossed by Senate as amended
02/27/12 Senate: Passed Senate with amendments (40-Y 0-N)
02/28/12 House: Placed on Calendar

HB 1140 Carisoprodol; added to list of Schedule IV controlled substances.

Chief patron: Hodges

Summary as introduced:
Carisoprodol added to list of Schedule IV controlled substances. Adds carisoprodol to the list of Schedule IV controlled substances in the Drug Control Act.

02/13/12 House: Read second time and engrossed
02/14/12 House: Read third time and passed House BLOCK VOTE (100-Y 0-N)
02/14/12 House: VOTE: BLOCK VOTE PASSAGE (100-Y 0-N)
02/15/12 Senate: Constitutional reading dispensed
02/15/12 Senate: Referred to Committee on Education and Health

HB 1141 Ezogabine; added to list of Schedule V controlled substances.

Chief patron: Hodges

Summary as introduced:
Ezogabine; add to Schedule V. Adds ezogabine to Schedule V of the Drug Control Act.

02/13/12 House: Read second time and engrossed
02/14/12 House: Read third time and passed House BLOCK VOTE (100-Y 0-N)

02/14/12 House: VOTE: BLOCK VOTE PASSAGE (100-Y 0-N)
02/15/12 Senate: Constitutional reading dispensed
02/15/12 Senate: Referred to Committee on Education and Health

HB 1161 Methamphetamine precursors; sale and tracking, penalties.

Chief patron: Cline

Summary as introduced:

Methamphetamine precursors; sale and tracking; penalties. Requires the Department of State Police to enter into a memorandum of understanding to establish the Commonwealth's participation in a real-time electronic recordkeeping and monitoring system for the nonprescription sale of ephedrine or related compounds. Most pharmacies and retail distributors will be required to enter nonprescription sales of ephedrine or related compounds into the electronic system. The bill retains the existing sales limit of no more than 3.6 grams of ephedrine or related compounds per day per individual retail customer and no more than 9 grams per 30-day period. The bill is effective January 1, 2013. This bill is identical to SB 294.

02/22/12 Senate: Read third time
02/22/12 Senate: Passed Senate (38-Y 0-N)
02/27/12 House: Enrolled
02/27/12 House: Bill text as passed House and Senate (HB1161ER)
02/27/12 House: Impact statement from DPB (HB1161ER)

SB 592 Tramadol; added to list of Schedule IV controlled substances.

Chief patron: Puckett

Summary as introduced:
Tramadol added to list of Schedule IV controlled substances. Adds tramadol, an opiate painkiller, to the list of Schedule IV controlled substances.

02/13/12 House: Read first time
02/13/12 House: Referred to Committee on Health, Welfare and Institutions
02/16/12 House: Reported from Health, Welfare and Institutions (21-Y 0-N)
02/16/12 House: Referred to Committee on Appropriations
02/17/12 House: Assigned App. sub: Public Safety

Regulatory Actions (as of February 28, 2012
Board of Pharmacy

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Continuous quality improvement programs Stage: Emergency/NOIRA - *At Governor's Office for 76 days* *Regulations were required to be effective by 12/20/11*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Modifications to requirements for automated dispensing devices Stage: NOIRA - *Register Date: 11/21/11* *Comment closed 12/20/11* *Proposed regulations to be adopted 3/13/12*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Change to run-dry requirement for automated counting devices Stage: NOIRA - *Register Date: 3/26/12* *Comment closes 4/25/12*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Repackaging in CSB's and BHA's Stage: Proposed - *Register Date: 11/21/11* *Comment closed 1/20/12* *Final regulations to be adopted 3/13/12*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Administrative fees for duplicate licenses and verification Stage: Proposed - *At Secretary's Office for 208 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Amendments to address on-hold prescriptions Stage: Proposed - *At Secretary's Office for 47 days*

Adoption of Final Regulations for Repackaging in Community Service Boards and Behavioral Health Authorities

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 37.2-500, 37.2-601, 54.1-3420.2, and 54.1-3423 of the Code of Virginia, relating to possession, storage, and dispensing of medications by community services boards, behavioral health authorities, and crisis stabilization units.

[H 150]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 37.2-500, 37.2-601, 54.1-3420.2, and 54.1-3423 of the Code of Virginia are amended and reenacted as follows:

§ 37.2-500. Purpose; community services board; services to be provided.

The Department, for the purposes of establishing, maintaining, and promoting the development of mental health, mental retardation, and substance abuse services in the Commonwealth, may provide funds to assist any city or county or any combinations of cities or counties or cities and counties in the provision of these services. Every county or city shall establish a community services board by itself or in any combination with other cities and counties, unless it establishes a behavioral health authority pursuant to Chapter 6 (§ 37.2-600 et seq.) of this title. Every county or city or any combination of cities and counties that has established a community services board, in consultation with that board, shall designate it as an operating community services board, an administrative policy community services board or a local government department with a policy-advisory community services board. The governing body of each city or county that established the community services board may change this designation at any time by ordinance. In the case of a community services board established by more than one city or county, the decision to change this designation shall be the unanimous decision of all governing bodies.

The core of services provided by community services boards within the cities and counties that they serve shall include emergency services and, subject to the availability of funds appropriated for them, case management services. The core of services may include a comprehensive system of inpatient, outpatient, day support, residential, prevention, early intervention, and other appropriate mental health, mental retardation, and substance abuse services necessary to provide individualized services and supports to persons with mental illnesses, mental retardation, or substance abuse. *Community services boards may establish crisis stabilization units that provide residential crisis stabilization services.*

In order to provide comprehensive mental health, mental retardation, and substance abuse services within a continuum of care, the community services board shall function as the single point of entry into publicly funded mental health, mental retardation, and substance abuse services.

§ 37.2-601. Behavioral health authorities; purpose.

The Department, for the purposes of establishing, maintaining, and promoting the development of behavioral health services in the Commonwealth, may provide funds to assist certain cities or counties in the provision of these services.

The governing body of the Cities of Virginia Beach or Richmond or the County of Chesterfield may establish a behavioral health authority and shall declare its intention to do so by resolution.

The behavioral health services provided by behavioral health authorities within the cities or counties they serve shall include emergency services and, subject to the availability of funds appropriated for them, case management services. The behavioral health services may include a comprehensive system of inpatient, outpatient, day support, residential, prevention, early intervention, and other appropriate mental health, mental retardation, and substance abuse services necessary to provide individualized services and supports to persons with mental illnesses, mental retardation, or substance abuse. *Behavioral health authorities may establish crisis stabilization units that provide residential crisis stabilization services.*

In order to provide comprehensive mental health, mental retardation, and substance abuse services within a continuum of care, the behavioral health authority shall function as the single point of entry into publicly funded mental health, mental retardation, and substance abuse services.

§ 54.1-3420.2. Delivery of prescription drug order.

A. Whenever any pharmacy permitted to operate in this Commonwealth or nonresident pharmacy registered to conduct business in the Commonwealth delivers a prescription drug order by mail, common carrier, or delivery service, when the drug order is not personally hand delivered directly, to the patient or his agent at the person's residence or other designated location, the following conditions shall be required:

1. Written notice shall be placed in each shipment alerting the consumer that under certain

57 circumstances chemical degradation of drugs may occur; and
58 2. Written notice shall be placed in each shipment providing a toll-free or local consumer access
59 telephone number which is designed to respond to consumer questions pertaining to chemical
60 degradation of drugs.
61 B. If a prescription drug order *for a Schedule VI controlled substance* is not personally hand
62 delivered directly to the patient or the patient's agent, or if the prescription drug order is not delivered to
63 the residence of the patient, the delivery location shall hold a current permit, license, or registration with
64 the Board that authorizes the possession of controlled substances at that location. The Board shall
65 promulgate regulations related to the security, access, required records, accountability, storage, and
66 accuracy of delivery of such drug delivery systems. *Schedule II through Schedule V controlled*
67 *substances shall be delivered to an alternate delivery location only if such delivery is authorized by*
68 *federal law and regulations of the Board.*
69 *C. Prescription drug orders dispensed to a patient and delivered to a community services board or*
70 *behavioral health authority facility licensed by the Department of Behavioral Health and Developmental*
71 *Services upon the signed written request of the patient or the patient's legally authorized representative*
72 *may be stored, retained, and repackaged at the facility on behalf of the patient for subsequent delivery*
73 *or administration. The repackaging of a dispensed prescription drug order retained by a community*
74 *services board or behavioral health authority facility for the purpose of assisting a client with*
75 *self-administration pursuant to this subsection shall only be performed by a pharmacist, pharmacy*
76 *technician, nurse, or other person who has successfully completed a training program for repackaging*
77 *of prescription drug orders as authorized by the subsection that has been approved by the Board. The*
78 *Board shall promulgate regulations relating to training, packaging, labeling, and record keeping for*
79 *such repackaging.*
80 *D. Prescription drug orders dispensed to a patient and delivered to a Virginia Department of Health*
81 *or local health department clinic upon the signed written request of a patient, a patient's legally*
82 *authorized representative, or a Virginia Department of Health district director or his designee may be*
83 *stored and retained at the clinic on behalf of the patient for subsequent delivery or administration.*
84 § 54.1-3423. Board to issue registration unless inconsistent with public interest; authorization to
85 conduct research; application and fees.
86 A. The Board shall register an applicant to manufacture or distribute controlled substances included
87 in Schedules I through V unless it determines that the issuance of that registration would be inconsistent
88 with the public interest. In determining the public interest, the Board shall consider the following
89 factors:
90 1. Maintenance of effective controls against diversion of controlled substances into other than
91 legitimate medical, scientific, or industrial channels;
92 2. Compliance with applicable state and local law;
93 3. Any convictions of the applicant under any federal and state laws relating to any controlled
94 substance;
95 4. Past experience in the manufacture or distribution of controlled substances, and the existence in
96 the applicant's establishment of effective controls against diversion;
97 5. Furnishing by the applicant of false or fraudulent material in any application filed under this
98 chapter;
99 6. Suspension or revocation of the applicant's federal registration to manufacture, distribute, or
100 dispense controlled substances as authorized by federal law; and
101 7. Any other factors relevant to and consistent with the public health and safety.
102 B. Registration under subsection A does not entitle a registrant to manufacture and distribute
103 controlled substances in Schedule I or II other than those specified in the registration.
104 C. Practitioners must be registered to conduct research with controlled substances in Schedules II
105 through VI. Practitioners registered under federal law to conduct research with Schedule I substances
106 may conduct research with Schedule I substances within this Commonwealth upon furnishing the
107 evidence of that federal registration.
108 D. The Board may register other persons or entities to possess controlled substances listed on
109 Schedules II through VI upon a determination that (i) there is a documented need, (ii) the issuance of
110 the registration is consistent with the public interest, (iii) the possession and subsequent use of the
111 controlled substances complies with applicable state and federal laws and regulations, and (iv) the
112 subsequent storage, use, and recordkeeping of the controlled substances will be under the general
113 supervision of a licensed pharmacist, practitioner of medicine, osteopathy, podiatry, dentistry or
114 veterinary medicine as specified in the Board's regulations. The Board shall consider, at a minimum, the
115 factors listed in subsection A of this section in determining whether the registration shall be issued.
116 Notwithstanding the exceptions listed in § 54.1-3422 A, the Board may mandate a controlled substances
117 registration for sites maintaining certain types and quantities of Schedules II through VI controlled

substances as it may specify in its regulations. The Board shall promulgate regulations related to requirements or criteria for the issuance of such controlled substances registration, storage, security, supervision, and recordkeeping.

E. The Board may register an animal shelter or pound as defined in § 3.2-6500 to purchase, possess, and administer certain Schedule II-VI controlled substances approved by the State Veterinarian for the purpose of euthanizing injured, sick, homeless, and unwanted domestic pets and animals; and to purchase, possess, and administer certain Schedule VI controlled substances for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. The drugs used for euthanasia shall be administered only in accordance with protocols established by the State Veterinarian and only by persons trained in accordance with instructions by the State Veterinarian. The list of Schedule VI drugs used for treatment and prevention of communicable diseases within the animal shelter or pound shall be determined by the supervising veterinarian of the shelter or pound and the drugs shall be administered only pursuant to written protocols established or approved by the supervising veterinarian of the shelter or pound and only by persons who have been trained in accordance with instructions established or approved by the supervising veterinarian. The shelter or pound shall maintain a copy of the approved list of drugs, written protocols for administering, and training records of those persons administering drugs on the premises of the shelter or pound.

F. *The Board may register a crisis stabilization unit established pursuant to § 37.2-500 or 37.2-601 and licensed by the Department of Behavioral Health and Developmental Services to maintain a stock of Schedule VI controlled substances necessary for immediate treatment of patients admitted to the crisis stabilization unit, which may be accessed and administered by a nurse pursuant to a written or oral order of a prescriber in the absence of a prescriber. Schedule II through Schedule V controlled substances shall only be maintained if so authorized by federal law and Board regulations.*

G. Applications for controlled substances registration certificates and renewals thereof shall be made on a form prescribed by the Board and such applications shall be accompanied by a fee in an amount to be determined by the Board.

~~G.~~ *H.* Upon (i) any change in ownership or control of a business, (ii) any change of location of the controlled substances stock, (iii) the termination of authority by or of the person named as the responsible party on a controlled substances registration, or (iv) a change in the supervising practitioner, if applicable, the registrant or responsible party shall immediately surrender the registration. The registrant shall, within fourteen days following surrender of a registration, file a new application and, if applicable, name the new responsible party or supervising practitioner.

2. That an emergency exists and this act is in force from its passage.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

Project 2366 – Proposed regulations

BOARD OF PHARMACY

Repackaging in CSB's and BHA's

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.	$250
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.	
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 December 31	$90
2. Pharmacist inactive license – due December 31	$45
3. Pharmacy technician registration – due December 31	$25
4. Pharmacy permit – due April 30	$270
5. Physician permit to practice pharmacy – due February 28	$270
6. Medical equipment supplier permit – due February 28	$180
7. Humane society permit – due February 28	$20
8. Nonresident pharmacy – due April 30	$270
9. Controlled substances registrations – due 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

I. For the annual renewal due on the stated dates, the following fees shall be imposed for a license, permit or registration:

1. Pharmacist active license – December 31, 2009	$50
2. Pharmacist inactive license – December 31, 2009	$25
3. Pharmacy technician registration – December 31, 2009	$15
4. Pharmacy permit – April 30, 2010	$210
5. Physician permit to practice pharmacy – February 28, 2010	$210
6. Medical equipment supplier permit – February 28, 2010	$140
7. Humane society permit – February 28, 2010	$20
8. Nonresident pharmacy – April 30, 2010	$210
9. Controlled substances registrations – February 28, 2010	$50

18VAC110-20-275. Delivery of dispensed prescriptions.

A. Pursuant to § 54.1-3420.2 B of the Code of Virginia, in addition to direct hand delivery to a patient or patient's agent or delivery to a patient's residence, a pharmacy may deliver ~~prescriptions~~ a dispensed prescription drug order for Schedule VI controlled substances to another pharmacy, to a practitioner of the healing arts licensed to practice pharmacy or to sell controlled substances, or to an authorized person or entity holding a controlled substances registration issued for this purpose in compliance with this section and any other applicable state or federal law. Prescription drug orders for Schedule II through Schedule V controlled substances may not be delivered to an alternate delivery location unless such delivery is authorized by federal law and regulations of the board.

B. Delivery to another pharmacy.

1. One pharmacy may fill prescriptions and deliver the prescriptions to a second pharmacy for patient pickup or direct delivery to the patient provided the two pharmacies have the same owner, or have a written contract or agreement specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with all applicable federal and state law.

2. Each pharmacy using such a drug delivery system shall maintain and comply with all procedures in a current policy and procedure manual that includes the following information:

a. A description of how each pharmacy will comply with all applicable federal and state law;

b. The procedure for maintaining required, retrievable dispensing records to include which pharmacy maintains the hard-copy prescription, which pharmacy maintains the active prescription record for refilling purposes, how each pharmacy will access prescription information necessary to carry out its assigned responsibilities, method of recordkeeping for identifying the pharmacist or pharmacists responsible for dispensing the prescription and counseling the patient, and how and where this information can be accessed upon request by the board;

c. The procedure for tracking the prescription during each stage of the filling, dispensing, and delivery process;

d. The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription;

e. The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information;

f. The policy and procedure for ensuring accuracy and accountability in the delivery process;

g. The procedure and recordkeeping for returning to the initiating pharmacy any prescriptions that are not delivered to the patient; and

h. The procedure for informing the patient and obtaining consent for using such a dispensing and delivery process.

3. Drugs waiting to be picked up at or delivered from the second pharmacy shall be stored in accordance with subsection A of 18VAC110-20-200.

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 a 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;

b. Procedure for providing counseling;

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

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

e. The procedure for informing the patient and obtaining consent for using such a delivery process.

3. 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 that cannot be easily moved and that 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.

D. The contracts or agreements and the policy and procedure manuals required by this section for alternate delivery shall be maintained both at the originating pharmacy as well as the alternate delivery site.

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.

Part XVI
Controlled Substances Registration for Other Persons or Entities

18VAC110-20-685. Definitions for controlled substances registration.

For purposes of this part, the following definitions shall apply:

"CSB" means a community services board facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

"BHA" means a behavioral health authority facility licensed by the Department of Behavioral Health and Developmental Services that holds a controlled substances registration issued by the board.

~~Part XVI~~
~~Controlled Substances Registration for Other Persons or Entities~~

18VAC110-20-690. Persons or entities authorized or required to obtain a controlled substances registration.

A. A person or entity which maintains or intends to maintain a supply of Schedule II through Schedule VI controlled substances, other than manufacturers' samples, in accordance with provisions of the Drug Control Act (§ 54.1-3400 et seq. of the Code of Virginia) may apply for a controlled substances registration on forms approved by the board.

B. Persons or entities which may be registered by the board shall include, but not be limited to, hospitals without in-house pharmacies, nursing homes without in-house pharmacies that use automated drug dispensing systems, ambulatory surgery centers, outpatient clinics, alternate delivery sites, crisis stabilization units, and emergency medical services agencies provided such persons or entities are otherwise authorized by law and hold required licenses or appropriate credentials to administer the drugs for which the registration is being sought.

C. In determining whether to register an applicant, the board shall consider factors listed in subsections A and D of § 54.1-3423 of the Code of Virginia and compliance with applicable requirements of this chapter.

1. The proposed location shall be inspected by an authorized agent of the board prior to issuance of a controlled substances registration.

2. Controlled substances registration applications that indicate a requested inspection date, or requests that are received after the application is filed, shall be honored provided a 14-day notice is allowed prior to the requested inspection date.

3. Requested inspection dates that 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.

4. Any person wishing to change an approved location of the drug stock, make structural changes to an existing approved drug storage location, or make changes to a previously approved security system shall file an application with the board and be inspected consistent with subsection B of this section.

5. Drugs shall not be stocked within the proposed drug storage location or moved to a new location until approval is granted by the board.

D. The application shall be signed by a person who will act as a responsible party for the controlled substances. The responsible party may be a prescriber, nurse, pharmacist, or pharmacy technician for alternate delivery sites or other person approved

by the board who is authorized to administer ~~or otherwise possess~~ the controlled substances ~~for that type entity~~.

E. The board may require a person or entity to obtain a controlled substances registration upon a determination that Schedule II through VI controlled substances have been obtained and are being used as common stock by multiple practitioners and that one or more of the following factors exist:

1. A federal, state, or local government agency has reported that the person or entity has made large purchases of controlled substances in comparison with other persons or entities in the same classification or category.

2. The person or entity has experienced a diversion, theft, or other unusual loss of controlled substances which requires reporting pursuant to § 54.1-3404 of the Drug Control Act.

3. The person or entity has failed to comply with recordkeeping requirements for controlled substances.

4. The person or entity or any other person with access to the common stock has violated any provision of federal, state, or local law or regulation relating to controlled substances.

18VAC110-20-700. Requirements for supervision for controlled substances registrants.

A. A practitioner licensed in Virginia shall provide supervision for all aspects of practice related to the maintenance and use of controlled substances as follows:

1. In a hospital or nursing home without an in-house pharmacy, a pharmacist shall supervise.

2. In an emergency medical services agency, the operational medical director shall supervise.

3. For any other type of applicant or registrant, a pharmacist or a prescriber whose scope of practice is consistent with the practice of the applicant or registrant and who is approved by the board may provide the required supervision.

B. The supervising practitioner shall approve the list of drugs which may be ordered by the holder of the controlled substances registration; possession of controlled substances by the entity shall be limited to such approved drugs. The list of drugs approved by the supervising practitioner shall be maintained at the address listed on the controlled substances registration.

C. Access to the controlled substances shall be limited to (i) the supervising practitioner or to those persons who are authorized by the supervising practitioner and who are authorized by law to administer drugs in Virginia, (ii) such other persons who

have successfully completed a training program for repackaging of prescription drug orders in a CSB or BHA as authorized in § 54.1-3420.2 of the Code of Virginia, or (iii) other such persons as designated by the supervising practitioner or the responsible party to have access in an emergency situation. If approved by the supervising practitioner, pharmacy technicians may have access for the purpose of delivering controlled substances to the registrant, stocking controlled substances in automated dispensing devices, conducting inventories, audits and other recordkeeping requirements, ~~and~~ overseeing delivery of dispensed prescriptions at an alternate delivery site, and repackaging of prescription drug orders retained by a CSB or BHA as authorized in § 54.1-3420.2 of the Code of Virginia. Access to stock drugs in a crisis stabilization unit shall be limited to prescribers, nurses, or pharmacists.

D. The supervising practitioner shall establish procedures for and provide training as necessary to ensure compliance with all requirements of law and regulation, including, but not limited to, storage, security, and recordkeeping.

E. Within 14 days of a change in the responsible party or supervising practitioner assigned to the registration, either the responsible party or outgoing responsible party shall inform the board and a new application shall be submitted indicating the name and license number, if applicable, of the new responsible party or supervising practitioner.

18VAC110-20-725. Repackaging by a CSB or BHA.

A. Definition. For purposes of this section, "repackaging" shall mean removing a drug from a container already dispensed and labeled by a pharmacy or medical practitioner authorized to dispense, for a particular client of a CSB or BHA, and placing it in a container designed for a person to be able to repackage his own dispensed prescription medications to assist with self-administration and compliance with dosage instructions. Such repackaging shall not include the preparation of a patient-specific label that includes drug name, strength, or directions for use or any other process restricted to a pharmacist or pharmacy technician under the direct supervision of a pharmacist.

B. Persons authorized to repackage. Repackaging shall be performed by a pharmacist, pharmacy technician, nurse, or such other person who has successfully completed a board-approved training program for repackaging of prescription drug orders as authorized in § 54.1-3420.2 of the Code of Virginia. A CSB or BHA using such other person shall maintain documentation of completion of an approved training program for at least one year from date of termination of employment or cessation of repackaging activities.

C. Requirements for repackaging.

1. The repackaging of a dispensed prescription drug order pursuant to § 54.1-3420.2 of the Code of Virginia shall only be done at a CSB or BHA.

2. The repackaging of dispensed prescription drugs shall be restricted to solid oral dosage forms and a maximum of a 14-day supply of drugs.

3. The drug container used for repackaging pursuant to this section shall bear a label containing the client's first and last name, and name and 24-hour contact information for the CSB or BHA.

4. A clean, well-closed container that assists the client with self-administration shall be used when multiple doses of a repackaged drug are provided to the client at one time.

5. A prescription drug order shall not be repackaged beyond the assigned expiration date noted on the prescription label of the dispensed drug, if applicable, or beyond one year from the date the drug was originally dispensed by a pharmacy, whichever date is earlier.

D. Written information for client. At the time a repackaged drug is initially given to a client, and upon any subsequent change in the medication order, the client shall be provided written information about the name and strength of the drug and the directions for use. Such written information shall have been prepared by a pharmacy or by a nurse at the CSB or BHA.

E. Retention, storage, and destruction of repackaged drugs.

1. Any portion of a client's prescription drug order not placed into a container intended to assist with self-administration may be either given to the client or retained by the CSB or BHA for subsequent repackaging. If retained by the CSB or BHA, the remaining portion shall be stored within the board-approved drug storage location in the original labeled container, and shall only be used for the client for whom the drug was originally dispensed.

2. Any portion of a prescription drug order remaining at the CSB or BHA that has exceeded any labeled expiration date or one year from the original pharmacy dispensing date on the label shall be separated from unexpired drugs, stored within a designated area of the board-approved drug storage location, and destroyed within 30 days of expiration with the written agreement of the client. Remaining portions of discontinued prescription drug orders retained by the CSB or BHA shall also be separated from active stock and either returned to the client or destroyed within 30 days of discontinuance with the written agreement of the client.

F. Recordkeeping.

1. A record of repackaging shall be made and maintained for one year from the date of repackaging and shall include the following:

a. Date of repackaging;

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Pharmacy name;

e. Drug name and strength;

f. Quantity of drug repackaged; and

g. Initials of the person performing the repackaging and verifying the accuracy of the repackaged drug container.

2. A record of destruction shall be made and maintained for one year for any prescription drug orders destroyed by the CSB or BHA and shall include the following:

a. Date of destruction:

b. Name of client;

c. Prescription number of the originally dispensed prescription drug order;

d. Drug name and strength;

e. Quantity of drug destroyed; and

f. Initials of the person performing the destruction.

18VAC110-20-726. Criteria for approval of repackaging training programs.

A. Application. Any person wishing to apply for approval of a repackaging training program shall submit the application fee prescribed in 18VAC110-20-20 and an application on a form approved by the board and shall meet the criteria established in this section. The application shall name a program director who is responsible for compliance with this section.

B. Curriculum. The curriculum for a repackaging training program shall include instruction in current laws and regulations applicable to a CSB or BHA for the purpose of assisting a client with self-administration pursuant to § 54.1-3420.2 of the Code of Virginia, and in the following repackaging tasks:

1. Selection of an appropriate container;

2. Proper preparation of a container in accordance with instructions for administration;

3. Selection of the drug;

4. Counting of the drug;

5. Repackaging of the drug within the selected container;

6. Maintenance of records;

7. Proper storage of drugs;

8. Translation of medical abbreviations;

9. Review of administration records and prescriber's orders for the purpose of identifying any changes in dosage administration;

10. Reporting and recording the client's failure to take medication;

11. Identification, separation and removal of expired or discontinued drugs; and

12. Prevention and reporting of repackaging errors.

C. Instructors and program director. Instructors for the program shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; or (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked in any jurisdiction in the United States. The program director shall maintain a list of instructors for the program.

D. Program requirements.

1. The length of the program shall be sufficient to prepare a program participant to competently perform repackaging consistent with § 54.1-3420.2 of the Code of Virginia and 18VAC110-20-725.

2. The program shall include a post-training assessment to demonstrate the knowledge and skills necessary for repackaging with safety and accuracy.

3. A program shall provide a certificate of completion to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by a CSB, BHA, or the board.

4. The program shall maintain records of training completion by persons authorized to repackage in accordance with § 54.1-3420.2 of the Code of Virginia. Records shall be retained for two years from date of completion of training or termination of the program.

5. The program shall report within 14 days any substantive change in the program to include a change in program name, program director, name of institution or business if applicable, address, program content, length of program, or location of records.

E. Expiration and renewal of program approval. A repackaging training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a

self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-20-727. Pharmacists repackaging for clients of a CSB or BHA.

As an alternative to repackaging as defined in 18VAC110-20-725, a pharmacist at a CSB or BHA may repackage a client's prescription drugs that have been dispensed by another pharmacy into compliance packaging that complies with the requirements of 18VAC110-20-340 B and subsections G, H, and J of 18VAC110-20-725. A primary provider pharmacy may also provide this service in compliance with the provisions of 18VAC110-20-535.

18VAC110-20-728. Drugs for immediate treatment in crisis stabilization units.

A. In accordance with § 54.1-3423 of the Code of Virginia, a crisis stabilization unit shall apply and obtain a controlled substances registration in order to maintain a stock of Schedule VI controlled substances for immediate treatment of patients in crisis. Schedule II-V controlled substances shall not be stocked. The responsible party listed on the application shall be a nurse who regularly administers controlled substances at the crisis stabilization unit and the supervising practitioner shall be either the medical director for the unit or a pharmacist from a provider pharmacy.

B. In consultation with a provider pharmacist, the medical director for the unit shall determine the list of controlled substances to be stocked at the crisis stabilization unit. The list shall be limited to Schedule VI controlled substances and only those drugs routinely used for treatment of patients admitted for crisis stabilization. Only drugs on this drug list may be stocked.

C. A nurse administering a drug from this stock pursuant to an oral order of a prescriber in accordance with § 54.1-3423 of the Code of Virginia, shall record such order in the patient's medical record.

D. Records.

1. A record shall be maintained of all drugs received as stock by the crisis stabilization unit.

2. A record shall be made documenting administration or other authorized disposition of stocked drugs that includes the following:

a. Name of patient;

b. Date and time of administration;

c. Drug name, strength, and quantity administered;

d. Name or initials of person administering; and

e. Prescriber name.

3. Records shall be maintained at the same location listed on the controlled substances registration or, if maintained in an off-site database, retrieved and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Any computerized system used to maintain records shall also provide retrieval via computer monitor display or printout of the history for drugs administered during the past two years. It shall also have the capacity of producing a printout of any data which the registrant is responsible for maintaining.

4. Manual records may be maintained as an electronic image that provides an exact image of the document and is clearly legible.

Guaranteed prices are those that will not increase for your family or estate at the time of your death. Basically, this means that your funeral arrangement for those items will be covered by and will not exceed your funding and the interest it earns. Nonguaranteed prices are those which might increase or decrease. The nonguaranteed prices may be written in at the time of this contract with you understanding that the price is an estimate only and may increase or decrease. A settlement to that effect may have to be made with your family or representative after your death.

-- Can the contract seller and I negotiate a projected charge for the nonguaranteed items based on the rate of inflation?

It is entirely up to the contract seller to inform you of the funeral home policy in that regard.

CASKETS AND CONTAINERS

-- Do I have to buy a vault or a container to surround the casket in the grave?

In most areas of the country, state and local laws do not require that you buy a container to surround the casket in the grave. However, many cemeteries ask that you have such a container to support the earth above the grave. Either a burial vault or a grave liner will satisfy if such requirements exist.

-- Is a casket required?

A casket is not required for direct cremation. If you want to arrange a direct cremation, you may use an unfinished wood box or an alternative container made of heavy cardboard or composition materials. You may choose a canvas pouch.

-- Do certain cemeteries and crematoriums have special requirements?

Particular cemeteries and crematoriums may have policies requiring that certain goods and services be purchased. If you decide not to purchase goods and services required by a particular cemetery or crematorium, you have the right to select another location that has no such policy.

EMBALMING

-- Is embalming always required?

Except in certain special cases, embalming is not required by law. Embalming may be necessary, however, if you select certain funeral arrangements such as viewing or visitation with an open casket. You do not have to pay for embalming you did not approve if you select arrangements such as a direct cremation or immediate burial. If the funeral home must charge to conduct an embalming, your designee will be notified of the reasons in writing.

ASSISTANCE

-- This is all very confusing to me. May I pick someone close to me to help with all of this? May this person also work with the funeral home to ensure that my wishes as written in the preneed contract are carried out?

You may designate in writing a person of your choice to work with the funeral home and contract seller either before or after your death to ensure that your wishes are fulfilled. You must sign the statement and have it notarized. The person that you designate must agree to this in writing. Under the laws governing preneed contracts, the individual whom you designate has final authority at the time of your death.

-- Where can I complain if I have a problem concerning my preneed contract, the contract seller, or the funeral home?

You may direct your complaints or concerns to:

The Board of Funeral Directors and Embalmers
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233
Telephone Number (804) 367-4479
Toll Free Number 1-800-533-1560
Fax: (804) 527-4413

VA.R. Doc. No. R12-2958; Filed October 31, 2011, 2:39 p.m.

BOARD OF PHARMACY

Proposed Regulation

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-20, 18VAC110-20-275, 18VAC110-20-690, 18VAC110-20-700; adding 18VAC110-20-685, 18VAC110-20-725, 18VAC110-20-726, 18VAC110-20-727, 18VAC110-20-728).**

Statutory Authority: § 54.1-2400 of the Code of Virginia.

Public Hearing Information:

December 14, 2011 - 9 a.m. - Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2, Richmond, VA

Public Comment Deadline: January 20, 2012.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4416, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

Basis: Section 54.1-2400 of the Code of Virginia provides the Board of Pharmacy with the general authority to promulgate regulations to administer the regulatory system.

Chapter 28 of the 2010 Acts of Assembly mandates that the board promulgate regulations to establish criteria for possession and repackaging of drugs by community services boards and behavioral health authorities.

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DEC 2 8 2011
DHP

December 21, 2011

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

Dear Caroline Juran:

The Virginia Association of Community Psychiatric Nurses (VACPN) would like to make a statement regarding the repackaging regulations (18 VAC 110 – 20) during the public comment period currently in progress. The VACPN is comprised of professional nurses at all levels and from all regions of the State of Virginia. At our VACPN business meeting, the majority of our members voted in opposition to these repackaging regulations.

Prior to these new regulations, only individuals who have dispensed or administered medication could fill pill boxes (i.e. pharmacists, nurses). These new regulations permit persons who have no experience in medication administration to fill pill boxes, following a brief training. In essence, the individual filling the pill box is performing advance medication administration. For this reason, we believe that only individuals experienced in medication administration should be filling pill boxes. Medication administration is a skill that incorporates several safety practices to protect patients. We feel that these safeguards are inadequately addressed, in the brief, six hour VACSB training program.

Thank you in advance for your consideration of our concern and opinion. As nurses, our members place priority on the safety of our clients.

Sincerely,

Lisa Babilon RNBC

Lisa Babilon RN BC
President, VACPN

Form: TH-11
07/10

townhall.virginia.gov

Request to Extend Life of Emergency Regulation up to Six Months

According to § 2.2-4011.D of the Code of Virginia (effective 7/1/07): **In the event that an agency concludes that despite its best efforts, a replacement regulation [for an emergency regulation] cannot be adopted before expiration of the 12-month period..., it may seek the prior written approval of the Governor to extend the duration of the emergency regulation for a period of not more than six additional months.**

Any such request must be submitted to the Governor at least 30 days prior to the scheduled expiration of the emergency regulation and shall include a description of the agency's efforts to adopt a replacement regulation together with the reasons that a replacement regulation cannot be adopted before the expiration of the emergency regulation. Upon approval of the Governor, the duration of the emergency regulation shall be extended for a period of no more than six months. Such approval shall be in the sole discretion of the Governor and shall not be subject to judicial review. Agencies shall notify the Registrar of Regulations of the new expiration date of the emergency regulation as soon as practicable.

Agency name	Board of Pharmacy, Department of Health Professions
Regulation Title/ VAC Citation	18VAC110-20 Regulations Governing the Practice of Pharmacy
Action title	Possession and repackaging of drugs in certain mental health facilities
Stage	Proposed – replacement of emergency regulations
Town Hall action/stage #	3255 / 5827
Date emergency reg expires	12/19/11
Requested new expiration date	6/18/11

Rationale

*Please describe the **agency's** best efforts to promulgate a permanent regulation before the expiration of the emergency regulation and provide the reason(s) why the effective period of this emergency regulation should be extended up to 18 months.*

Chapter 28 (HB150) of the 2010 Acts of the Assembly required the Board of Pharmacy to promulgate regulations to authorize community services boards and behavioral health authorities to possess, repackage and deliver or administer medications and crisis stabilization units to store

and administer a stock of drugs needed for emergency treatment. Regulations promulgated pursuant to the legislative mandate set forth requirements for registration of a community service board (CSB) or behavioral health authority (BHA) to possess, repackage and deliver or administer drugs and for a program to train non-pharmacists in repackaging for CSB's or BHA's.

Emergency regulations were submitted on Townhall on 3/31/10; the Governor's approval was received on 12/9/10. The NOIRA to replace emergency regulations was published simultaneously with the emergency regulations with comment requested from 1/3/11 to 2/2/11.

Proposed regulations were adopted at the next board meeting and submitted on Townhall on 3/17/11; DPB approval was given on 5/1/11. *The proposed regulations have been awaiting the Secretary's approval since that date (143 days as on 9/21/11).*

In order to have final regulations in effect by the 12/19/11 deadline, the final regulations would have had to be adopted, submitted, approved by DPB, the Secretary and the Governor by 10/19/11.

It is now impossible for the Board to replace the emergency regulations within the statutory deadline of 12 months. Therefore, the Board of Pharmacy voted at its meeting on September 20, 2011 to request a six-month extension to ensure that the repackaging of drugs by CSB's and BHA's, as mandated by the Code of Virginia, does not expire.

Submitted by

Name: Elaine J. Yeatts Title: Agency Regulatory Coordinator

Signature: Elaine J. Yeatts Date: September 21, 2011

Send this form directly to in the Governor's Policy Office and send copies of this form to your Cabinet Secretary and Melanie West of DPB.

Approved by

Governor's Office

Name: W. Jason Entz Title: Counsel & Sr. Policy Advisor

Signature: Date: 10/30/11

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Adoption of Proposed Regulations for Automated Dispensing Devices

aquatic communities or exceptional recreational opportunities for added protection. Once designated, the antidegradation policy provides that no water quality degradation would be allowed in the exceptional state waters (i.e., no new, additional, or increased point source discharge of sewage, industrial wastes, or other pollution, including storm water, would be allowed into waters designated exceptional state waters). The only exception would be temporary, limited impact activities. By ensuring that no water quality degradation is allowed to occur in waters with exceptional environmental settings and either exceptional recreational opportunities and/or exceptional aquatic communities, the board is protecting these special waters at their present quality for use and enjoyment by future generations of Virginians.

The agency does not intend to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: § 62.1-44.15 of the Code of Virginia; federal Clean Water Act (33 USC § 1251 et seq.); 40 CFR Part 131.

Public Comment Deadline: January 3, 2012.

Agency Contact: David C. Whitehurst, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4121, FAX (804) 698-4116, or email david.whitehurst@deq.virginia.gov.

VA.R. Doc. No. R12-3003; Filed October 20, 2011, 2:25 p.m.

Withdrawal of Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board has WITHDRAWN the Notice of Intended Regulatory Action for **9VAC25-720, Water Quality Management Planning Regulation,** which was published in 25:8 VA.R. 1483 December 22, 2008. The need for regulatory action has been superseded by State Water Control Board action that revised the total nitrogen waste load allocation for Fauquier County Water and Sewer Authority - Vint Hill.

Agency Contact: John M. Kennedy, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4312, FAX (804) 698-4116, TTY (804) 698-4021, or email jmkennedy@deq.virginia.gov.

VA.R. Doc. No. R09-1527; Filed October 28, 2008, 3:32 p.m.

Withdrawal of Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board has WITHDRAWN the Notice of Intended Regulatory Action for **9VAC25-720, Water Quality Management Planning Regulation,** which was published in 25:23 VA.R. 4188 July 20, 2009. The need for regulatory action has been superseded by State Water Control Board action amending the regulation to conform the wasteload allocation for Fauquier County WSA's Vint Hill plant to that established in the EPA-issued Chesapeake Bay TMDL.

Agency Contact: Alan E. Pollock, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4002, FAX (804) 698-4116, or email alan.pollock@deq.virginia.gov.

VA.R. Doc. No. R09-1981; Filed October 24, 2011, 10:40 a.m.

Withdrawal of Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the State Water Control Board has WITHDRAWN the Notice of Intended Regulatory Action for **9VAC25-720, Water Quality Management Planning Regulation,** which was published in 25:26 VA.R. 4466 August 31, 2009. This rulemaking is being withdrawn due to the time that has elapsed since the rulemaking was initiated. If action is considered necessary in the future, a new rulemaking will be initiated.

Agency Contact: Arthur Butt, Department of Environmental Quality, 629 East Main Street, P.O. Box 1105, Richmond, VA 23218, telephone (804) 698-4314, FAX (804) 698-4116, or email arthur.butt@deq.virginia.gov.

VA.R. Doc. No. R09-2001; Filed October 24, 2011, 10:40 a.m.

◆ ◆

TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Notice of Intended Regulatory Action

Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to amend **18VAC110-20, Regulations Governing the Practice of Pharmacy.** The Board of Pharmacy received three petitions for rulemaking from hospital pharmacists requesting an amendment to subdivision 5 of 18VAC110-20-490, which provides requirements for automated devices for dispensing and administration of drugs. The petitioners requested less burdensome requirements for verification of storage, location, expiration dates, drug security, and validity of access codes. While the board agreed that the petition was reasonable and the specific requirements in subdivision 5 may need to be modified for consistency with current technology, it concluded that all of 18VAC110-20-490 should be examined for possible amendments that would ensure drug security and integrity but would make compliance less burdensome.

The agency intends to hold a public hearing on the proposed action after publication in the Virginia Register.

Statutory Authority: §§ 54.1-2400 and 54.1-3307 of the Code of Virginia.

Public Comment Deadline: December 21, 2011.

Agency Contact: Caroline Juran, RPh, Executive Director, Board of Pharmacy, 9960 Mayland Drive, Suite 300, Richmond, VA 23233-1463, telephone (804) 367-4416, FAX (804) 527-4472, or email caroline.juran@dhp.virginia.gov.

VA.R. Doc. No. R11-45; Filed October 25, 2011, 9:17 a.m.

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Yeatts, Elaine J. (DHP)

From: Hublar, Nancy [CORP03519] [Nancy.Hublar@goldenliving.com]
Sent: Monday, November 21, 2011 3:20 PM
To: Yeatts, Elaine J. (DHP)
Cc: Warnock, Robert; Goss, Paul [GL03519]
Subject: #5 of 18VAC110-20-490 in Chapter 20

Comment on Virginia Board of Pharmacy Decision

November 21, 2011

Elaine J. Yeatts
Agency Regulatory Coordinator
Deparment of Health Professionals
9960 Mayland Drive
Suite 300
Richmond, VA 23233

RE: Petition for Rulemaking
Agency Decision; Vol. 28, Issue 4, Virginia Register 2011-10-24 p.187

Dear Ms. Yeatts:

Golden Living supports the Virginia Board of Pharmacy's decision concerning the petition to amend #5 of 18VAC110-20-490 in Chapter 20, which provides requirements for automated devices for dispensing and administration of drugs in which the petitioners requested less burdensome requirements for verification of storage, location, expiration dates, drug security, and validity of access codes. Golden Living agrees with the Board decision that specific requirements in #5 may need to be modified for consistency with current technology. Golden Living supports the use of Pharmacy Remote Dispensing Units. Golden Living experience is that the use of these remote units increase patient safety, enhance the patient's quality of life, reduces waste, and frees up the time of the licensed RN. Golden Living agree that the standards in place in the State of Virginia are necessary to protect patient safety.

In way of introduction, I am the Senior Vice President of Pharmacy Services at Golden Living. Golden Living operates 12 LivingCenters and 3 Community Centers in the state of Virgina, employing a little under 3,000 full time employees annually. Golden Living family companies Aegis Therapies and AseraCare Hospice also have operations in the state of Virginia. Golden Living operates nationally in 41 states; collectively, the Golden Living family of companies has more than 40,000 employees who provide quality healthcare to more than 60,000 patients every day.

Thank you and the Virginia Board of Pharmacy for their time and consideration of the view of Golden Living. If you have any questions or comments please feel free to contact me at 972-372-6313; cell: 770-880-6901; or e-mail robert.warnock@goldenliving.com

Sincerely,

Robert Warnock, D.Ph., CGP, FASCP
Senior Vice President, Pharmacy Services
Golden Living

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DRAFT Proposed Regulations

BOARD OF PHARMACY

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

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. The following conditions shall apply:

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.

2. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, ~~dose to be administered~~, date and time of withdrawal from the device, and identity of person withdrawing the drug.

3. The PIC or his designee shall conduct at least a monthly audit to review distribution and administration of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

b. A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

c. The audit shall include a review ~~of a sample~~ of administration records from each device per month for possible diversion by fraudulent charting. A sample shall include all Schedule II-V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

~~d. The audit shall include a check of medical records to ensure that a valid order exists for a random sample of doses recorded as administered.~~

~~e. The audit shall also check for compliance with written procedures for security and use of the automated dispensing devices, accuracy of distribution from the device, and proper recordkeeping.~~

~~f.~~d. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

e. The PIC or his designee shall be exempt from the audit requirements in 3c of this subsection if reconciliation software which provides a statistical analysis over a period of time based on peer-to-peer comparisons of use for that unit or department to monitor overrides and open discrepancies is used to identify suspicious activity which includes, but is not limited to, use beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed at least monthly. Reports identifying suspicious activity and a record of the focused audit shall be maintained.

4. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

5. Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and,

d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

6. The audit shall also check for compliance with written policy and procedures consistent with 54.1-3434.02 A for security and use of the automated dispensing devices, to include procedures for timely termination of access codes when applicable, accuracy of distribution from the device, and proper recordkeeping. 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 biometic identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

7. 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.

8. All records required by this section shall be filed in chronological order from date of issue and 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:

a. Manual Schedule VI distribution records and reports indicating suspicious activity with focused audits 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.

b. Distribution and delivery records and required ~~signatures~~ initials may be generated or maintained electronically provided:

(1) 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.

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

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

c. Schedule II-V distribution and delivery records may only be stored offsite or electronically as described in subdivisions 9 a and b of this section ~~if authorized by~~ consistent with DEA or in federal law or regulation.

d. 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.

Consideration of Petition for Rulemaking

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

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

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

Petitioner's full name (Last, First, Middle initial, Suffix,) Kaufman, Louis M.		
Street Address 20465 Seneca Meadows Parkway	Area Code and Telephone Number 301-353-0300 x4534	
City Germantown	State MD	Zip Code 20876
Email Address (optional) lkaufman@robertshomemedical.com	Fax (optional)	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18VAC110-20-680-C "A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing..." has been interpreted by the Board to mean the specific medical equipment supplier (MES) location must receive the order prior to dispensing. From the Board: "While one pharmacy may transfer a prescription to another pharmacy, there is no provision in law or regulation that allows for the transfer of a prescription received at one Medical Equipment Supplier to another Medical Equipment Supplier (MES). The original order must be received at the MES location from which the product is dispensed."

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

A non-controlled substance medication prescription that is provided to a specific CVS or other chain store pharmacy. The prescription can be dispensed at any location of the same chain, or transferred to another chain. It appears our dispensing of a Schedule VI legend item within our company is similar to a same chain dispensing, and request the MES rule be interpreted or changed to allow for the transfer of a prescription received at one Medical Equipment Supplier to another Medical Equipment Supplier (MES).

There are a number of MES with multiple locations in Virginia. Prescriptions frequently require equipment delivery to multiple locations. For example, a patient requiring oxygen and being discharged from a hospital in Charlottesville to home in Harrisonburg would require a delivery to the hospital of portable oxygen equipment for travel to home from our Charlottesville office and a delivery to home of long-term oxygen equipment from our Harrisonburg office. Instead of the current practice of receiving the prescription in Charlottesville, the prescribing practitioner would need to provide two prescriptions sent to two locations.

Several national durable medical equipment suppliers have MES licenses in Virginia. At least one national supplier has centralized order intake in another state and distributes the orders to their local branches from there. Complying with the stated regulation would require a significant change to their process.

Many state and regional durable medical equipment suppliers have "satellite" facilities which dispense Products but have a centralized order intake process. This reduces delivery times and improves access for patients. Complying with the stated regulation would require a significant change to their process.

Finally, the Centers for Medicare and Medicaid Services, as part of both the competitive bid program and certificate of medical necessity process for oxygen, require transfer of prescriptions and documentation between durable medical equipment suppliers—different companies, not different locations of the same company—to maintain continuity of care.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference. 54.1-2400 #6: To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) which are reasonable and necessary to administer effectively the regulatory system.

Signature: Louis M. Kaufman, RRT-NPS, AE-C, FAARC

Date: 01/19/2012

18VAC110-20-680. Medical equipment suppliers.

A. A medical equipment supplier's location shall be inspected by the board prior to engaging in business. The location shall be clean and sanitary and shall have a system of temperature control to provide for specified storage conditions for any Schedule VI drug or device.

B. Hypodermic needles and syringes and Schedule VI drugs shall not be placed on open display or in an open area where patrons will have access to such items. No Schedule VI devices shall be placed in an area where responsible parties cannot exercise reasonable supervision and control.

C. A medical equipment supplier shall receive a valid order from a practitioner prior to dispensing and shall maintain this order on file on the premises for a period of two years from date of last dispensing. The original order may be kept at a centralized office as long as it is readily retrievable within 48 hours and a copy of the order is kept on the premises of the dispensing supplier. In lieu of a hard copy, an electronic image of an order may be maintained in an electronic database provided it preserves and provides an exact image of the order that is clearly legible and made available within 48 hours of a request by a person authorized by law to have access to prescription information.

D. Medical equipment suppliers shall make a record at the time of dispensing. This record shall be maintained on the premises for two years from date of dispensing and shall include:

1. Name and address of patient;

2. Item dispensed and quantity, if applicable; and

3. Date of dispensing.

Request to Amend Pharmacy Technician to Pharmacist Ratio in 18VAC110-20-270

- Regulation Committee's report and recommendation – Jody H. Allen, Committee Chairman

Possible Board options:

- Motion to approve request to amend Regulation 18VAC110-20-270 and adopt Notice of Intended Regulatory Action to eliminate the restriction of a pharmacist not being permitted to supervise more than four persons acting as pharmacy technicians at one time, **OR**

- Motion to deny request to amend Regulation 18VAC110-20-270

Review of Walgreens' mechanisms for transferring prescriptions

Two mechanisms: TransferSafe and TransferRx.

TransferSafe is used for transferring Schedule VI controlled substances only.
TransferRx is used for transferring all prescriptions after communication with a pharmacist.

Possible Board options:

- Motion indicating, in concept, that the TransferSafe and TransferRx mechanisms as described by Walgreens appears to meet compliance with Regulation 18VAC110-20-360 for the transfer of prescriptions for drugs in Schedule VI, **OR**

- Motion indicating, in concept, that the TransferSafe and TransferRx mechanisms as described by Walgreens appears to NOT meet compliance with Regulation 18VAC110-20-360 for the transfer of prescriptions for drugs in Schedule VI

Walgreens
The Pharmacy America Trusts®

TransferSafe is Walgreens latest innovation to improve quality and service for patients. Using the TransferSafe secure Web site allows competitor pharmacists to quickly process transfer-outs, providing more time for patient care.

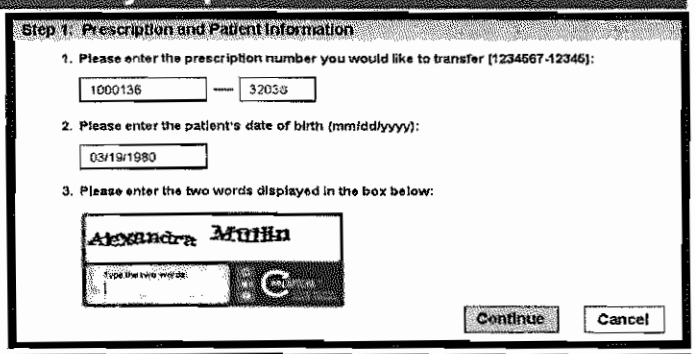
- Go to transfersafe.walgreens.com for a simple online job aid that walks through the process.
- TransferSafe requires a printer, Internet access, and a web browser (Internet Explorer, etc).

Transfer prescriptions from Walgreens in 3 easy steps

Step 1: Enter the Walgreens prescription.

Include the following information:

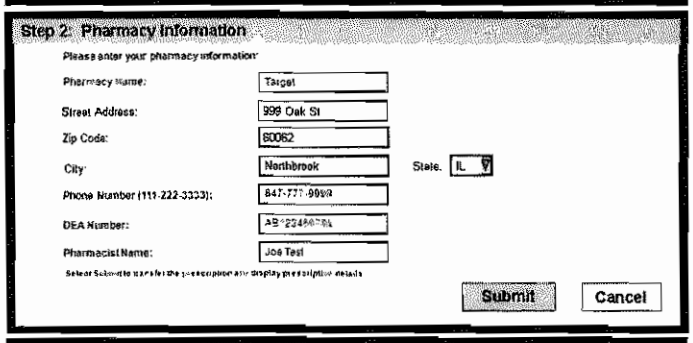
- Walgreens prescription number (located on the bottle)
- Patient's date of birth in mm/dd/yyyy format
- Two words displayed in the security box. Leave one space between each word
- Press Continue



Step 2: Enter your pharmacy's information.

Enter the following information:

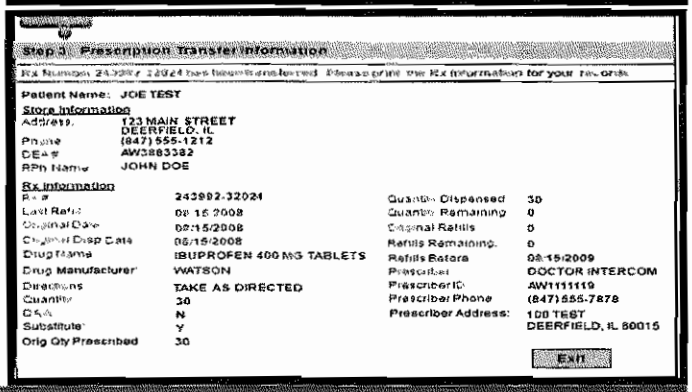
- Pharmacy Name
- Pharmacist's Name
- Pharmacy Address
- Pharmacy Telephone Number
- Pharmacy DEA Number
- Press Submit only once



Step 3: Verify the prescription information and print.

- Verify the Patient's Name and Prescription Details
- Print the Prescription Information
- Press Exit

To protect patients and monitor quality, Walgreens collects all data entered and displays it in TransferSafe.



Frequently asked questions

Is TransferSafe legal?

- Yes. TransferSafe complies with many state regulations regarding the transfer of prescriptions.

What if I have a request to transfer a controlled prescription?

- Transfers of controlled prescriptions are not currently able to be processed using TransferSafe. Contact the Walgreens pharmacy directly to transfer a prescription for a controlled substance.

Why did I receive the message "This script cannot be transferred using this application?"

- Some prescriptions, such as compounds or Walgreens specific products, are not able to be processed using TransferSafe. Contact the Walgreens pharmacy directly to transfer the prescription.

Why do I have to press the "I Agree" button to use the application?

- TransferSafe is designed to be used under the direction of a registered pharmacist only. This statement and associated "I Agree" button are additional safeguards to prevent unauthorized use of the application and the associated pharmacy DEA number.

WHAT IS IT?

TransferRx is an authenticator based application that provides our pharmacists and pharmacy interns with a quick and easy way to transfer prescriptions directly to a competitor pharmacist via fax or verbal communication. The application also has a look up feature that allows our pharmacist to view prescription information within Intercom Plus.

Note: This system is not available in Puerto Rico

WHY ARE WE DOING IT?

TransferRx decreases the amount of time to complete transfers by allowing our pharmacist to transfer multiple prescriptions at the same time and by displaying the necessary information for verbal transfers.

HOW DOES IT WORK?

There are three main functions of the TransferRx application.

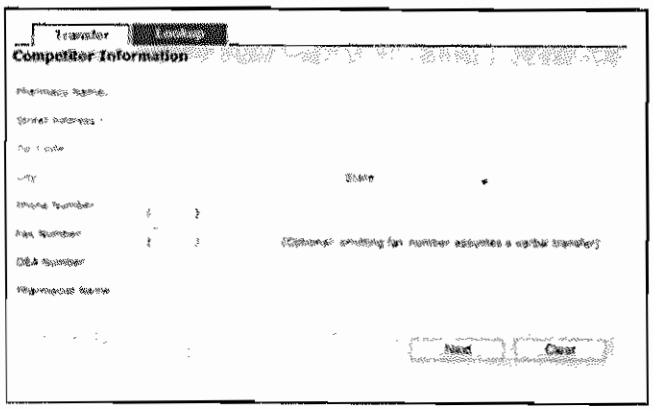
- Fax Transfers: use this function to transfer prescription information electronically via facsimile.
- Verbal Transfers: use this function when the Fax Transfer function is not available or your state regulations prohibit electronic transfers via facsimile. (e.g Oklahoma)
- Look Up: use this function to view any prescription information within Intercom Plus

FAX TRANSFERS

1. Access the TransferRx application in StoreNet> Rx Admin> Pharmacy Maintenance

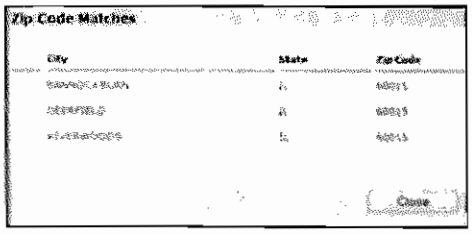
Note: Certain states allow only verbal transfers.

2. Complete all **Competitor Information** fields, and select the **Next** button.



FAX TRANSFERS

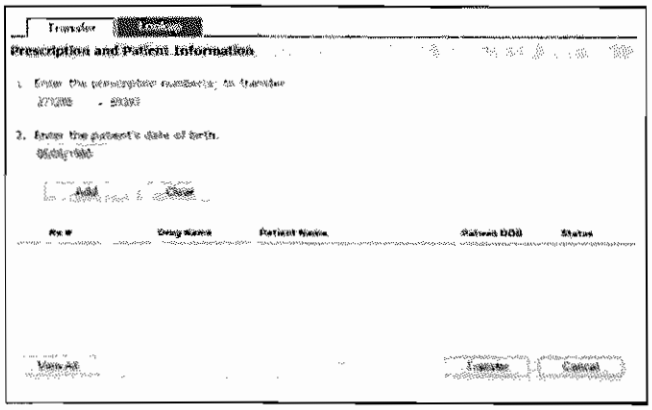
3. If the entered zip code has multiple cities, a pop-up window displays listing the options. Choose the city, and select the **Close** button.



4. Enter the **Prescription Number(s)** and patient's **Date of Birth.** Select the **Add** button. Repeat for each prescription.

Notes:

- If transferring to the same competitor, you can include prescriptions from multiple patients or Walgreens stores.
- If the prescription is closed, expired, or has no refills available, you will receive an error message.

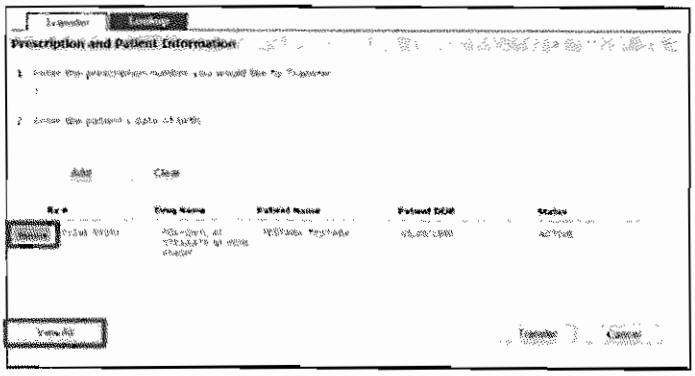


FAX TRANSFERS

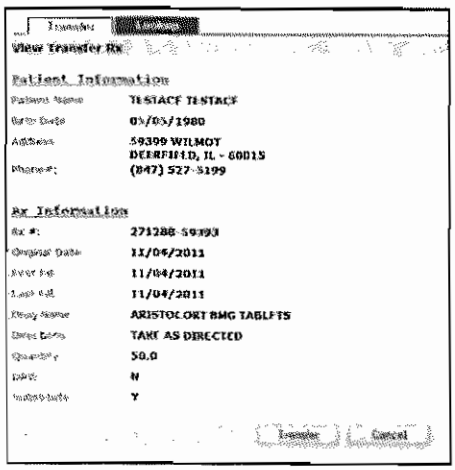
5. Review the prescriptions that you added to the transfer list.

6. Confirm the **Patient Name(s)** are correct for each transfer.
   - If you need to remove a prescription, select the **Remove** button by the prescription.
   - If you would like to view the details of the prescriptions, select the **View All** button.

Note: If **View All** is selected, and there is more information than can display on the screen, a scroll bar appears on the right side to scroll through the additional information.

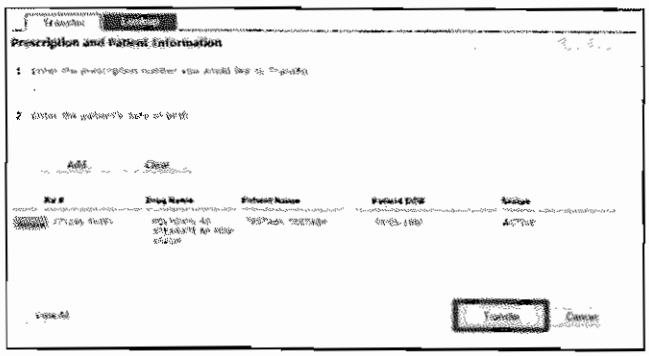


When the **View All** button is clicked, the **View Transfer Rx** displays:



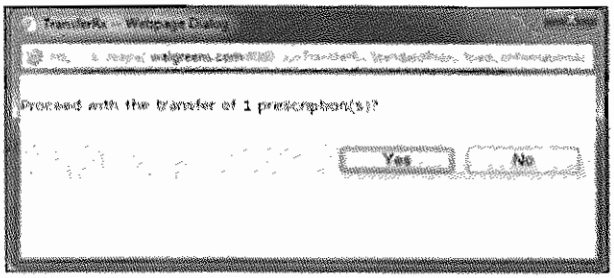
7. Select the **Transfer** button on the **Prescription and Patient Information** window, or the **View All** screen.

Prescription and Patient Information screen:



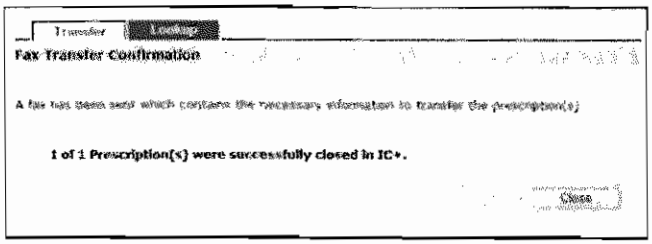
Fax Transfers

8. Select the **Yes** button on the **TransferRx** window to complete the transfer.



9. Select the **Close** button on the **Fax Transfer Confirmation** page.

   Note: The **Fax Transfer Confirmation** confirms the transfer was sent to the competitor **and the prescriptions were closed in Intercom Plus**. It does **NOT** confirm the competitor received the fax.

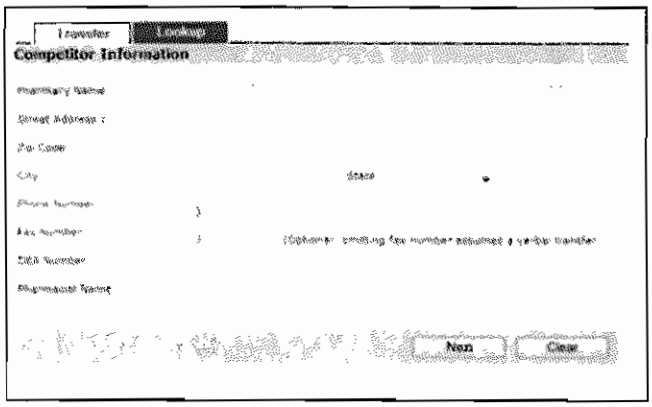


Verbal Transfers

1. Access the TransferRx application in StoreNet> Rx Admin> Pharmacy Maintenance

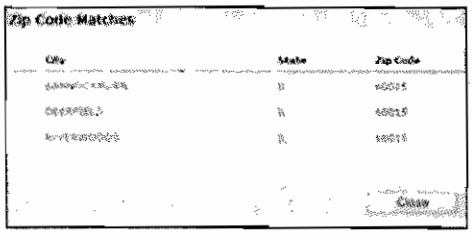
Note: Certain states allow only verbal transfers.

2. Complete all **Competitor Information** fields, except the **Fax Number** field, and select the **Next** button.



VERBAL TRANSFERS

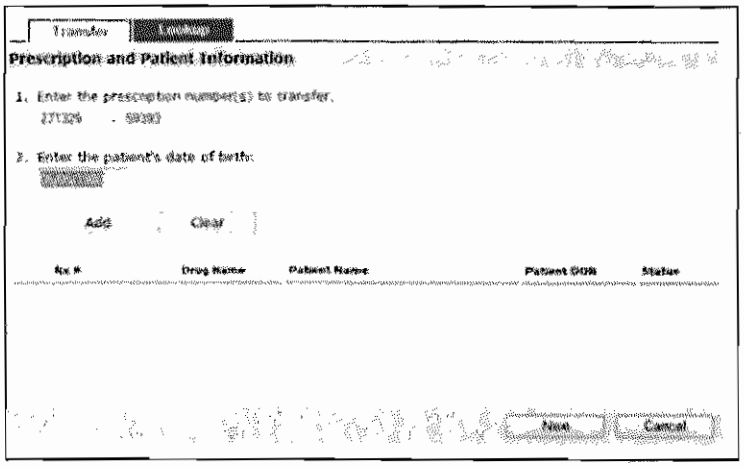
3. If the entered zip code has multiple cities, a pop-up window displays listing the options. Choose the city, and select the **Close** button.



4. Enter the **Prescription Number(s)** and patient's **Date of Birth.** Select the **Add** button. Repeat for each prescription.

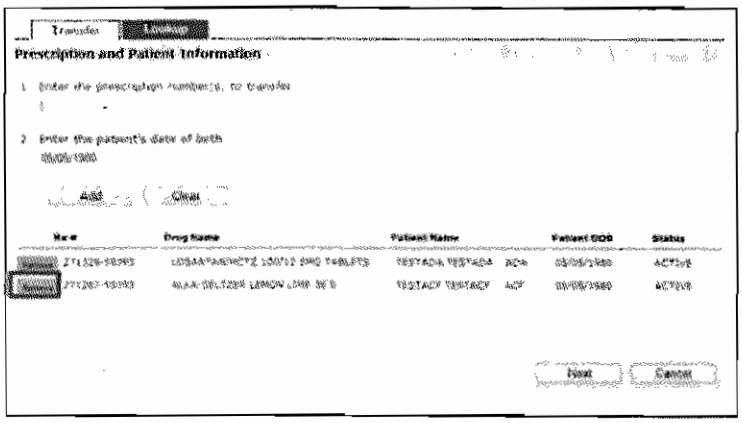
Notes:

- If transferring to the same competitor, you can include prescriptions from multiple patients or Walgreens stores.
- If the prescription is closed, expired, or has no refills available, you will receive an error message.



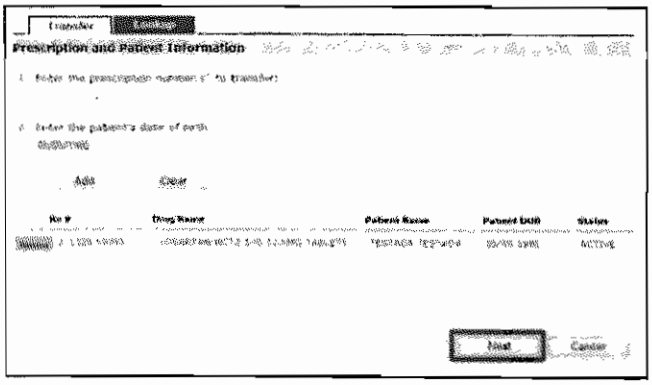
5. Review the prescriptions that you added to the transfer list.

6. Confirm the **Patient Name(s)** are correct for each transfer.
   - If you need to remove a prescription, select the **Remove** button by the prescription.



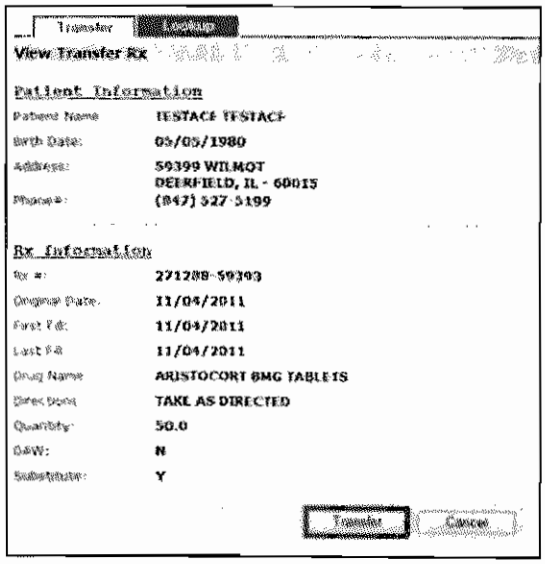
VERBAL TRANSFERS

7. Select the **Next** button on the **Prescription and Patient Information** window.

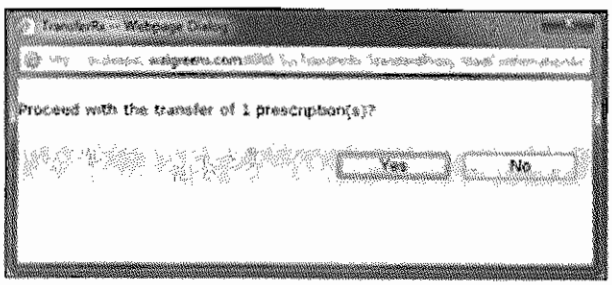


8. Provide the transfer information to the competitor using the information displayed on the **View Transfer Rx** window. Scroll down as needed to view all prescription details.
9. Select the **Transfer** button.

Note: If **View All** is selected, and there is more information than can display on the screen, a scroll bar appears on the right side to scroll through the additional information.



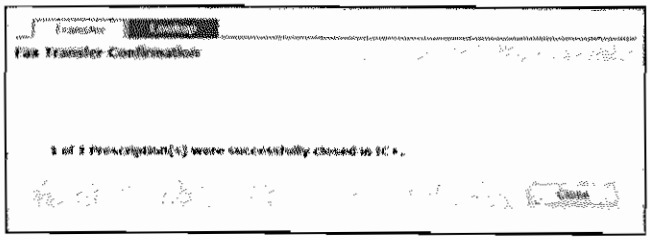
10. Select the **Yes** button on the **TransferRx** window to complete the transfer.



VERBAL TRANSFERS

11. Select the **Close** button on the **Fax Transfer Confirmation** page.

    Note: The **Fax Transfer Confirmation** confirms the transfer was given to the competitor **and the prescriptions were closed in Intercom Plus.**

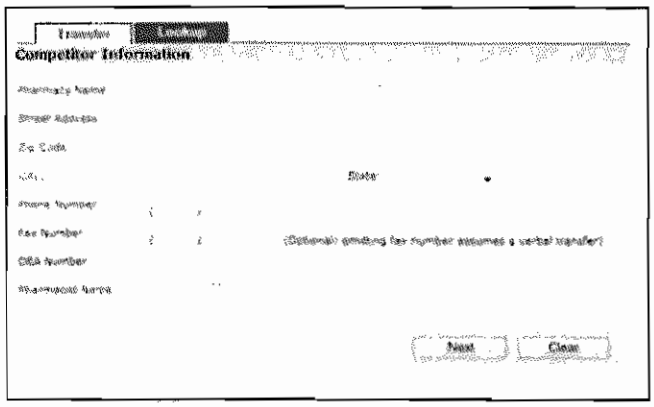


PRESCRIPTION LOOKUP

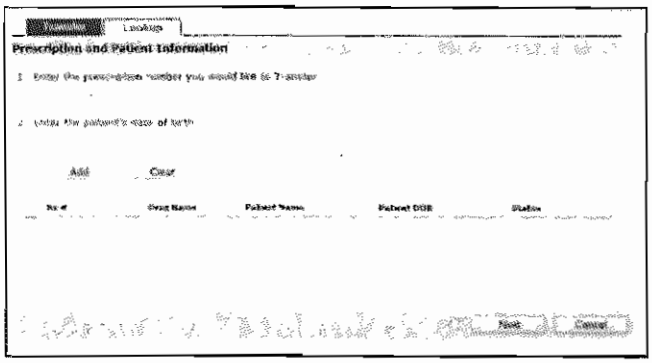
The **TransferRx Lookup** tab can be used to look up prescription information.

1. Access the TransferRx application by following this pathway in StoreNet> Rx Admin> Pharmacy Maintenance.

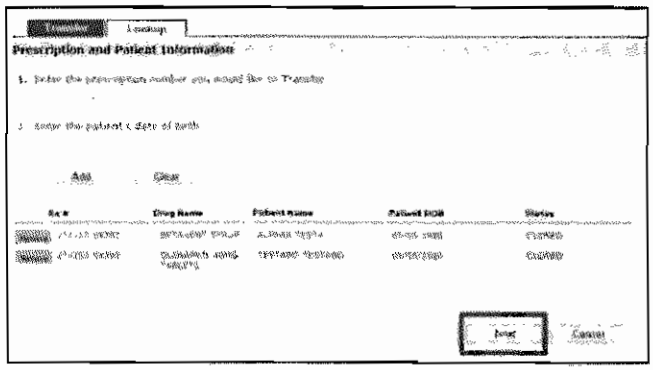
2. Select the **Lookup** tab.



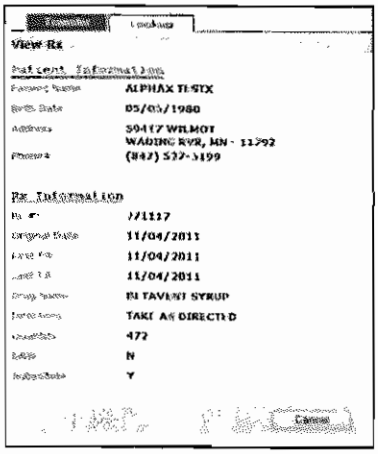
3. Enter the **Prescription Number(s)** and patient's **Date of Birth**. Select the **Add** button.



4. When all prescriptions are listed, select the **Next** button.



PRESCRIPTION LOOKUP

5. When done reviewing information, select the **Cancel** button. **Note:** No Transfer action can be taken from the **Lookup** screen, other than giving information verbally. Remember to look for the scroll bar on the right to view multiple prescriptions.	
To close **TransferRx**, close the browser window.	

18VAC110-20-360. Issuing a copy of a prescription that can be refilled.

A. Consistent with federal laws and regulations, a copy of a prescription shall be given upon request by one pharmacy to another pharmacy provided the drug can be filled or refilled pursuant to §§ 54.1-3410 and 54.1-3411 of the Code of Virginia and provided the patient has given permission for the transfer.

B. The transfer of original prescription information for a drug listed in Schedules III through VI for the purpose of dispensing is permissible between pharmacies if the transfer is communicated directly between the two pharmacies either orally by direct communication between the transferring pharmacist and the receiving pharmacist, or by facsimile machine or by electronic transmission, provided:

1. The transferring pharmacy:

a. Records the word "VOID" on the face of the invalidated prescription;

b. Records on the reverse of the invalidated prescription the name, address, and, except for a prescription for a Schedule VI drug, the (DEA) number of the pharmacy to which it was transferred, and, for an oral transfer, the name of the pharmacist receiving the prescription information;

c. Records the date of the transfer and, in the case of an oral transfer, the name of the pharmacist transferring the information; and

2. The receiving pharmacy:

a. Writes the word "TRANSFER" on the face of the transferred prescription.

b. Provides all information required to be on a prescription to include:

(1) Date of issuance of original prescription;

(2) Original number of refills authorized on the original prescription;

(3) Date of original dispensing, if applicable;

(4) Number of valid refills remaining and date of last dispensing;

(5) Pharmacy name, address, DEA registry number except for Schedule VI prescriptions, and original prescription number from which the prescription information was transferred; and

(6) Name of transferring pharmacist, if transferred orally.

Both the original and transferred prescription shall be maintained for a period of two years from the date of last refill.

C. Nothing in this regulation shall prevent the giving of a prescription marked "For Information Only" to a patient.

D. In lieu of recording the required information in subsection B of this section on a hard copy prescription, a pharmacy may record all required information in an automated data processing system used for storage and retrieval of dispensing information in accordance with 18VAC110-20-250.

E. For prescriptions transferred between pharmacies using a common database, the pharmacy receiving the prescription shall not be required to maintain a hard copy pursuant to 18VAC110-20-240 B provided that the system used is capable of generating a hard copy of the transferred prescription upon request or except as required by federal law.

Presentation and request from Walgreens for approval, in concept, of new store layout in Virginia locations

- Representatives from Walgreens to be present and show video of new store layout.

Possible Board options:

- Motion indicating, in concept, that the new store layout as described by Walgreens appears to meet compliance with Regulations 18VAC110-20-150, 18VAC110-20-180, and 18VAC110-20-190 regarding physical and security standards, and the use of cameras and monitors for pharmacists on-duty to supervise pharmacy technicians and verify the accuracy of dispensed drugs appears to comply with 18VAC110-20-270 , **OR**

- Motion indicating, in concept, that the new store layout as described by Walgreens appears to NOT meet compliance with Regulations 18VAC110-20-150, 18VAC110-20-180, and 18VAC110-20-190 regarding physical and security standards, and the use of cameras and monitors for pharmacists on-duty to supervise pharmacy technicians and verify the accuracy of dispensed drugs appears to comply with 18VAC110-20-270

18VAC110-20-150. Physical standards for all pharmacies.

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet U.S.P.-N.F. specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary record keeping.

F. A sink with hot and cold running water shall be within the prescription department.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department, if the pharmacy stocks such drugs.

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.

18VAC110-20-190. Prescription department enclosures; access to prescription department.

A. The prescription department of each pharmacy shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be constructed in such a manner that it protects the prescription drugs from unauthorized entry and from pilferage at all times whether or not a pharmacist is on duty.

2. The enclosure shall be locked and alarmed at all times when a pharmacist is not on duty.

3. The enclosure shall be capable of being locked in a secure manner at any time the pharmacist on duty is not present in the prescription department.

18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.

A. In addition to the acts restricted to a pharmacist in §54.1-3320 A of the Code of Virginia, a pharmacist shall provide personal supervision of compounding of extemporaneous preparations by pharmacy technicians.

C. After the prescription has been prepared and prior to the delivery of the order, the pharmacist shall inspect the prescription product to verify its accuracy in all respects, and place his initials on the record of dispensing as a certification of the accuracy of, and the responsibility for, the entire transaction. Such record showing verification of accuracy shall be maintained on a pharmacy record for the required time period of two years, unless otherwise specified in regulation

Request to Discuss Length of Time Associated with and Access to Final Orders

- Request from Crady Adams to discuss the length of time a final order resulting from a disciplinary matter remains on a licensee's record and on the Board's website for viewing.

Background:

Currently, public record requirements in the Freedom of Information Act and requirements regarding the finality of orders in the Administrative Process Act require orders to be maintained and accessible to the public for 85 years. Additionally, agency policy requires all boards to post orders on the agency's website once the orders become final.

Request from *The Pharmacy Alliance* to Implement Mandates to Address "System Induced Errors"

Possible Board options:

- Motion to refer request from *The Pharmacy Alliance* to the Regulation Committee for further consideration of each suggested topic of rulemaking, **OR**
- Motion to deny request from *The Pharmacy Alliance* for possible rulemaking

Juran, Caroline (DHP)

From: Board of Pharmacy
Sent: Thursday, January 12, 2012 12:15 PM
To: Juran, Caroline (DHP)
Subject: FW: Please forward this and/or attached *.pdf to your exec director and/or board president
Attachments: phyboard.pdf

Importance: High

From: pharmaciststeve [mailto:steve@steveariens.com]
Sent: Thursday, January 12, 2012 11:45 AM
To: William.harvey@state.nm.us; virginia_herold@dca.ca.gov; susan.boyer@doh.wa.gov; st-pharmacy@pa.gov; sher.zinn@alaska.gov; roklein@mt.gov; randy.jones@state.sd.us; ramsdellr@michigan.gov; PWickizer@pla.IN.gov; pharmbd@mail.nysed.gov; Board of Pharmacy; pharmacy@pr.mo.gov; pharmacy@pharmacy.ok.gov; pharmacy@pharmacy.nv.gov; pharmacy@dora.state.co.us; pharmacy@dcca.hawaii.gov; pharmacy.board@state.or.us; pharmacy.board@state.mn.us; pharmacy.board@nh.gov; pharmacy.board@ky.gov; patricia.dantonio@dc.gov; ndboph@btinet.net; MQA_Pharmacy@doh.state.fl.us; mdbop@dhmh.state.md.us; Mark.Johnston@bop.idaho.gov; lpoe@utah.gov; lloyd.jessen@iowa.gov; kristy.pirie@sec.state.vt.us; John.Kirtley@arkansas.gov; jcampbell@ncbop.org; James.d.coffey@state.ma.us; info@pharmacy.la.gov; hbobo@albop.com; geraldine.l.betts@maine.gov; gay.dodson@tsbp.state.tx.us; FPR.PRFGROUP10@illinois.gov; fgammill@mbp.state.ms.us; exec-office@nabp.net; exec@bop.ohio.gov; eugene.santos@dphss.guam.gov; drlboards@wisconsin.gov; delinda.brown-jagne@ct.gov; deborah.richardson@usvi-doh.org; dbillingsley@pharmacy.ks.gov; david.e.potters@wv.gov; customerservice.dpr@state.de.us; chunter@azpharmacy.gov; Catherine.Cordy@health.ri.gov; bundricl@llr.sc.gov; boyerj@dca.lps.state.nj.us; BOP@wyo.gov; becky.wisell@nebraska.gov; hbobo@albop.com; sher.zinn@alaska.gov; chunter@azpharmacy.gov; John.Kirtley@arkansas.gov; virginia_herold@dca.ca.gov; pharmacy@dora.state.co.us; delinda.brown-jagne@ct.gov; customerservice.dpr@state.de.us; patricia.dantonio@dc.gov; MQA_Pharmacy@doh.state.fl.us; eugene.santos@dphss.guam.gov; pharmacy@dcca.hawaii.gov
Subject: Please forward this and/or attached *.pdf to your exec director and/or board president

The Pharmacy Alliance
6023 Avenue S, Box #134, Galveston, TX 77551
Steve Ariens, P.D.
National Public Relations Director
steve@steveariens.com

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Jan 12, 2012

Dear Pharmacy Board:

We, at The Pharmacy Alliance, are concerned about the typical work environment of our colleagues and the patients that are being harmed because of errors resulting from such environments.

While we understand that most boards decline to address prescription volume and staffing man hours, we are concerned no board has addressed aribritary time production metrics that are widely being forced on Rx dept staff. Study after study, involving many professions and industries , demonstrates a person working more than 8-10 hrs, particularly without breaks, becomes both less efficient and more prone to errors. Recently the Joint Commission published results of such a study http://www.jointcommission.org/sea_issue_48/

We respectively request that each state Board of Pharmacy, place on their next agenda and discuss the implementation of mandates that will address these system induced errors. With a reported 100,000 people dying from medical mistakes and 1.5 million being harmed from medication errors. We think that it is time to help prevent the next "Eric Cropp incident".

In our opinion, some of the health and safety issues that need to be addressed:

1. Prohibit any Rx ready in minutes guarantee or advertisement that promotes how fast Rxs can/will be filled.
2. Limit the number of hours a RPh can work in a given day to no more than 10 hrs, including breaks.
3. Mandatory 30 minutes meal break for RPh scheduled working => 6 hrs. If pharmacy is being staffed by a single RPh, require mandatory closing of Rx dept.
4. Drive Thru windows are to be closed when there is no tech support in the Rx dept.
5. Eliminate any/all corporate mandatory Rx or vaccination production metrics or quotas.
6. Other timed metrics (answering phone, drive thru, cash register) can only be imposed on ancillary/tech staff , not Pharmacists
7. Mandate that any settlement with a patient for medication error that involves a settlement, greater than the cost of the medication(s), be reported to the board.
8. Pharmacies will report these errors noting chain, store, Rph. Any chain, store or RPh that demonstrates annual error rates in the top 25 percentile ... will have to submit to the board, a written plan, how CQI is being implemented/improved to reduce errors.
9. Any non-Pharmacist employee, of the permit holder, that attempts to influence the professional decision of a Pharmacist can be charged with practicing pharmacy without a license and/or permit holder fined for allowing such behavior, or both.

We would appreciate a response to our request, at your earliest convenience

Sincerely,

Steve Ariens, P.D.

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