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 9, 2011

9:00AM

TOPIC	PAGE(S)
Call to Order: Brandon Yi, Chairman	
• Welcome and Introductions	
• Reading of emergency evacuation script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	
· December 15, 2011, Full Board Meeting	1-9
· December 22, 2010, Special Conference Committee	10-12
· February 2, 2011, Telephone Conference Call	13-14
· February 8, 2011, Telephone Conference Call	15-16
· February 9, 2011, Panel Formal Hearing	17-20
· February 9, 2011, Informal Conference Committee	21-23
· February 23, 2011, Special 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	24-38
Regulations: Update - Elaine Yeatts	39-52
Update on Action Items: Caroline Juran	
• On-hold prescriptions	
· Provide status of Ad Hoc committee	
· Discuss possible need for regulations	
· Consider approval of NOIRA, if necessary	53-56
• Status of pharmacy routine inspection program – Sammy Johnson	Handout
Miscellaneous: Caroline Juran	
• Review amended language in guidance document 110-34 regarding submission of social security numbers or control numbers	57
• Discuss inventory requirements to determine if Schedule II-V drugs must be physically counted or if Schedule III-V drugs may be estimated consistent with federal rules	58-64

- Amend deficiencies major 13 and 14 on guidance document 110-9, if necessary 65-71
- Agency Operating Efficiency Measures – consideration for staff emailing agenda packets for business portion of full board meetings, in lieu of mailing hard copies

Reports:

- Report – Ralph Orr 72
  - Report on DEA public meetings held January 19-20, 2011 to discuss the development of procedures for the surrender of unwanted controlled substances by ultimate users and long term care facilities
  - DEA's announcement regarding second National Prescription Drug Take Back Day, April 30, 2011
  - Possible regulatory action regarding PMP reporting requirements
- Report on Board of Health Professions – David C. Kozera
- Report on disciplinary matters – Cathy Reiniers-Day
- Executive Director's Report - Caroline D. Juran
  - Announcement of J. Samuel (Sammy) Johnson, Jr. assuming role as Deputy Executive Director overseeing licensure program
  - Awarding of contract for administrator of the Virginia Federal and State Drug Law Exam
  - NABP 107th Annual Meeting, May 21-24, 2011, San Antonio, TX
  - Rescheduling of September full board meeting

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
DRAFT/ MINUTES OF BOARD MEETING

December 15, 2010
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

DRAFT UNAPPROVED

CALL TO ORDER: The meeting was called to order at 9:12 AM.

PRESIDING: Brandon Yi, Chairman

MEMBERS PRESENT:
Gill B. Abernathy
Jody H. Allen
John O. Beckner
Gerard Dabney
David C. Kozera
Robert M. Rhodes
Leo H. Ross
Ellen B. Shinaberry
Pratt P. Stelly

STAFF PRESENT:
Caroline D. Juran, Acting Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Howard M. Casway, Senior Assistant Attorney General
Dianne L. Reynolds-Cane, 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.

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

APPROVAL OF MINUTES: The Board reviewed draft minutes for September 8, 2010 (board meeting); September 8, 2010 (panel formal hearings); September 21, 2010; September 28, 2010; October 28, 2010; November 17, 2010; and December 2, 2010. With no changes to the minutes, the minutes were approved as presented.

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

DHP DIRECTOR'S REPORT: Dr. Dianne L. Reynolds-Cane discussed the state of the agency, highlighting accomplishments and challenges during the past year. As Director, Dr. Cane participated as an advisor to the Reform Health Council, served on the State Lyme Disease Taskforce, and participated with the National Drug Take-back Program and the Homeless Advisory Committee. Additionally, she briefly stated

that fiscal matters are currently under review due to an uncontrollable increase in fees from Northrop-Grumman/Virginia Information Technologies Agency. Other highlights over the past year included: the Administrative Proceedings Division having closed 640 disciplinary cases; the Health Practitioners' Monitoring Program having accepted 102 participants; and the Prescription Monitoring Program having doubled the number of registered users and quintupled the number of requests for information. She concluded by announcing that second-round interviews for the Executive Director position of the Board of Pharmacy would be held in the near future and a hiring decision would be made by the end of January 2011.

LEGISLATION:

- Legislation update

Ms. Yeatts reported that multiple bills have already been filed to add synthetic marijuana to Schedule I for the upcoming General Assembly. Additionally, she stated that the Board's legislative proposal to add tramadol and carisoprodol to Schedule IV and conform state law to federal rule by adding immediate precursors of amphetamine, methamphetamine, phencyclidine, and fentanyl to Schedule II had not been approved by the Governor. She added that it's possible that another legislator could choose to introduce similar language, but that the proposal would not be included in the Governor's package. She further stated that she anticipated the submission of a bill to amend the requirement passed in 2010 regarding proof of identity when picking up a dispensed Schedule II drug.

REGULATIONS:

- Regulation update

Ms. Yeatts reported that the emergency regulations authorizing the repackaging of certain dispensed drugs within a community service board or behavioral health authority have been signed by the Governor and will be effective December 20, 2010 to December 19, 2011. Public comment on the notice of intended regulatory action for permanent regulations will close on February 2, 2011. Additionally, Ms. Yeatts reported that the following fast-track regulations remain under administrative review: the signing of the delivery record for automated dispensing devices in hospitals; the addition of administrative fees; and, the elimination of an alarm system for certain emergency medical service agencies.

- PHARMACY INSPECTION PROGRAM:

Sammy Johnson, Assistant Director, Enforcement Division, provided an update on the recently revised routine pharmacy inspection process. He referenced the December 2010 Board e-newsletter article regarding the most commonly cited deficiencies

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in community pharmacies; i.e., deficiencies regarding inventories, records for partial dispensings, records for filling automated counting devices, proper labeling of prescriptions, back-up for security systems, proper storage of emergency keys, and proper storage of drugs within refrigerators and freezers. He further stated that, for the 146 routine inspections of community pharmacies performed between July 1, 2010, and November 30, 2010, 51 inspections resulted in no cited deficiencies, 34 inspections resulted in a cited deficiency, and 61 inspections resulted in a cited deficiency with a monetary penalty. Additionally, he reported that 12 pilot inspections had been performed in pharmacies providing services to hospitals between July 1, 2010, and November 30, 2010, and that four inspections had resulted in a cited deficiency and eight inspections resulted in a cited deficiency that would have imposed a monetary penalty had it not been a pilot inspection.

Action Item:

Twelve pilot inspections had been performed in pharmacies providing services to hospitals, therefore, the Board determined that enforcement should continue piloting the inspections in this environment and would review the statistics at the March 2011 meeting for consideration as to whether to go "live" with the inspection program in the hospital/institutional environment. Additionally, regarding cited deficiencies for not properly reporting a drug loss to the Board, Gill Abernathy commented that confusion may exist for when a drug loss should be reported. After discussion, the Board agreed that staff should include an article in the next e-newsletter regarding the reporting requirements for the theft or loss of drugs.

GUIDANCE DOCUMENT REVISION:

- Guidance Document 110-9 Pharmacy Inspection Deficiency Monetary Penalty Guide

Ms. Juran reviewed possible changes to certain deficiencies listed in Guidance Document 110-9. It was decided that only those deficiencies that impact the community pharmacies would be reviewed for amendment, since the inspection program will continue to perform pilot inspections of pharmacies that provide services to hospitals and other institutions. There was discussion regarding increasing the number of minor deficiencies that must be cited, from three to five, prior to the imposition of a $250 monetary penalty as a means of decreasing the number of pre-hearing consent orders issued. However, Ms. Juran reported that this change would not have an overall impact on whether the inspection resulted in the issuance of a pre-hearing consent order. Statistics indicate that most pre-hearing consent orders involve the citing of a major deficiency which automatically imposes a monetary penalty and the issuance of a pre-hearing consent order. Thus, the Board agreed

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that no amendment was necessary.

For major deficiency #8, the Board agreed to the condition that the temperature may be "determined using inspector's or pharmacy's calibrated thermometer".

For major deficiency #9, Ms. Juran stated that, thus far, if a pharmacy alarm was incapable of sending an alarm signal to the monitoring entity when breached if the communication line was not operational, then the pharmacy was cited with this deficiency and a $1,000 monetary penalty was imposed. There was discussion regarding creating a separate major deficiency for this requirement with a reduced monetary penalty since the alarm system was otherwise operational and being set. The Board agreed to create a new major deficiency, #9a, "Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational" with a monetary penalty of $250.

For major deficiency #13, the Board agreed to modify the language as "No biennial inventory, or over 30 days late or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed".

For major deficiency #14, the Board agreed to modify the language as "No incoming change of PIC inventory taken within 5 days or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed".

For major deficiency #15, there was discussion as to whether the Board should implement a 10% threshold for determining compliance with the perpetual inventory requirement. It was determined that the perpetual inventory requirement aided the detection of diversion and that a threshold should not be implemented.

Motion: **The Board voted unanimously to amend guidance document 110-9 as follows:**

major 8, the Board agreed to the condition that the temperature may be "determined using inspector's or pharmacy's calibrated thermometer";

major 9a was added to read "Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational" and states a suggested monetary penalty of $250;

major 13 was modified to read "No biennial inventory, or over

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30 days late or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed"; and,

major 14 was changed to read "No incoming change of PIC inventory taken within 5 days or substantially incomplete; i.e., did not include all drugs in Schedules II-V, or a physical count was not performed". (motion by Kozera, second by Dabney)

UPDATE ON ACTION ITEMS:

- Reporting of disciplinary action to NPDB-HIPDB

Per the Board's request at the September meeting, Ms. Juran reported that she had researched whether other states were reporting disciplinary action taken against a facility permit to NPDB-HIPDB and whether reported disciplinary action taken against a facility permit would jeopardize a contract to receive government funds. She referenced a survey recently performed by the Texas Board of Pharmacy which indicates that of the 25 states responding to the survey, 19 states report action taken against a pharmacy and 6 do not. Additionally, she stated that on October 13, 2010, she participated in a telephone conference call with Regina Keegan, Policy Analyst, NPDB-HIPDB, SRA International, Inc. During the conference call, Ms. Keegan explained that other states have been reporting facility-related disciplinary action since 1992 and that she is not familiar with an instance wherein a pharmacy was denied a government contract due to a reported action. Ms. Keegan further explained that a state is required to report action involving an administrative fine that is connected to health care delivery. Because many of the possible deficiencies resulting from a routine inspection may be construed to be connected to health care delivery and the agency's policy is to report all publicly available disciplinary actions taken by the Board to NPDB, HIPDB, and Section 1921, these disciplinary actions shall continued to be reported.

- Survey of other states' filing requirements regarding "on-hold" prescriptions

Per the Board's request from the September meeting, Ms. Juran requested NABP to send an electronic survey of specific questions to the other states to solicit information on their rules or policies for filing "on-hold" prescriptions. Fourteen states responded and a summary of responses was provided in the agenda packet. Only two states addressed the handling of "on-hold" prescriptions in rule. However, the survey results indicated that there is some concern for the potential of pharmacists not verifying the data entry of an on-hold prescription which could and has led to dispensing errors. The Board members shared this concern. Additionally, as follow-up to the September meeting, Ms. Juran reported that she had contacted Mark Caverly, Chief, Liaison and Policy Section, Office of

DATUM PROPOSED

Diversion Control, Drug Enforcement Administration, who confirmed that federal law and regulation do not directly address whether a prescription shall be filed by date of initial dispensing or initial entry into the pharmacy electronic record keeping system. Therefore, it was determined that an ad-hoc committee should be appointed to consider the need for regulatory action regarding the requirements for data-entry of on-hold prescriptions, pharmacist verification of the accuracy of the entered data, and the filing of these prescriptions.

Motion:

The Board voted unanimously to the formation of an ad hoc committee to consider the need for regulatory action regarding the requirements for data-entry of on-hold prescriptions, pharmacist verification of the accuracy of the entered data, and the filing requirements for these prescriptions, and to appoint John Beckner, Robbie Rhodes, Jody Allen, David Kozera, and Brandon Yi to this committee. (motion by Beckner, second by Dabney)

MISCELLANEOUS:

- Sanctioning Reference Points Training

The Board of Health Professions has recently requested that Kimberly Langston and Neil Kauder from VisualResearch, Inc. provide training to the various boards on the sanctioning reference points. This training is periodically provided to afford new board members an opportunity to learn of this tool and ask questions of these experts. Ms. Langston was present and reviewed with the Board that sanctioning reference points is a tool for the Board to use to increase consistency in disciplinary matter outcomes. Ms. Langston also reviewed a "Sample Case" with the Board.

REPORTS:

- Report on Collection of Data and Information about Utilization of the Prescription Monitoring Program pursuant to SJR 73 and SJR 75 (2010)

Ralph Orr, Program Director of Virginia's Prescription Monitoring Program (PMP), gave an overview of the program's report submitted to the General Assembly as required by SJR 73 and SJR 75. Mr. Orr thanked the Board for the opportunity to present information about the report and then gave a brief description of the Advisory Panel which was instrumental in helping develop the report and recommendations.

Mr. Orr stated that there were seven specific questions to which the program was asked to respond. He then provided highlights of the responses to each of the questions. Overall, the PMP has seen exceptional growth since the implementation of 24/7 access which resulted from the implementation of auto response software in October 2009. The number of registered users has doubled and the number of reports processed quadrupled from the previous year. At

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the same time, data indicates a possible effect at reducing the number of patients seeking care from multiple prescribers and pharmacies in the first six months of 2010 compared to previous data.

Recommendations for enhancing the PMP were also requested to be included in the report to the General Assembly. Mr. Orr explained that most of the recommendations are specifically related to meeting minimum eligibility requirements for federal grant funding. There is no proposed legislation or regulatory action being initiated at this time that is related to these recommendations.

Mr. Yi asked for an update of the 2009 security breach and Mr. Orr provided basic background information. Mr. Orr stated that the breach is still an ongoing criminal investigation being conducted by federal and state law enforcement. Mr. Orr explained that the PMP had been. The program software and database were scheduled to move to a new facility with new software and equipment 30 days after the breach that occurred on April 30, 2009, and are now housed in the Commonwealth's CESC facility using state-of-art network security.

Mr. Beckner asked if pharmacists and prescribers can receive information from other states' PMPs. Mr. Orr stated all of Virginia's border states with PMPs (does not include Maryland and Washington, DC) currently allow pharmacists and prescribers in Virginia to register to use their programs. Currently, a user has to have multiple accounts and make separate requests to receive prescription information from the various state programs. There is an effort underway that will allow a user in Virginia to receive information from the Virginia PMP and from other state programs with which there is an agreement for sharing information while only needing to have an account with Virginia's PMP. The system will be easy to use once in place. A user will simply indicate from which state programs (from those available) information is needed and the receiving of the report will occur much as it does now. This feature should become available in a limited format in late 2011.

At approximately 12:00, Ms. Abernathy departed from the meeting.

- Report on NABP Member Forum Meeting

John Beckner reported on his attendance at the NABP Member Forum Meeting held on September 22-23, 2010 in Mount Prospect, Illinois. He stated the meeting was an opportunity for members of other state boards and NABP staff to discuss concerns regarding relevant topics such as the use of pharmacy coupons, prescription drug abuse, and proper disposal of drugs. Further, he stated that the Meeting was worthwhile and his being able to meet both other state

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board members and NABP staff was beneficial.

- Disciplinary Process Report

Ms. Reiniers-Day explained the four priorities used in the disciplinary process as well as the "no" priority. Further, she explained the use of status levels used and that, as of December 8, 2010, there were 152 docketed cases with 69 at the enforcement level, 48 at the probable cause level, two at the informal conference level, one at the OAG level and five at the formal hearing level.

- Acting Executive Director's report

Ms. Juran provided a summary of the two current Board-approved innovative (pilot) programs. The first involves pharmacy technicians at seven pharmacies owned by Omnicare using bar-code scanning technology to perform the final verification check of bingo cards containing Schedule VI drugs. Terms and conditions are outlined in the consent order which include a requirement for pharmacists to verify the accuracy of 10% of these dispensings. To date, the required quarterly reports indicate no errors associated with this process. The second innovative (pilot) program waives the requirement in Regulation 18VAC110-20-555 which restricts the use of automated dispensing devices to nursing homes and authorizes The Pines, a residential environment for youth, to qualify for the use of these dispensing devices. The Pines uses only nurses to administer drugs and demonstrated a similarity to a nursing home environment. Ms. Juran also stated that a Board committee has reviewed and approved an application for the use of Instymeds technology which stores and prepares drugs for dispensing in a device similar to a vending machine, but that the applicant had withdrawn the application. Based on telephone calls received by Ms. Juran, she anticipates another application for the use of Instymeds to be submitted in the near future.

Ms. Juran then reported that the Board of Pharmacy is currently not represented on the Board of Health Professions ("BHP") and that the Executive Director of BHP advised that, at the September 29, 2010, Board Meeting, the Board finalized its studies on medication aide expansion into nursing homes, medical laboratory scientists and technicians, and kinesiotherapists. The request for a review of grand aides has been withdrawn due to a conflict with the nursing scope of practice laws. Additionally, the Board will continue to review developments relative to Community Health Workers as they are emerging to take on a greater role in filling support service gaps, especially in underserved areas, and it continues to review the need to create a Allied Health Board.

Ms. Juran announced that one bid had been received for the RFP to obtain an examination contractor for the Virginia Federal and State Drug Law Exam. Negotiations will begin in the near future. The contract for the current contractor ends June 30, 2010.

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Ms. Juran attended the NABP District I and II meeting held on October 29-31, 2010, in Cooperstown, New York.. She stated that the focus of the meeting was information sharing to learn how other states are addressing current concerns. She felt Virginia was positioned well on most subjects relative to the other states in attendance, particularly regarding the use of collaborative practice agreements, administration of immunizations, and registration of pharmacy technicians.

Lastly, Ms. Juran provided the Board with a copy of a recent news release from the American Pharmacists Association which announced the renaming of the APhA Summer Internship Program to the Carl Emswiller Summer Internship in Association Management. It stated that a generous memorial fund had been established by his wife and it honors his contributions to the profession. Mr. Emswiller, who died in December 2009, co-owned and operated Emswiller Pharmacy in Leesburg, Virginia, received the Remington Honor Medal in 1999 from APhA, and served as a past chairman of the Board of Pharmacy.

NEW BUSINESS

There was no new business discussed.

RECOGNITION OF FORMER BOARD MEMBERS

During a working lunch, Mr. Yi and Elizabeth Scott "Scotti" Russell, the former Executive Director, presented plaques of recognition to the following former board members: Bobby Ison, Jennifer Edwards, and Michael Stredler. Willie Brown was not able to attend, but was recognized.

ADJOURN:

With all business concluded, the meeting adjourned at 1:30p.m.

Caroline D. Juran
Acting Executive Director

Brandon Yi, Board Chairman

Date

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Wednesday, December 22, 2010
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: John O. Beckner, Committee Chair

MEMBERS PRESENT: David C. Kozera, Committee Member

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

NADER ABEDINZADEH
Pharmacist Reinstatement Applicant
License # 0202-011595

Nader Abedinzadeh appeared with James E. Moore, his attorney, to discuss his petition for reinstatement of his pharmacist license and to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 22, 2010, Notice.

Closed Meeting: Upon a motion by Mr. Kozera, and duly seconded by Mr. Beckner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Nader Abedinzadeh. 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. Kozera, and duly seconded by Mr. Beckner, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order that requires Mr. Abedinzadeh to successfully pass the Virginia Drug Law Examination and, following

that, his pharmacist license will be reinstated contingent upon his complying with certain terms and conditions.

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

LISA R. BRADY
Registration No. 0230-015089

Lisa R. Brady appeared with Allen Farmer, her brother-in-law, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 22, 2010, Notice.

Closed Meeting:

Upon a motion by Mr. Kozera, and duly seconded by Mr. Beckner, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, ("Code"), for the purpose of deliberation to reach a decision in the matter of Lisa R. Brady. 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. Kozera, and duly seconded by Mr. Beckner, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order that places Ms. Brady's pharmacy technician registration under the term that she comply with her contract with the Health Practitioner's Monitoring Program.

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

received from Ms. Brady 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 1:25 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

John O. Beckner, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Wednesday, February 2, 2011

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 9:05 a.m., on February 2, 2011, to consider the summary suspension of the registration of Kaylann M. Chapman to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING: Brandon K. Yi, Chair

MEMBERS PRESENT:
Gill B. Abernathy
Jody H. Allan
John O. Beckner
Gerard Dabney
David C. Kozera
Leo H. Ross
Ellen B. Shinaberry
Pratt P. Stelly

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

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

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

KAYLANN M. CHAPMAN
Registration No. 0230-016949

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

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

ADJOURN:

With all business concluded, the conference call adjourned at 9:13 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Brandon K. Yi, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Tuesday, February 8, 2011

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

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

TIME & PURPOSE:

Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held at 10:00 a.m., on February 8, 2011, to consider the possible settlement Consent Orders for Jodi V. Ettare and James V. Ettare to practice as pharmacists in the Commonwealth of Virginia.

PRESIDING:

John O. Beckner

MEMBERS PRESENT:

Jody H. Allan
David C. Kozera
Robert M. Rhodes
Pratt P. Stelly

STAFF PRESENT:

Cathy M. Reiniers-Day, Deputy Executive Director
Caroline D. Juran, Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Howard Casway, Senior Assistant Attorney General

JODI V. ETTARE
License # 0202-205862
and
JAMES V. ETTARE
License # 0202-206317

John O. Beckner called the meeting to order to discuss the possible settlement Consent Orders for Ms. Ettare and Mr. Ettare.

Closed Meeting:

Upon a motion by Mr. Kozera, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision regarding the settlement Consent Orders in the matter of Jodi V. Ettare and James V. Ettare. Additionally, he moved that, Cathy Reiniers-Day, Eusebia Joyner, Caroline Juran and Howard Casway attend the closed meeting.

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the

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Code, the panel re-convened in open meeting and announced the decision.

Upon a motion by Mr. Kozera and duly seconded by Mr. Rhodes, the panel voted 5-0 that the Consent Orders for Ms. Ettare and Mr. Ettare be approved should the respondents agree to the addition of "and conclusions of law" to the consent portion on page 2, paragraph number 5.

ADJOURN: With all business concluded, the conference call adjourned at 10:35 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

John O. Beckner, Chairman for
the Ettares formal administrative hearings

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Wednesday, February 9, 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 1:10 p.m.

PRESIDING: John O. Beckner, Chair

MEMBERS PRESENT:
Jody Allen
Gerard Dabney
David C. Kozera
Robert M. Rhodes
Pratt P. Stelly

STAFF PRESENT:
Caroline Juran, Deputy 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
James E. Schliessmann, Assistant Attorney General
Corie E. Tillman Wolf, Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

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

BETHANY L. BOYD
Registration # 0230-007836

Ms. Boyd did not appear at the formal hearing. The panel chose to proceed in her absence as the Notice was mailed to Ms. Boyd's legal address of record, both by regular and certified mail. The panel discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia as stated in the January 10, 2011, Notice.

James E. Schliessmann, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Susan A. Beasecker, BOP Compliance Case Manager testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0, 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 Bethany L. Boyd. Additionally, he moved that Cathy Reiniers-Day, Eusebia Joyner, Caroline Juran 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. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Schliessmann and amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0 that Ms. Boyd's pharmacy technician registration be indefinitely suspended with certain terms and conditions. Further, Ms. Boyd shall be issued a reprimand.

ELISABETH A. WILLIAMS
Registration # 0230-015687

A formal hearing was held in the matter of Elisabeth A. Williams following the summary suspension of her pharmacy technician registration on December 2, 2010, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Williams was not present at the hearing. The panel proceeded in Ms. Williams absence as the Notice of Formal Hearing dated December 3, 2010, was mailed to Ms. Williams legal address of record, both by regular and certified mail. Mr. Beckner ruled that adequate notice was provided to Ms. Williams and the hearing proceeded in her absence.

Corie E. Tillman Wolf, Assistant Attorney General, prosecuted the case with the assistance of Mykl D. Egan, DHP Adjudication Specialist.

Vicki G. Garrison, DHP Pharmacy Inspector; Ralph Martin, CVS/pharmacy District Manager; and Jo Ann Campbell, CVS/pharmacy Supervisor, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0, 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 Elisabeth A. Williams. Additionally, he moved that Cathy Reiniers-Day, Eusebia Joyner, Caroline Juran, 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. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Ms. Wolf and amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0 that Ms. Williams' registration to practice as a pharmacy technician be revoked.

KELLY N. HAYES
Registration # 0230-009090

A formal hearing was held in the matter of Kelly N. Hayes following the summary suspension of her pharmacy technician registration on October 28, 2010, and to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Ms. Hayes was not present at the hearing. The panel proceeded in Ms. Hayes absence as the Notice of Formal Hearing dated November 9, 2010, was mailed to Ms. Hayes legal address of record, both by regular and certified mail. Mr. Beckner ruled that adequate notice was provided to Ms. Hayes and the hearing proceeded in her absence.

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

Closed Meeting: Upon a motion by Mr. Kozera and duly seconded by Mr. Rhodes, the panel voted 6-0, 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 Kelly N. Hayes. Additionally, he moved that Cathy Reiniers-Day, Eusebia Joyner, Caroline Juran, 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. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0 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. Kozera and duly seconded by Mr. Dabney, the panel voted 6-0 that Ms. Hayes' registration to practice as a pharmacy technician be revoked.

Adjourn: With all business concluded, the meeting adjourned at 3:15 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

John O. Beckner, Formal Hearings Chair

Date

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

Wednesday, February 9, 2011
Second Floor
Board Room #2

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Richmond, Virginia 23233

CALL TO ORDER: A meeting of an informal conference committee of the Board of Pharmacy was called to order at 3:35pm.

PRESIDING: John O. Beckner, Committee Chairman

MEMBERS PRESENT: David C. Kozera

STAFF PRESENT: Caroline D. Juran, Executive Director
Sammy Johnson, Deputy Director, Enforcement

Anita Chatman, M.D.
License # 0101-052287

Mr. Edward D. Rickert, Esq., Krieg DeVault, Julie Geason, Vice-President of Pharmacy Services, InstyMeds, and Jennifer O'Connell, Office Manager, Dulles Urgent Care Center were present to discuss the application, received December 28, 2010, for approval of an innovative (pilot) program wherein Dulles Urgent Care Center would use an automated drug delivery system manufactured by InstyMeds Corporation to dispense acute care drugs to their own patients. Because the physician licensed to dispense would not visually inspect the drug prior to patient delivery, an allowance is necessary for waiving certain provisions of Board regulation 18VAC110-30-40.

Decision: After consideration of the application and statements concerning the innovative (pilot) program, Mr. Beckner stated that the Committee approved the innovative (pilot) program for a period of one year from the date of inspection approving the dispensing device under the auspices of a limited-use practitioner of the healing arts to sell controlled substances license, and it is contingent upon receiving additional information and upon other terms and conditions.

Required additional information for submission includes:

1. An application for a limited-use practitioner of the healing arts to sell controlled substances license from each physician, to include Anita Chatman, M.D., requesting the ability to dispense drug to his own patients and the

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designation of a physician assuming the responsibility for the drug stock, the required inventories, the records of receipt and destruction, safeguards against diversion and compliance with the laws and regulations. Upon a change in the responsible licensee so designated at the location, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in §54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board.

2. An amended page 12 and 18 of the application to correct a discrepancy in the request for years of approval for the innovative (pilot) program and designation of the physician responsible for overseeing the innovative (pilot) program.

Other terms and conditions include:

1. Either the dispensing device shall be located in an area protected by a security system compliant with Regulation 18VAC110-30-120, i.e., consisting of motion detectors monitored by an outside entity that will notify appropriate law enforcement when breached with the code being restricted to dispensing physicians, or the dispensing device shall have a monitored alarm within the device with the alarm code restricted to the dispensing physicians that will notify appropriate law enforcement;
2. Access to the code or key for opening and loading the device shall be restricted to times when a dispensing licensee is on-site and shall only be given to a registered pharmacy technician, or a nurse or physician assistant with training in compliance with Regulation 18VAC110-30-40;
3. Drugs delivered for loading into the device shall be immediately placed in the device upon receipt to prevent possible diversion;
4. Dulles Urgent Care Center shall be subject to one random, unannounced inspection by the Board or its designated representative within 12 months following the implementation of the innovative (pilot) program. This inspection is independent from any routine inspection. Anita Chatman, M.D., on behalf of Dulles Urgent Care Center, shall be solely responsible for the payment of an inspection fee of $150.00 to be paid to the Board within thirty days from the date of the statement of monies owed which will be mailed following the inspection;

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5. A visual inspection to verify accuracy of the final dispensed drug prior to delivery as performed in the process of verifying the accuracy of the dispensed drug in its entirety as required in Board regulation 18VAC110-30-40 will be waived, as well as certain provisions of Regulation 18VAC110-30-240 B and C, based on the presented information regarding the device's automation and bar-code technology. Additionally, a sign shall be posted near the dispensing device informing patients that nonspecial packaging or non-safety closures are not available.
6. All drugs which must be reconstituted shall be mixed by a registered pharmacy technician, nurse or physician assistant with training in compliance with Regulation 18VAC110-30-40, or the dispensing physician prior to delivery.
7. All prescription errors and theft or loss of any drug in Schedules II-V shall be immediately reported to the Board and other authorities as necessary.
8. The dispensing physician is ultimately responsible for any counseling provided to the patient as required in Regulation 18VAC110-20-40.
9. The dispensing physicians shall comply with all other laws and regulations regarding the dispensing of controlled substances.
10. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification; and,
11. Reports of failure to comply with the terms and conditions of the waiver as set forth above shall constitute grounds for the rescission of the approval and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

ADJOURN: With all business concluded, the meeting adjourned at approximately 5:45pm.

Caroline D. Juran, Executive Director

John O. Beckner, Chairman

Date

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Report of the 2011 General Assembly

Board of Pharmacy

HB 1434 Marijuana, synthetic; penalties for possession, intent to sell, distribute, etc.

Chief patron: Garrett

Summary as passed House:
Penalties for possession, sale, gift, distribution or possession with intent to sell, give or distribute synthetic marijuana. Creates a new category for "synthetic marijuana" as a series of controlled substances listed in Schedule 1 (§ 54.1-3446) of the Drug Control Act (§ 54.1-3400 et seq.). Notwithstanding the provisions regarding punishment for possession and distribution of controlled substances listed in Schedule 1, punishment for possession and distribution of synthetic marijuana is largely in accord with the provisions for actual marijuana. The bill contains an emergency clause.

EMERGENCY

02/18/11 Senate: Engrossed by Senate - committee substitute HB1434S1
02/18/11 Senate: Passed Senate with substitute (40-Y 0-N)
02/21/11 House: Placed on Calendar
02/22/11 House: Senate substitute rejected by House 11105337D-S1 (3-Y 94-N)
02/22/11 House: VOTE: REJECTED (3-Y 94-N)

HB 1459 Medical malpractice; increases cap on recovery in actions against health care providers.

Chief patron: Albo

Summary as introduced:
Remedies; limitation on recovery in certain medical malpractice actions. Increases from $2 million to $2.05 million, on July 1, 2012, the cap on the recovery in actions against health care providers for medical malpractice. Thereafter, the cap is increased by $50,000 annually with the last increase on July 1, 2031.

02/16/11 House: VOTE: ADOPTION (89-Y 7-N)
02/17/11 House: Enrolled
02/17/11 House: Bill text as passed House and Senate (HB1459ER)
02/17/11 House: Signed by Speaker
02/20/11 Senate: Signed by President

HB 1968 Physician assistants; signature to be included when law requires signature, etc., of a physician.

Chief patron: Robinson

Summary as introduced:
Physician assistants; when signature accepted. Provides that whenever any law or regulation requires a signature, certification, stamp, verification, affidavit, or endorsement by a physician, it shall be deemed to include a signature, certification, stamp, verification, affidavit, or endorsement by a physician assistant.

02/17/11 House: Enrolled
02/17/11 House: Bill text as passed House and Senate (HB1968ER)
02/17/11 House: Impact statement from DPB (HB1968ER)
02/17/11 House: Signed by Speaker
02/20/11 Senate: Signed by President

HB 2216 Laboratory results; authority to provide directly to insurance carrier, etc.

Chief patron: Stolle

Summary as passed House:
Laboratory results; authority to receive directly. Allows a laboratory, if so requested by the patient or his legal guardian and in a manner consistent with state and federal law, to provide a copy of the report of the results directly to the insurance carrier, health maintenance organization, or self-insured plan that provides health insurance or similar coverage to the patient. This bill is identical to SB 1116.

02/16/11 House: Senate amendments agreed to by House (97-Y 0-N)
02/16/11 House: VOTE: ADOPTION (97-Y 0-N)
02/22/11 House: Enrolled
02/22/11 House: Bill text as passed House and Senate (HB2216ER)
02/23/11 House: Impact statement from DPB (HB2216ER)

HB 2220 Pharmacies; implement continuous quality improvement program for analysis of dispensing errors.

Chief patron: Rust

Summary as passed House:
Pharmacies; continuous quality improvement program. Requires pharmacies to implement a continuous quality improvement program to provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. This bill requires the Board of Pharmacy to work cooperatively with pharmacists representing all areas of pharmacy practice in implementing the requirements of this act.

02/17/11 House: Enrolled
02/17/11 House: Bill text as passed House and Senate (HB2220ER)
02/17/11 House: Impact statement from DPB (HB2220ER)
02/17/11 House: Signed by Speaker
02/20/11 Senate: Signed by President

HB 2255 Disclosure of health records; health care providers who dispense controlled substances.

Chief patron: Nutter

Summary as introduced:
Disclosure of health records; dispensing of controlled substances. Clarifies that nothing in the Health Records Privacy Act shall prohibit a health care provider who dispenses a controlled substance to a patient from disclosing information obtained from the Prescription Monitoring Program and contained in a patient's health care record to another health care provider when such disclosure is related to the care or treatment of the patient. This bill also provides that nothing shall prevent a person who prescribes or dispenses a controlled substance from redisclosing information obtained from the Prescription Monitoring Program to another prescriber or dispenser who prescribes or dispenses a controlled substance to a recipient. This bill is identical to SB 1029 (Puckett).

02/17/11 House: Enrolled
02/17/11 House: Bill text as passed House and Senate (HB2255ER)
02/17/11 House: Impact statement from DPB (HB2255ER)
02/17/11 House: Signed by Speaker
02/20/11 Senate: Signed by President

HB 2256 Schedule II drugs; identification required for filling prescriptions.

Chief patron: Nutter

Summary as passed House:
Schedule II drugs; identification required in filling prescriptions. Specifies that certain duties imposed upon a pharmacist in the delivery of Schedule II drugs may be undertaken by the agent of the pharmacist. The bill also provides that if the person seeking to take delivery of a drug listed on Schedule II pursuant to a prescription is not the patient for whom the drug is prescribed and the person is not known to the pharmacist or his agent, the pharmacist or his agent shall either make a photocopy or electronic copy of the person's identification or record the full name and address of the person. The bill also reduces the period of time for which the pharmacist must maintain records of the names and addresses or copies of the proof of identification of persons taking delivery of Schedule II drugs when they are not the person for whom the drug is prescribed from on year to one month. This bill is identical to SB 1150.

02/07/11 Senate: Referred to Committee on Education and Health
02/17/11 Senate: Reported from Education and Health (14-Y 1-N)
02/18/11 Senate: Constitutional reading dispensed (40-Y 0-N)
02/21/11 Senate: Read third time
02/21/11 Senate: Passed Senate (37-Y 2-N)

HB 2373 Medical malpractice; privileged communications of certain committees.

Chief patron: Peace

Summary as passed House:
Medical malpractice; privileged communications of certain committees. Provides that nothing in the statute governing privileged communications of certain health committees shall be construed as providing any privilege to any health care provider, emergency medical services agency, community services board, or behavioral health authority with respect to any factual information regarding specific patient health care or treatment, including patient health care incidents, whether oral, electronic, or written. However, the analysis, findings, conclusions, recommendations, and the deliberative process of any medical staff committee, utilization review committee, or other committee, board, group, commission, or other entity, as well as the proceedings, minutes, records, and reports, including the opinions and reports of experts, of such entities shall be privileged in their entirety under the aforementioned statute.

02/16/11 House: Enrolled
02/16/11 House: Bill text as passed House and Senate (HB2373ER)
02/16/11 House: Impact statement from DPB (HB2373ER)
02/16/11 House: Signed by Speaker
02/16/11 Senate: Signed by President

HB 2464 Drug Control Act; conforms Schedule II to federal drug classification schedule.

Chief patron: Nutter

Summary as introduced:
Drug Control Act; Schedule II. Conforms Schedule II of the Drug Control Act to the federal drug classification schedule.

02/17/11 House: Bill text as passed House and Senate (HB2464ER)
02/17/11 House: Impact statement from DPB (HB2464ER)
02/17/11 House: Signed by Speaker
02/18/11 House: Impact statement from VCSC (HB2464ER)
02/20/11 Senate: Signed by President

SB 742 Neighborhood assistance tax credits; eligibility of certain pharmacists.

Chief patron: Howell

Summary as introduced:
Neighborhood assistance tax credits; eligibility of certain pharmacists. Clarifies that pharmacists donating pharmaceutical services to patients of a free clinic, which clinic is an organization exempt from taxation under the provisions of § 501(c)(3) of the Internal Revenue Code, with such pharmaceutical services performed at the direction of an approved neighborhood organization, shall be eligible for neighborhood assistance tax credits.

02/16/11 House: VOTE: BLOCK VOTE PASSAGE (97-Y 0-N)
02/21/11 Senate: Enrolled
02/21/11 Senate: Bill text as passed Senate and House (SB742ER)

02/21/11 House: Signed by Speaker
02/22/11 Senate: Signed by President

SB 1029 Disclosure of health records; health care providers who dispense controlled substances.

Chief patron: Puckett

Summary as introduced:
Disclosure of health records; dispensing of controlled substances. Clarifies that nothing in the Health Records Privacy Act shall prohibit a health care provider who dispenses a controlled substance to a patient from disclosing information obtained from the Prescription Monitoring Program and contained in a patient's health care record to another health care provider when such disclosure is related to the care or treatment of the patient. This bill also provides that nothing shall prevent a person who prescribes or dispenses a controlled substance from redisclosing information obtained from the Prescription Monitoring Program to another prescriber or dispenser who prescribes or dispenses a controlled substance to a recipient.

02/16/11 Senate: Enrolled
02/16/11 Senate: Bill text as passed Senate and House (SB1029ER)
02/16/11 Senate: Impact statement from DPB (SB1029ER)
02/16/11 Senate: Signed by President
02/16/11 House: Signed by Speaker

SB 1078 Child care; administration of certain medicines of those regulated by local government.

Chief patron: Barker

Summary as introduced:
Local government run child care; administration of certain medicines. Allows the employees of a child care regulated by a local government to administer medication to a child if such employee (i) has satisfactorily completed a training program for this purpose approved by the Board of Nursing and taught by a registered nurse, licensed practical nurse, doctor of medicine or osteopathic medicine, or pharmacist; (ii) has obtained written authorization from a parent or guardian; (iii) administers drugs only to the child identified on the prescription label in accordance with the prescriber's instructions pertaining to dosage, frequency, and manner of administration; and (iv) administers only those drugs that were dispensed from a pharmacy and maintained in the original, labeled container that would normally be administered by a parent or guardian to the child.

02/17/11 House: Amendment by Delegate Orrock agreed to
02/17/11 House: Engrossed by House as amended
02/17/11 House: Passed House with amendment BLOCK VOTE (98-Y 0-N)
02/17/11 House: VOTE: BLOCK VOTE PASSAGE (98-Y 0-N)
02/21/11 Senate: House amendment agreed to by Senate (40-Y 0-N)

SB 1096 Pharmacies; shall have access to Prescription Monitoring Program.

Chief patron: Hanger

Summary as passed Senate:
Pharmacies; access to Prescription Monitoring Program. Provides that the Board of Pharmacy shall include in its regulations that nothing shall prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program from requesting and receiving such information.

02/21/11 House: Read third time
02/21/11 House: Committee amendment agreed to
02/21/11 House: Engrossed by House as amended
02/21/11 House: Passed House with amendment BLOCK VOTE (99-Y 0-N)
02/21/11 House: VOTE: BLOCK VOTE PASSAGE (99-Y 0-N)

SB 1147 Health professions; social security numbers for investigations.

Chief patron: Quayle

Summary as introduced:
Health professions; social security numbers for investigations. Allows the investigative personnel of the Department of Health Professions to request and receive social security numbers from practitioners or federal employee identification numbers from facilities.

02/16/11 Senate: Enrolled
02/16/11 Senate: Bill text as passed Senate and House (SB1147ER)
02/16/11 Senate: Impact statement from DPB (SB1147ER)
02/16/11 Senate: Signed by President
02/16/11 House: Signed by Speaker

SB 1150 Schedule II drugs; identification required for filling prescriptions.

Chief patron: Quayle

Summary as introduced:
Schedule II drugs; identification required in filling prescriptions. Specifies that certain duties imposed upon a pharmacist in the delivery of Schedule II drugs may be undertaken by the agent of the pharmacist. The bill also makes discretionary provisions enacted in 2010 requiring that a pharmacist record the name and address of any person who seeks to fill a prescription for a Schedule II drug if the person is not the patient for whom the drug is prescribed, make photocopies of proof of identity and maintain records of names and addresses. The bill eliminates the requirement that copies of identification documents be kept for at least one year.

02/21/11 Senate: Enrolled
02/21/11 Senate: Bill text as passed Senate and House (SB1150ER)
02/21/11 House: Signed by Speaker
02/22/11 Senate: Impact statement from DPB (SB1150ER)
02/22/11 Senate: Signed by President

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 54.1-3434.1 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03, relating to continuous quality improvement of pharmacies.

[H 2220]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3434.1 of the Code of Virginia is amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.03 as follows:

§ 54.1-3434.03. Continuous quality improvement program.

Each pharmacy shall implement a program for continuous quality improvement, according to regulations of the Board. Such program shall provide for a systematic, ongoing process of analysis of dispensing errors that uses findings to formulate an appropriate response and to develop or improve pharmacy systems and workflow processes designed to prevent or reduce future errors. The Board shall promulgate regulations to further define the required elements of such program.

Any pharmacy that actively reports to a patient safety organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41), shall be deemed in compliance with this section.

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

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

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

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

3. As a prerequisite to registering with the Board, the nonresident pharmacy shall submit a copy of the most recent inspection report resulting from an inspection conducted by the regulatory or licensing agency of the jurisdiction in which it is located. The inspection report shall be deemed current if the inspection was conducted within the past five years. However, if the nonresident pharmacy has not been inspected by the regulatory or licensing agency of the jurisdiction in which it is licensed within the past five years, the Board may accept an inspection report or other documentation from another entity that is satisfactory to the Board or the Board may cause an inspection to be conducted by its duly authorized agent and may charge an inspection fee in an amount sufficient to cover the costs of the inspection.

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

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

57 6. That its pharmacists do not knowingly fill or dispense a prescription for a patient in Virginia in
58 violation of § 54.1-3303 and that it has informed its pharmacists that a pharmacist who dispenses a
59 prescription that he knows or should have known was not written pursuant to a bona fide
60 practitioner-patient relationship is guilty of unlawful distribution of a controlled substance in violation of
61 § 18.2-248.
62 *7. That it maintains a continuous quality improvement program as required of resident pharmacies,*
63 *pursuant to § 54.1-3434.03.*
64 The requirement that a nonresident pharmacy have a Virginia licensed pharmacist in charge shall not
65 apply to a registered nonresident pharmacy that provides services as a pharmacy benefits administrator.
66 B. Any pharmacy subject to this section shall, during its regular hours of operation, but not less than
67 six days per week, and for a minimum of 40 hours per week, provide a toll-free telephone service to
68 facilitate communication between patients in the Commonwealth and a pharmacist at the pharmacy who
69 has access to the patient's records. This toll-free number shall be disclosed on a label affixed to each
70 container of drugs dispensed to patients in the Commonwealth.
71 C. Pharmacies subject to this section shall comply with the reporting requirements of the Prescription
72 Monitoring Program as set forth in § 54.1-2521.
73 D. The registration fee shall be the fee specified for pharmacies within Virginia.
74 E. A nonresident pharmacy shall only deliver controlled substances that are dispensed pursuant to a
75 prescription, directly to the consumer or his designated agent, or directly to a pharmacy located in
76 Virginia pursuant to regulations of the Board.
77 **2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this**
78 **act to be effective within 280 days of its enactment.**
79 **3. That the Board of Pharmacy shall work cooperatively with pharmacists representing all areas of**
80 **pharmacy practice in implementing the requirements of this act.**

2011 SESSION

HOUSE SUBSTITUTE

11104753D

HOUSE BILL NO. 2256

AMENDMENT IN THE NATURE OF A SUBSTITUTE

(Proposed by the House Committee on Health, Welfare and Institutions on February 1, 2011)

(Patron Prior to Substitute—Delegate Nutter)

A BILL to amend and reenact § 54.1-3420.1 of the Code of Virginia, relating to identification required for filling prescriptions.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3420.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3420.1. Identification required for filling prescriptions.

A. Before dispensing any drug listed on Schedules III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.

B. A pharmacist*, or his agent,* shall require proof of identity *at the time of delivery* from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription ~~before dispensing such drug~~, unless such person is known to the pharmacist *or to his agent.* If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, *and the person is not known to the pharmacist or his agent,* the pharmacist *or his agent* shall ~~record the full name and address of such person, regardless of whether the person seeking to take delivery of the drug is known to the pharmacist. When proof of identity is required from a person seeking to take delivery of a drug pursuant to this subsection, the pharmacist shall make a photocopy or electronic copy of his proof of identity, or an electronic record documenting that proof of identity was provided~~ *either make a photocopy or electronic copy of such person's identification or record the full name and address of such person.* The pharmacist shall keep records of the names and addresses ~~and~~ *or* copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one ~~year~~ *month.* For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.

C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

HOUSE SUBSTITUTE

HB2256H1

2/1/11 22:54

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2011 SESSION

ENROLLED

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 32.1-127.1:03 and 54.1-2525 of the Code of Virginia, relating to disclosure of information related to dispensing of controlled substances.

[S 1029]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 32.1-127.1:03 and 54.1-2525 of the Code of Virginia are amended and reenacted as follows:

§ 32.1-127.1:03. Health records privacy.

A. There is hereby recognized an individual's right of privacy in the content of his health records. Health records are the property of the health care entity maintaining them, and, except when permitted or required by this section or by other provisions of state law, no health care entity, or other person working in a health care setting, may disclose an individual's health records.

Pursuant to this subsection:

1. Health care entities shall disclose health records to the individual who is the subject of the health record, except as provided in subsections E and F of this section and subsection B of § 8.01-413.

2. Health records shall not be removed from the premises where they are maintained without the approval of the health care entity that maintains such health records, except in accordance with a court order or subpoena consistent with subsection C of § 8.01-413 or with this section or in accordance with the regulations relating to change of ownership of health records promulgated by a health regulatory board established in Title 54.1.

3. No person to whom health records are disclosed shall redisclose or otherwise reveal the health records of an individual, beyond the purpose for which such disclosure was made, without first obtaining the individual's specific authorization to such redisclosure. This redisclosure prohibition shall not, however, prevent (i) any health care entity that receives health records from another health care entity from making subsequent disclosures as permitted under this section and the federal Department of Health and Human Services regulations relating to privacy of the electronic transmission of data and protected health information promulgated by the United States Department of Health and Human Services as required by the Health Insurance Portability and Accountability Act (HIPAA) (42 U.S.C. § 1320d et seq.) or (ii) any health care entity from furnishing health records and aggregate or other data, from which individually identifying prescription information has been removed, encoded or encrypted, to qualified researchers, including, but not limited to, pharmaceutical manufacturers and their agents or contractors, for purposes of clinical, pharmaco-epidemiological, pharmaco-economic, or other health services research.

B. As used in this section:

"Agent" means a person who has been appointed as an individual's agent under a power of attorney for health care or an advance directive under the Health Care Decisions Act (§ 54.1-2981 et seq.).

"Certification" means a written representation that is delivered by hand, by first-class mail, by overnight delivery service, or by facsimile if the sender obtains a facsimile-machine-generated confirmation reflecting that all facsimile pages were successfully transmitted.

"Guardian" means a court-appointed guardian of the person.

"Health care clearinghouse" means, consistent with the definition set out in 45 C.F.R. § 160.103, a public or private entity, such as a billing service, repricing company, community health management information system or community health information system, and "value-added" networks and switches, that performs either of the following functions: (i) processes or facilitates the processing of health information received from another entity in a nonstandard format or containing nonstandard data content into standard data elements or a standard transaction; or (ii) receives a standard transaction from another entity and processes or facilitates the processing of health information into nonstandard format or nonstandard data content for the receiving entity.

"Health care entity" means any health care provider, health plan or health care clearinghouse.

"Health care provider" means those entities listed in the definition of "health care provider" in § 8.01-581.1, except that state-operated facilities shall also be considered health care providers for the purposes of this section. Health care provider shall also include all persons who are licensed, certified, registered or permitted or who hold a multistate licensure privilege issued by any of the health regulatory boards within the Department of Health Professions, except persons regulated by the Board of Funeral Directors and Embalmers or the Board of Veterinary Medicine.

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Pages 2-7 unchanged

421 submitted health records should be disclosed, return all submitted health records to the health care entity
422 in a sealed envelope; (ii) upon determining that all submitted health records should be disclosed, provide
423 all the submitted health records to the party on whose behalf the subpoena was issued; or (iii) upon
424 determining that only a portion of the submitted health records should be disclosed, provide such portion
425 to the party on whose behalf the subpoena was issued and return the remaining health records to the
426 health care entity in a sealed envelope.
427 8. Following the court or administrative agency's resolution of a motion to quash, the party on whose
428 behalf the subpoena duces tecum was issued shall have the duty to certify in writing to the subpoenaed
429 health care entity a statement of one of the following:
430 a. All filed motions to quash have been resolved by the court or administrative agency and the
431 disclosures sought in the subpoena duces tecum are consistent with such resolution; and, therefore, the
432 health records previously delivered in a sealed envelope to the clerk of the court or administrative
433 agency will not be returned to the health care entity;
434 b. All filed motions to quash have been resolved by the court or administrative agency and the
435 disclosures sought in the subpoena duces tecum are consistent with such resolution and that, since no
436 health records have previously been delivered to the court or administrative agency by the health care
437 entity, the health care entity shall comply with the subpoena duces tecum by returning the health records
438 designated in the subpoena by the return date on the subpoena or five days after receipt of certification,
439 whichever is later;
440 c. All filed motions to quash have been resolved by the court or administrative agency and the
441 disclosures sought in the subpoena duces tecum are not consistent with such resolution; therefore, no
442 health records shall be disclosed and all health records previously delivered in a sealed envelope to the
443 clerk of the court or administrative agency will be returned to the health care entity;
444 d. All filed motions to quash have been resolved by the court or administrative agency and the
445 disclosures sought in the subpoena duces tecum are not consistent with such resolution and that only
446 limited disclosure has been authorized. The certification shall state that only the portion of the health
447 records as set forth in the certification, consistent with the court or administrative agency's ruling, shall
448 be disclosed. The certification shall also state that health records that were previously delivered to the
449 court or administrative agency for which disclosure has been authorized will not be returned to the
450 health care entity; however, all health records for which disclosure has not been authorized will be
451 returned to the health care entity; or
452 e. All filed motions to quash have been resolved by the court or administrative agency and the
453 disclosures sought in the subpoena duces tecum are not consistent with such resolution and, since no
454 health records have previously been delivered to the court or administrative agency by the health care
455 entity, the health care entity shall return only those health records specified in the certification,
456 consistent with the court or administrative agency's ruling, by the return date on the subpoena or five
457 days after receipt of the certification, whichever is later.
458 A copy of the court or administrative agency's ruling shall accompany any certification made
459 pursuant to this subdivision.
460 9. The provisions of this subsection have no application to subpoenas for health records requested
461 under § 8.01-413, or issued by a duly authorized administrative agency conducting an investigation,
462 audit, review or proceedings regarding a health care entity's conduct.
463 The provisions of this subsection shall apply to subpoenas for the health records of both minors and
464 adults.
465 Nothing in this subsection shall have any effect on the existing authority of a court or administrative
466 agency to issue a protective order regarding health records, including, but not limited to, ordering the
467 return of health records to a health care entity, after the period for filing a motion to quash has passed.
468 A subpoena for substance abuse records must conform to the requirements of federal law found in 42
469 C.F.R. Part 2, Subpart E.
470 I. Health care entities may testify about the health records of an individual in compliance with
471 §§ 8.01-399 and 8.01-400.2.
472 J. If an individual requests a copy of his health record from a health care entity, the health care
473 entity may impose a reasonable cost-based fee, which shall include only the cost of supplies for and
474 labor of copying the requested information, postage when the individual requests that such information
475 be mailed, and preparation of an explanation or summary of such information as agreed to by the
476 individual. For the purposes of this section, "individual" shall subsume a person with authority to act on
477 behalf of the individual who is the subject of the health record in making decisions related to his health
478 care.
479 *K. Nothing in this section shall prohibit a health care provider who dispenses a controlled substance*
480 *required to be reported to the Prescription Monitoring Program established pursuant to Chapter 25.2*
481 *(§ 54.1-2519 et seq.) of Title 54.1 to a patient from disclosing information obtained from the*

482 *Prescription Monitoring Program and contained in a patient's health care record to another health care*
483 *provider when such disclosure is related to the care or treatment of the patient who is the subject of the*
484 *record.*
485 § 54.1-2525. Unlawful disclosure of information; disciplinary action authorized; penalties.
486 A. It shall be unlawful for any person having access to the confidential information in the possession
487 of the ~~Program~~ *program* or any data or reports produced by the program to disclose such confidential
488 information except as provided in this chapter. Any person having access to the confidential information
489 in the possession of the program or any data or reports produced by the program who discloses such
490 confidential information in violation of this chapter shall be guilty of a Class 1 misdemeanor upon
491 conviction.
492 B. It shall be unlawful for any person who lawfully receives confidential information from the
493 Prescription Monitoring Program to redisclose or use such confidential information in any way other
494 than the authorized purpose for which the request was made. Any person who lawfully receives
495 information from the Prescription Monitoring Program and discloses such confidential information in
496 violation of this chapter shall be guilty of a Class 1 misdemeanor upon conviction.
497 C. *Nothing in this section shall prohibit a person who prescribes or dispenses a covered substance*
498 *required to be reported to the program from redisclosing information obtained from the Program to*
499 *another prescriber or dispenser who has prescribed or dispensed a covered substance to a recipient.*
500 *D.* Unauthorized use or disclosure of confidential information received from the Prescription
501 Monitoring Program shall also be grounds for disciplinary action by the relevant health regulatory board.

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SENATE BILL NO. 1096

Senate Amendments in [ ] — February 1, 2011

A BILL to amend and reenact § 54.1-3434 of the Code of Virginia, relating to pharmacies; access to Prescription Monitoring Program.

Patron Prior to Engrossment—Senator Hanger

Referred to Committee on Education and Health

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3434 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

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

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

An application for a pharmacy permit shall be accompanied by a fee determined by the Board. All

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60 permits shall expire annually on a date determined by the Board in regulation.
61 Every pharmacy ~~must~~ *shall* be equipped so that prescriptions can be properly filled. The Board of
62 Pharmacy shall prescribe the minimum of such professional and technical equipment and reference
63 material which a pharmacy shall at all times possess. [~~*Such regulations shall include a requirement that*~~
64 ~~*(i) every pharmacy permitted pursuant to this section shall ensure that at least one pharmacist who is*~~
65 ~~*physically present at the pharmacy shall have access to the Prescription Monitoring Program*~~
66 ~~*established pursuant to Chapter 25.2 (§ 54.1-2519 et seq.) at all times, and (ii) nothing*~~ *Nothing*] *shall*
67 *prevent a pharmacist who is eligible to receive information from the Prescription Monitoring Program*
68 *from requesting and receiving such information.* No permit shall be issued or continued for the conduct
69 of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations
70 promulgated by the Board.
71 Each day during which a person is in violation of this section shall constitute a separate offense.

; however, no pharmacy shall be required to maintain Internet access to the Prescription Monitoring Program

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VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact § 54.1-3420.1 of the Code of Virginia, relating to identification required for filling prescriptions.

[S 1150]

Approved

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3420.1 of the Code of Virginia is amended and reenacted as follows:

§ 54.1-3420.1. Identification required for filling prescriptions.

A. Before dispensing any drug listed on Schedules III through V, a pharmacist may require proof of identity from any patient presenting a prescription or requesting a refill of a prescription.

B. A pharmacist, *or his agent,* shall require proof of identity *at the time of delivery* from any person seeking to take delivery of any drug listed on Schedule II pursuant to a valid prescription ~~before dispensing such drug~~, unless such person is known to the pharmacist *or to his agent.* If the person seeking to take delivery of a drug listed on Schedule II pursuant to a valid prescription is not the patient for whom the drug is prescribed, *and the person is not known to the pharmacist or his agent,* the pharmacist *or his agent* shall ~~record the full name and address of such person, regardless of whether the person seeking to take delivery of the drug is known to the pharmacist. When proof of identity is required from a person seeking to take delivery of a drug pursuant to this subsection, the pharmacist shall make a photocopy or electronic copy of his proof of identity, or an electronic record documenting that proof of identity was provided~~ *either make a photocopy or electronic copy of such person's identification or record the full name and address of such person.* The pharmacist shall keep records of the names and addresses ~~and~~ *or* copies of proof of identity of persons taking delivery of drugs as required by this subsection for a period of at least one ~~year~~ *month.* For the purposes of this subsection, "proof of identity" means a driver's license, government-issued identification card, or other photo identification along with documentation of the person's current address.

C. Whenever any pharmacist permitted to operate in the Commonwealth or nonresident pharmacist registered to conduct business in the Commonwealth delivers a prescription drug order for any drug listed on Schedule II by mail, common carrier, or delivery service to a Virginia address, the method of delivery employed shall require the signature of the recipient as confirmation of receipt.

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Regulatory Actions

Board of Pharmacy

Chapter	Action / Stage Information	
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:	Repackaging in CSB's and BHA's
	Stage:	Emergency/NOIRA - *Register Date: 1/3/11* *Emergency effective 12/10/10 to 12/19/11* *Proposed regulations to be adopted 3/9/11*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:	Signing of automated dispensing devices in hospitals
	Stage:	Fast-Track - *Register Date: 1/31/11* *Effective date: 3/2/11*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action:	Elimination of alarm system for certain EMS agencies
	Stage:	Fast-Track - *At Governor's Office* Action bifurcated - administrative fees by regular APA process

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.

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Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) citation	18VAC110-20-10 et seq.
Regulation title	Regulations Governing the Practice of Pharmacy
Action title	On-hold prescriptions
Document preparation date	3/9/2011

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 21 (2002) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Purpose

Please describe the subject matter and intent of the planned regulatory action. Also include a brief explanation of the need for and the goals of the new or amended regulation.

Regulations of the Board of Pharmacy address requirements for filing prescriptions and pharmacist verification of data entry into an automated data processing system, when pharmacies make use of such a system. While the regulations satisfy the handling of prescriptions intended to be dispensed that day, pharmacists are experiencing increased requests from patients to place prescriptions for routine medications "on-hold" until the patient is in need of the prescribed drug.

Because regulations do not specifically address when the data entry of these prescriptions must be performed, some pharmacies store these prescriptions in a single file until needed. Others perform data entry of the prescription and file by the date of entry into the computer which is non-compliant with the current regulation, but find it burdensome to retrieve and move the prescription to the file associated with the date of initial dispensing. Additionally, when the data entry is performed on a separate date than the date of initial dispensing a pharmacist may not be verifying the accuracy of the data entered at the time of entry.

The lack of regulation on this issue may contribute to misplacing of the prescription which may impede patients from obtaining their medication when needed, the dispensing of prescriptions fraudulently due to improper handling of the prescriptions, and possibly dispensing errors

resulting from data entry being performed on a separate date from the date of initial dispensing without pharmacist verification of the accuracy of the data. Therefore, the Board will consider the promulgation of amendments to regulation to address concerns regarding on-hold prescriptions.

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including (1) the most relevant law and/or regulation, including Code of Virginia citation and General Assembly chapter number(s), if applicable, and (2) promulgating entity, i.e., agency, board, or person. Describe the legal authority and the extent to which the authority is mandatory or discretionary.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards
The general powers and duties of health regulatory boards shall be:
...
6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title.

The specific authority to issue licenses and permits to pharmacists and pharmacies and to control the sale and dispensing of prescription drugs is found in the Code of Virginia in Chapters 33 and 34 of Title 54.1.
http://leg1.state.va.us/cgi-bin/legp504.exe?000+cod+TOC5401000

Substance

Please detail any changes that will be proposed. For new regulations, include a summary of the proposed regulatory action. Where provisions of an existing regulation are being amended, explain how the existing regulation will be changed. Include the specific reasons why the agency has determined that the proposed regulatory action is essential to protect the health, safety, or welfare of citizens. Delineate any potential issues that may need to be addressed as the regulation is developed.

The following sections of the regulations have been identified as having issues that may need to be addressed in the promulgation of amended regulations:

18VAC110-20-240 Manner of maintaining records, prescriptions, inventory records.

The current requirement that all prescriptions shall be filed chronologically by date of initial dispensing is problematic when filing on-hold prescriptions which are prescriptions presented by

the patient to the pharmacist and maintained by the pharmacist for days or weeks until the patient is in need for the prescription to be dispensed. As written, the regulation currently requires a pharmacist to physically retrieve and relocate the prescription from the file that it was originally maintained in on the date of receipt to the file associated with the date of initial dispensing. This appears to be creating an undue burden on practicing pharmacists, particularly in community pharmacies where on-hold prescriptions are more frequently received. Therefore, this regulation may be amended to create a less burdensome filing requirement for on-hold prescriptions.

Additionally, current regulations do not specifically address when data entry of the on-hold prescription must be performed and how the prescription must be maintained prior to the initial dispensing, therefore, the following concerns may exist: if data entry and proper filing for the on-hold prescription is not performed on or about the date of receipt, then the prescription may be misplaced which may impede a patient from readily obtaining the drug when needed, or it may increase the possibility for it being diverted and dispensed fraudulently either at the receiving pharmacy or another pharmacy. Thus, regulations may be promulgated that specifically address data entry requirements and maintaining of on-hold prescriptions.

18VAC110-20-250. Automated data processing records of prescriptions.
The current regulation requires pharmacists making use of an automated data processing system to document on a daily printout or logbook that the information entered into the computer each time a pharmacist fills a prescription for a drug is correct. Because the Board may promulgate regulations requiring the data entry of an on-hold prescription prior to the initial dispensing of the drug, this regulation may be amended to require a pharmacist to document the fact that the information entered into the computer that day is correct, regardless of whether the prescription is dispensed that day.

Alternatives

Please describe all viable alternatives to the proposed regulatory action that have been or will be considered to meet the essential purpose of the action.

In September 2010, the Board reviewed and denied a petition for rulemaking to amend the filing requirements in Regulation 18VAC110-20-240 to allow prescriptions to be filed by date of initial dispensing or date of initial entry into the pharmacy's electronic record keeping system if such a system is employed by the pharmacy. The petition was submitted based on a perceived burden in filing on-hold prescriptions under current filing requirements. Though the petition was denied, the Board agreed to research other states' requirements for filing on-hold prescriptions. At the request of Board staff, the National Association of Boards of Pharmacy surveyed all states on current requirements for processing and filing on-hold prescriptions. Fourteen states responded to the survey and the results of the survey were reviewed at the December 2010 board meeting. Two states currently have rules addressing on-hold prescriptions and other states commented in the survey that rules on this subject may be warranted due to concerns for diversion resulting from improper handling of these prescriptions or dispensing errors resulting from data entry being performed on a separate date from the date of initial dispensing without pharmacist verification of the accuracy of the data. In December, the Board assigned members

to an Ad Hoc committee to review the possibility for needed regulations. This committee was unable to meet prior to the March 2011 full board meeting due to a shortage in board staff and activities associated with the General Assembly. Therefore, the full Board discussed the possible need for regulations at the March 2011 full Board meeting and determined that the Board must proceed with a Notice of Intended Regulatory Action to potentially alleviate concerns associated with the improper handling of on-hold prescriptions and the undue burden with current filing requirements.

Family impact

Assess the potential impact of the proposed regulatory action on the institution of the family and family stability.

There is no impact of the proposed regulatory action on the institution of the family and family stability.

DRAFT

Virginia Board of Pharmacy

Wholesale Distributor Licensure Guidance

An entity located outside Virginia that does not physically possess and ship prescription drugs into Virginia does not need to register with the Virginia Board of Pharmacy as a non-resident wholesale distributor. Likewise, an entity located within Virginia that does not physically possess and ship prescription drugs within Virginia does not need to obtain a license from the Virginia Board of Pharmacy as a wholesale distributor. If, for example, a manufacturer or distributor uses a third-party to physically house and distribute prescription drugs into or within Virginia, that third-party is required to hold the wholesale distributor license, and that party's name must be on any invoice as the distributor.

Additionally, a non-resident wholesale distributor does **not** need to obtain a Virginia Controlled Substances Registration in order to distribute Schedule II-V controlled substances. This registration is required for a licensed wholesale distributor located within Virginia that possesses Schedule II-V controlled substances.

To comply with the requirements for submission of a social security number or control number as required in Regulation 18VAC110-50-70, the following individuals shall provide a social security number or control number:

- *the person serving as the responsible party, and;*
- *the individual owner or sole proprietor, or;*
- *each partner, or corporate officer and director, who is specifically responsible for the operations of the facility listed on the application.*

DRAFT

§ 54.1-3404. Inventories of controlled substances required of certain persons; contents and form of record.

A. Except as set forth in subsection G, every person manufacturing, compounding, processing, selling, dispensing or otherwise disposing of drugs in Schedules I, II, III, IV or V shall take a complete and accurate inventory of all stocks of Schedules I through V drugs on the date he first engages in business. If there are no controlled substances on hand at that time, he shall record this fact as part of the inventory. An inventory taken by use of an oral recording device shall be promptly reduced to writing and maintained in a written, typewritten or printed form. Such inventory shall be made either as of the opening of business or as of the close of business on the inventory date.

B. After the initial inventory is taken, every person described herein shall take a new inventory at least every two years of all stocks on hand of Schedules I through V drugs. The biennial inventory shall be taken on any date which is within two years of the previous biennial inventory.

C. The record of such drugs received shall in every case show the date of receipt, the name and address of the person from whom received and the kind and quantity of drugs received, the kind and quantity of drugs produced or removed from process of manufacture, and the date of such production or removal from process of manufacture. The record shall in every case show the proportion of morphine, cocaine, or ecgonine contained in or producible from crude opium or coca leaves received or produced.

D. The record of all drugs sold, administered, dispensed, or otherwise disposed of, shall show the date of selling, administering, or dispensing, the name and address of the person to whom or for whose use, or the owner and species of animal for which the drugs were sold, administered or dispensed, and the kind and quantity of drugs. Any person selling, administering, dispensing or otherwise disposing of such drugs shall make and sign such record at the time of each transaction. The keeping of a record required by or under the federal laws, containing substantially the same information as is specified above, shall constitute compliance with this section, except that every such record shall contain a detailed list of any drugs lost, destroyed or stolen, the kind and quantity of such drugs, and the date of the discovery of such loss, destruction or theft. The form of records shall be prescribed by the Board.

E. Whenever any registrant or licensee discovers a theft or any other unusual loss of any controlled substance, he shall immediately report such theft or loss to the Board. If the registrant or licensee is unable to determine the exact kind and quantity of the drug loss, he shall immediately make a complete inventory of all Schedule I through V drugs.

Within 30 days after the discovery of a loss of drugs, the registrant or licensee shall furnish the Board with a listing of the kind, quantity and strength of such drugs lost.

F. All records required pursuant to this section shall be maintained completely and accurately for two years from the date of the transaction recorded.

G. Each person authorized to conduct chemical analyses using controlled substances in the Department of Forensic Science shall comply with the inventory requirements set forth in subsections A through F; however, the following substances shall not be required to be included in such inventory: (i) controlled substances on hand at the time of the inventory in a quantity of less than one kilogram, other than a hallucinogenic controlled substance listed in Schedule I of this chapter; or (ii) hallucinogenic controlled substances, other than lysergic acid diethylamide, on hand at the time of the inventory in a quantity of less than 20 grams; or (iii) lysergic acid diethylamide on hand at the time of the inventory in a quantity of less

than 0.5 grams. Further, no inventory shall be required of known or suspected controlled substances that have been received as evidentiary materials for analyses by the Department of Forensic Science.

(1970, c. 650, § 54-524.56; 1972, c. 798; 1978, c. 833; 1979, c. 435; 1980, c. 203; 1982, c. 278; 1988, c. 765; 1998, c. 105; 2004, c. 51; 2005, cc. 868, 881.)

§ 54.1-3434. Permit to conduct pharmacy.

No person shall conduct a pharmacy without first obtaining a permit from the Board.

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

The application shall (i) show the corporate name and trade name, (ii) list any pharmacist in addition to the pharmacist-in-charge practicing at the location indicated on the application, and (iii) list the hours during which the pharmacy will be open to provide pharmacy services. Any change in the hours of operation, which is expected to last more than one week, shall be reported to the Board in writing and posted, at least fourteen days prior to the anticipated change, in a conspicuous place to provide notice to the public. The Board shall promulgate regulations to provide exceptions to this prior notification.

If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.

The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

Upon termination of practice by the pharmacist-in-charge, or upon any change in partnership composition, or upon the acquisition, as defined in Board regulations, of the existing corporation by another person or the closing of a pharmacy, the permit previously issued shall be immediately surrendered to the Board by the pharmacist-in-charge to whom it was issued, or by his legal representative, and an application for a new permit may be made in accordance with the requirements of this chapter.

The Board shall promulgate regulations (i) defining acquisition of an existing permitted, registered or licensed facility or of any corporation under which the facility is directly or indirectly organized; (ii) providing for the transfer, confidentiality, integrity, and security of the pharmacy's prescription dispensing records and other patient records, regardless of where located; and (iii) establishing a reasonable time period for designation of a new pharmacist-in-charge. At the conclusion of the time period for designation of a new pharmacist-in-charge, a pharmacy which has failed to designate a new pharmacist-in-charge shall not operate as a pharmacy nor maintain a stock of prescription drugs on the premises. The Director shall immediately notify the owner of record that the pharmacy no longer holds a valid permit and that the owner shall make provision for the proper disposition of all Schedule II through VI drugs and devices on the premises within fifteen days of receipt of this notice. At the conclusion of the fifteen-day period, the

Director or his authorized agent shall seize and indefinitely secure all Schedule II through VI drugs and devices still on the premises, and notify the owner of such seizure. The Director may properly dispose of the seized drugs and devices after six months from the date of the notice of seizure if the owner has not claimed and provided for the proper disposition of the property. The Board shall assess a fee of not less than the cost of storage of said drugs upon the owner for reclaiming seized property.

The succeeding pharmacist-in-charge shall cause an inventory to be made of all Schedule I, II, III, IV and V drugs on hand. Such inventory shall be completed as of the date he becomes pharmacist-in-charge and prior to opening for business on that date.

The pharmacist to whom such permit is issued shall provide safeguards against diversion of all controlled substances.

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

Every pharmacy must be equipped so that prescriptions can be properly filled. The Board of Pharmacy shall prescribe the minimum of such professional and technical equipment and reference material which a pharmacy shall at all times possess. No permit shall be issued or continued for the conduct of a pharmacy until or unless there is compliance with the provisions of this chapter and regulations promulgated by the Board.

Each day during which a person is in violation of this section shall constitute a separate offense.

(1970, c. 650, § 54-524.31; 1972, c. 798; 1976, c. 614; 1977, c. 302; 1980, c. 288; 1983, c. 286; 1986, c. 207; 1988, cc. 445, 765; 1994, c. 299; 1998, c. 470; 2000, c. 135; 2008, c. 320.)

18VAC110-20-110. Pharmacy permits generally.

A. A pharmacy permit shall not be issued to a pharmacist to be simultaneously in charge of more than two pharmacies.

B. The pharmacist-in-charge (PIC) or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

C. When the PIC ceases practice at a pharmacy or no longer wishes to be designated as PIC, he shall immediately return the pharmacy permit to the board indicating the effective date on which he ceased to be the PIC.

D. Although not required by law or regulation, an outgoing PIC shall have the opportunity to take a complete and accurate inventory of all Schedule II through V controlled substances on hand on the date he ceases to be the PIC, unless the owner submits written notice to the board showing good cause as to why this opportunity should not be allowed.

E. A PIC who is absent from practice for more than 30 consecutive days shall be deemed to no longer be the PIC. Pharmacists-in-charge having knowledge of upcoming absences for longer than 30 days shall be responsible for notifying the board and returning the permit. For unanticipated absences by the PIC, which exceed 15 days with no known return date within the next 15 days, the owner shall immediately notify the board and shall obtain a new PIC.

F. An application for a permit designating the new PIC shall be filed with the required fee within 14 days of the original date of resignation or termination of the PIC on a form provided by the board. It shall be unlawful for a pharmacy to operate without a new permit past the 14-day deadline unless the board receives a request for an extension prior to the deadline. The executive director for the board may grant an extension for up to an additional 14 days for good cause shown.

G. Only one pharmacy permit shall be issued to conduct a pharmacy occupying the same designated prescription department space. A pharmacy shall not engage in any other activity requiring a license or permit from the board, such as manufacturing or wholesale-distributing, out of the same designated prescription department space.

H. Before any permit is issued, the applicant shall attest to compliance with all federal, state and local laws and ordinances. A pharmacy permit shall not be issued to any person to operate from a private dwelling or residence after September 2, 2009.

Section 1304.11 Inventory Requirements

(a)*General requirements.* Each inventory shall contain a complete and accurate record of all controlled substances on hand on the date the inventory is taken, and shall be maintained in written, typewritten, or printed form at the registered location. An inventory taken by use of an oral recording device must be promptly transcribed. Controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the registrant, including substances returned by a customer, ordered by a customer but not yet invoiced, stored in a warehouse on behalf of the registrant, and substances in the possession of employees of the registrant and intended for distribution as complimentary samples. A separate inventory shall be made for each registered location and each independent activity registered, except as provided in **paragraph (e)(4)** of this section. In the event controlled substances in the possession or under the control of the registrant are stored at a location for which he/she is not registered, the substances shall be included in the inventory of the registered location to which they are subject to control or to which the person possessing the substance is responsible. The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.

(b)*Initial inventory date.* Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances, in accordance with **paragraph (e)** of this section as applicable. In the event a person commences business with no controlled substances on hand, he/she shall record this fact as the initial inventory.

(c) *Biennial inventory date.* After the initial inventory is taken, the registrant shall take a new inventory of all stocks of controlled substances on hand at least every two years. The biennial inventory may be taken on any date which is within two years of the previous biennial inventory date.

(d)*Inventory date for newly controlled substances.* On the effective date of a rule by the Administrator pursuant to **§§1308.45**, **1308.46**, or **1308.47** of this chapter adding a substance to any schedule of controlled substances, which substance was, immediately prior to that date, not listed on any such schedule, every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand. Thereafter, such substance shall be included in each inventory made by the registrant pursuant to **paragraph (c)** of this section.

(e)*Inventories of manufacturers, distributors, dispensers, researchers, importers, exporters and chemical analysts.* Each person registered or authorized (by **§1301.13** or **§§1307.11–1307.13** of this chapter) to manufacture, distribute, dispense, import, export, conduct research or chemical analysis with controlled substances and required to keep records pursuant to **§1304.03** shall include in the inventory the information listed below.

(1) *Inventories of manufacturers.* Each person registered or authorized to manufacture controlled substances shall include the following information in the inventory:

(i) For each controlled substance in bulk form to be used in (or capable of use in) the manufacture of the same or other controlled or non-controlled substances in finished form, the inventory shall include:

(A) The name of the substance and

(B) The total quantity of the substance to the nearest metric unit weight consistent with unit size.

(ii) For each controlled substance in the process of manufacture on the inventory date, the inventory shall include:

(A) The name of the substance;

(B) The quantity of the substance in each batch and/or stage of manufacture, identified by the batch number or other appropriate identifying number; and

(C) The physical form which the substance is to take upon completion of the manufacturing process (e.g., granulations, tablets, capsules, or solutions), identified by the batch number or other appropriate identifying number, and if possible the finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter) and the number or volume thereof.

(iii)For each controlled substance in finished form the inventory shall include:

(A) The name of the substance;

(B) Each finished form of the substance (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(C) The number of units or volume of each finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial); and

(D) The number of commercial containers of each such finished form (e.g. four 100-tablet bottles or six 3-milliliter vials).

(iv)For each controlled substance not included in paragraphs **(e)(1)**
(i), **(ii)** or **(iii)** of this section (e.g., damaged, defective or impure substances awaiting disposal, substances held for quality control purposes, or substances maintained for extemporaneous compoundings) the inventories shall include:

(A) The name of the substance;

(B) The total quantity of the substance to the nearest metric unit weight or the total number of units of finished form; and

(C) The reason for the substance being maintained by the registrant and whether such substance is capable of use in the manufacture of any controlled substance in finished form.

(2) *Inventories of distributors.* Except for reverse distributors covered by paragraph (e)(3) of this section, each person registered or authorized to distribute controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs **(e)(1)(iii)** and **(iv)** of this section.

(3) *Inventories of dispensers, researchers, and reverse distributors.* Each person registered or authorized to dispense, conduct research, or act as a reverse distributor with controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs **(e)(1)(iii)** and **(iv)** of this section. In determining the number of units of each finished form of a controlled substance in a commercial container which has been opened, the dispenser, researcher, or reverse distributor shall do as follows:

(i) If the substance is listed in Schedule I or II, make an exact count or measure of the contents, or

(ii) If the substance is listed in Schedule III, IV or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

(4)*Inventories of importers and exporters.* Each person registered or authorized to import or export controlled substances shall include in the inventory the same information required of manufacturers pursuant to paragraphs **(e)(1) (iii)** and **(iv)** of this section. Each such person who is also registered as a manufacturer or as a distributor shall include in his/her inventory as an importer or exporter only those stocks of controlled substances that are actually separated from his stocks as a manufacturer or as a distributor (e.g., in transit or in storage for shipment).

(5)*Inventories of chemical analysts.* Each person registered or authorized to conduct chemical analysis with controlled substances shall include in his inventory the same information required of manufacturers pursuant to paragraphs **(e)(1) (iii)** and **(iv)** of this section as to substances which have been manufactured, imported, or received by such person. If less than 1 kilogram of any controlled substance (other than a hallucinogenic controlled substance listed in Schedule I), or less than 20 grams of a hallucinogenic substance listed in Schedule I (other than lysergic acid diethylamide), or less than 0.5 gram of lysergic acid diethylamide, is on hand at the time of inventory, that substance need not be included in the inventory. Laboratories of the Administration may possess up to 150 grams of any hallucinogenic substance in Schedule I without regard to a need for an inventory of those substances. No inventory is required of known or suspected controlled substances received as evidentiary materials for analysis.

[62 FR 13959, Mar. 24, 1997, as amended at 68 FR 41228, July 11, 2003]

Virginia Board of Pharmacy
Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. No PIC or PIC not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. PIC in place, inventory taken, but application not filed with Board	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns without monitoring, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320		500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320	per each technician over the ratio	100
7. COL or remodel without application or Board approval	18VAC110-20-140	must submit an application and fee	250
8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's or pharmacy's calibrated thermometer	100 Drugs may be embargoed
9. Alarm not operational or not being set	18VAC110-20-180 and 18VAC110-20-190		1000
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational	18VAC110-20-180		250

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
10. Unauthorized access to alarm or locking device for Rx department	18VAC110-20-180 and 18VAC110-20-190		1000
11. Insufficient enclosures or locking devices	18VAC110-20-190		500
12. Storage of Rx drugs not in prescription department	18VAC110-20-190		500
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V, or a physical count was not performed	54.1-3404 and 18VAC110-20-240		500
14. No incoming change of PIC inventory taken within 5 days or substantially incomplete, i.e., did not include all drugs in Schedules II-V, or a physical count was not performed	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained or monitored as required	18VAC110-20-240		250
16. Theft/loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required	54.1-3404 and 18VAC110-20-240		250
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging, compounding, or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
21. No clean room	54.1-3410.2		5000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 over 60 days late (6mo + 60 days)	54.1-3410.2		3000 per DCA

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
23. Certification of the buffer or clean room and ante room indicating ISO Class 8 or better over 60 days late (6mo+60 days)	54.1-3410.2		1000 per area
24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas	54.1-3410.2		2000
25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs; or, no documentation of initial and semi-annual media-fill testing for persons performing high-risk level CSPs; or, documentation that a person who failed a media-fill test has performed high-risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing media-fill test; or, high-risk drugs intended for use are improperly stored.	54.1-3410.2		5000 per incident within previous 30 days
26. Training documentation involving media-fill tests for low and medium-risk levels not maintained for > 30% of individuals preparing CSPs, or no documentation maintained of a passing media-fill test for any individual preparing low and medium-risk CSPs >45 days after receipt of a failed media-fill test	54.1-3410.2		500
27. Compounding using ingredients in violation	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450		500
31. For LTC, ADD being accessed for orders prior to pharmacist review and release	18VAC110-20-555		250

Minor Deficiencies

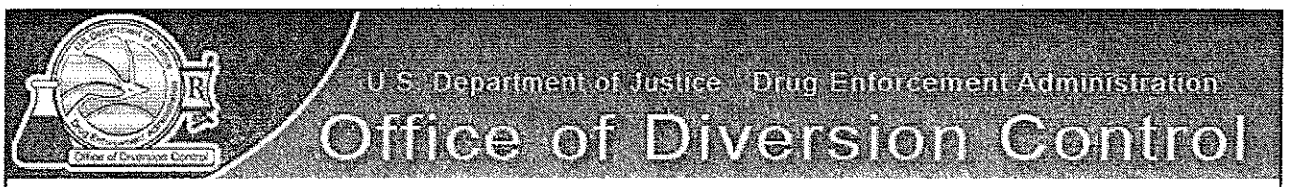
If three (3) or more minor deficiencies are cited, a $250 monetary penalty shall be imposed. Another $100 monetary penalty will be added for each additional minor deficiency over the initial three.

Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
1. Site specific training documentation not maintained as required	18VAC110-20-111	
2. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
3. Decreased hours of operation without public/Board notice	18VAC110-20-135	
4. No hot/cold running water	18VAC110-20-150	
5. No thermometer or non-functioning thermometer in refrigerator/freezer, but within range, +/-4 degrees	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
6. Rx department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
7. Current dispensing reference not maintained	18VAC110-20-170	
8. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
9. Expired drugs in working stock or dispensed drugs being returned to stock not in compliance	18VAC110-20-200 18VAC110-20-355	10% threshold
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	

Minor Deficiency	Law/Regulation Cite	Conditions
11. Storage of will-call not in compliance	18VAC110-20-200	
12. Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
13. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, CII not separate	54.1-3404 and 18VAC110-20-240	
14. Records of receipt (invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
15. Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
16. Prescriptions do not include required information	54.1-3408.01 and 54.1-3410	10% threshold
17. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
18. CII emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
19. Not properly documenting partial filling	54.1-3412, 18VAC110-20-255, and 18VAC110-20-320	
20. Offer to counsel not made as required	54.1-3319	
21. Prospective drug review not performed as required	54.1-3319	
22. Engaging in alternate delivery not in compliance	18VAC110-20-275	
23. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	

Minor Deficiency	Law/Regulation Cite	Conditions
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	
25. Compliance packaging or labeling does not conform to USP requirements	18VAC110-20-340	
26. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold
Repackaging, specialty dispensing, compounding:		
27. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
28. Unit dose procedures or records not in compliance	18VAC110-20-420	
29. Robotic pharmacy systems not in compliance	18VAC110-20-425	
30. Required compounding/dispensing/distribution records not complete and properly maintained; compounded products not properly labeled or assigned appropriate expiration date	54.1-3410.2	
31. Required "other documents" for USP 797 listed on inspection report are not appropriately maintained	54.1-3410.2	30% threshold
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	30% threshold
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	

Minor Deficiency	Law/Regulation Cite	Conditions
Hospital specific or long-term care specific:		
34. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
35. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
36. After hours access or records not in compliance	18VAC110-20-450	10% threshold
37. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
38. ADD loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	
39. EMS procedures or records not in compliance	18VAC110-20-500	10% threshold
40. Emergency kit or stat-drug box procedures or records not in compliance	18VAC110-20-540 and 18VAC110-20-550	10 % threshold
41. Maintaining floor stock in LTCF not authorized	18VAC110-20-520 and 18VAC110-20-560	

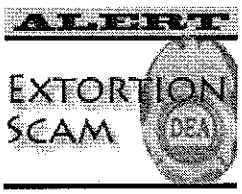


NATIONAL TAKE BACK INITIATIVE

This initiative addresses a vital public safety and public health issue. More than seven million Americans currently abuse prescription drugs, according to the 2009 Substance Abuse and Mental Health Administration's National Survey on Drug Use and Health. Each day, approximately, 2,500 teens use prescription drugs to get high for the first time according to the Partnership for a Drug Free America. Studies show that a majority of abused prescription drugs are obtained from family and friends, including the home medicine cabinet.

In an effort to address this problem, DEA, in conjunction with state and local law enforcement agencies throughout the United States, conducted the first ever National Prescription Drug Take Back Day on Saturday, September 25, 2010. The purpose of this National Take Back Day was to provide a venue for persons who wanted to dispose of unwanted and unused prescription drugs. This effort was a huge success in removing potentially dangerous prescription drugs, particularly controlled substances, from our nation's medicine cabinets. There were approximately 3,000 state and local law enforcement agencies throughout the nation that participated in the event. All told, the American Public turned in more than 121 tons of pills on this first National Take Back Day.

Due to the overwhelming success of the first event, DEA is planning a second National Prescription Drug Take Back Day which will take place on **Saturday, April 30, 2011**. This will be a great opportunity for those who missed the first event or who have subsequently accumulated unwanted, unused prescription drugs, to safely dispose of them. Further information about the second National Prescription Drug Take Back Day, including a link to locate a collection site near you, will be posted on this website.



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