COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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Tentative Agenda of Meeting

March 12, 2013

9:00AM

TOPIC	PAGE(S)
Call to Order: David C. Kozera, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
• Approval of Agenda	
• Approval of previous Board meeting minutes:	
◦ December 11, 2013, Regulation Committee Meeting	1-3
◦ December 12, 2013, Full Board Meeting	4-26
◦ December 18, 2013, Special Conference Committee & Informal Conference Committee	27-31
◦ January 14, 2013, Telephone Conference Call	32-33
◦ January 22, 2013, Panel Formal Hearing	34-35
◦ January 22, 2013, Examination Committee	36
◦ January 31, 2013, Informal Conference Committee for Innovative (Pilot) Programs	37-38
◦ February 1, 2013, Ad Hoc Committee for Nonresident Pharmacies Sterile Compounding Surveys	39-40
◦ February 4, 2013, Telephone Conference Call	41-42
◦ February 12, 2013, Special Conference Committee & Informal Conference Committee	43-48
◦ February 25, 2013, Telephone Conference Call	49-51
◦ March 8, 2013, Special Conference Committee & Informal Conference Committee	handout

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

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

Regulatory Actions: Elaine Yeatts	
• Legislative Update	52-72
• Regulatory Update	73
• Adoption of fast-track regulations resulting from regulatory reform	handout
• Revenue, Expenditures, & Cash Balance Analysis	73a

Miscellaneous: Caroline D. Juran

- Request for special considerations from Free Clinic of Franklin County, Inc 74-81
- Update on Sanctioning Reference Points evaluation and revision process- Kim Langston, Research Associate, Visual Research, Inc. 82
- Adoption of amended Guidance Document 110-9 83-92
- Request from staff for guidance regarding whether implanting of infusion pump by physician constitutes dispensing or administering 93

Reports:

- Report on Board of Health Professions – Robert M. Rhodes
- Report on Licensure Program – J. Samuel Johnson, Jr. Handout
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director's Report - Caroline D. Juran 94-99

New Business:

Consideration of consent orders (if any)

Adjourn

***The Board will have a working lunch at approximately 12pm, to include presentation of plaques to former board members, Gill Abernathy and Brandon Yi.**

Immediately following adjournment of the meeting, a panel will be convened for formal hearings.

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE

December 11, 2012
Second Floor
Training Room 1

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 3:12PM.

PRESIDING: Ellen B. Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Empsy Munden
Robert M. Rhodes
Cynthia Warriner

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

APPROVAL OF AGENDA: With no changes made to the agenda, the agenda was approved as presented (motion by Warriner, second by Munden).

The Regulation Committee met to discuss adoption of the proposed Regulations for Continuous Quality Improvement Programs and proposed Regulations for Working Conditions for Pharmacists. Additionally, the Committee discussed proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances, Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers, and Regulations for Collaborative Practice Agreements.

CONTINUOUS QUALITY IMPROVEMENT REGULATIONS

The Committee discussed adoption of the proposed regulations for Continuous Quality Improvement Programs to replace the Emergency Regulations that are in effect from October 1, 2012 until September 30, 2013. The public comment period had closed on November 7, 2012. Ms. Yeatts provided a summary of the one public comment received. The committee discussed and recommended changes to the definition of "dispensing error".

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Continuous Quality Improvement regulations with the following changes to the definition of "dispensing error": addition of the word "known" at the beginning of section (2)(a), (2)(b), (2)(c), and (20)(e) and removal of the words "if known" from (2)(b) and (2)(c) (motion by Wariner, second by Adams).

WORKING CONDITIONS FOR PHARMACISTS

The Committee discussed the adoption of proposed regulations for Working Conditions for Pharmacists. The public comment period had closed on October 10, 2012. Ms. Yeatts provided a summary of the approximately fourteen public comments received. A motion to withdraw the NOIRA was not carried. (motion by Munden, second by Warriner, opposed Adams, Rhodes, Shinnaberry). A motion to withdraw the NOIRA with a recommendation that the Regulation Committee be tasked with developing a guidance document to address working conditions was not carried (motion by Warriner, second by Munden, opposed Adams, Rhodes, Shinnaberry).

MOTION:

The Committee voted to recommend to the full Board on December 12, 2012, proposed regulations for Working Conditions for Pharmacists adding a new section B to Regulation 18VAC110-20-110 which states: Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least 6 hours of off time between consecutive shifts. A pharmacist working longer than 6 continuous hours shall be allowed to take a 30 minute break. (motion by Adams, second by Rhodes, opposed Warriner).

REGULATIONS FOR PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

The Committee reviewed proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances presented by Board staff.

- 18VAC110-30-20 – amendment suggested to conform language to Code
- 18VAC110-30-90, 18VAC110-30-100, and 18VAC110-30-130 – amendments suggested for consistency with regulations for pharmacies and to recognize allowances which are currently approved under a limited-use license

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed changes to the Regulations for Practitioners of the Healing Arts to Sell Controlled Substances (motion by Warriner, second by Rhodes).

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

The Committee reviewed proposed changes to the Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers presented by Board staff.

- 18VAC110-50-70 – amendment suggested to clarify who must provide a social security number or control number as currently indicated in Guidance Document 110-34
- 18VAC110-50-40 and 18VAC110-50-80 – amendments to clarify intent of regulations

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers (motion by Warriner, second by Adams).

REGULATIONS FOR COLLABORATIVE PRACTICE AGREEMENTS

The Committee reviewed proposed changes to the Regulations for Collaborative Practice Agreements presented by Board staff.

- 18VAC110-40-10 - consistent with the definition of "collaborative agreement" in §54.1-3300, a definition of "alternate practitioner" is suggested to clarify that a licensed nurse practitioner or physician assistant who is authorized in a practice agreement with a Virginia-licensed doctor of medicine, osteopathy, or podiatry may participate in a collaborative practice agreement.

MOTION:

The Committee voted unanimously to recommend to the full Board on December 12, 2012, adoption of the proposed Regulations for Collaborative Practice Agreements (motion by Rhodes, second by Munden).

ADJOURN:

With all business concluded, the meeting adjourned at 6:35PM.

Ellen Shinaberry, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

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(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 12, 2012
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:16 AM.

PRESIDING: David C. Kozera, Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Cynthia Warriner

MEMBERS ABSENT:
Pratt P. Stelly
Rebecca Thornbury

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

QUORUM: With eight 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 the October 1, 2012 (Full Board Meeting), October 24, 2012 (Special Conference Committee and Informal Conference Committee), November 6, 2012 (Special Conference Committee and Informal Conference Committee), November 20, 2012 (Telephone Conference Call), November 28, 2012 (Informal Conference Committee for Innovative Pilot Programs), and November 29, 2012 (Panel Formal Hearing). There was a suggestion to add the list of standing committees to page 7 of the October 1, 2012 full board meeting minutes under the "Scheduling of 2013 dates for full board meetings".

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

Unofficial Document

PUBLIC COMMENTS:

There were no public comments offered at this time.

DHP DIRECTOR'S REPORT:

Dr. Cane discussed with the Board the three legislative proposals that will be included in the Governor's package. The first one proposes to eliminate the Psychiatric Advisory Board since it has never had a need to meet. The second proposes a prohibition for a Department of Health Professional licensee from being able to practice on a suspended or revoked license pending appeal of the board's order. The third proposes placing the anabolic steroids prostanozol and methasterone into Schedule III of the Drug Control Act to conform to recent federal scheduling action.

Dr. Cane attended the Milbank Conference, along with state legislators and agency heads, to discuss how to reduce the abuse of prescription drugs. The Southwest Drug Abuse Summit was held November 14th in Wytheville, Virginia. Dr. Cane and Ralph Orr, Director of the Prescription Monitoring Program, attended. In January, Virginia's working committees associated with the National Governors Association policy grant efforts to reduce prescription drug abuse will meet. Arne Owens, Chief Deputy Director of the Department of Health Professions, will preside as Chair and work directly with Caroline Juran and Ralph Orr.

REGULATORY ACTIONS:

- Regulatory update

Ms. Yeatts provided the Board with an overview of regulatory processes. She stated the emergency regulations for continuous quality improvement programs (CQI) went into effect on October 1, 2012 and that they will expire in one year but may be extended for an additional six months after expiration. The proposed regulations for CQI to replace the emergency regulations will be presented during the meeting to the Board for adoption. The comment period for the notice of intended regulatory action (NOIRA) addressing the hours of continuous work by pharmacists closed on October 10, 2012. The proposed regulations for pharmacist working conditions (hours of continuous work by pharmacists) was drafted by the Regulation Committee at the December 11, 2012 meeting, and will be presented to the Board for adoption. The adopted regulations for administrative fees for duplicate licenses and verifications are currently at the Secretary's Office. Three sets of proposed regulations will be included in the Governor's fast-track regulatory reform initiative because they are less restrictive or burdensome: on-hold prescriptions; automated dispensing devices; and run-dry requirement for automated counting devices.

- Adoption of proposed regulations for CQI to replace emergency regulations:

Ms. Shinaberry discussed the Regulation Committee's recommendation for the proposed CQI regulations to replace the emergency regulations.

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MOTION:

The Board voted unanimously to adopt the proposed continuous quality improvement program (CQI) regulations as moved by the Regulation Committee. (second by Adams)

- Adoption of proposed regulations for working conditions of pharmacists:

Ms. Shinaberry stated the Regulation Committee's recommendation to adopt proposed regulations regarding working conditions of pharmacists. Specifically, the committee recommended adding a new section B to Regulation 18VAC110-20-110 which states: "Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30 minute break." There was discussion regarding whether regulatory action was needed or if a stepwise approach beginning with Board guidance was more appropriate. The term "emergency" as used in the proposed regulation was also discussed. It was agreed that staff sickness or inclement weather could constitute an "emergency".

MOTION:

The Board voted to adopt the proposed regulations regarding working conditions of pharmacists as recommended by the Regulation Committee. (second by Adams; opposed by Warriner, Allen, and Kozera)

- Adoption of fast-track regulations resulting from Governor's regulatory reform initiative:

Ms. Yeatts presented the Board for its consideration staff recommendations to amend certain regulations as part of the Governor's regulatory reform initiative. Because the amendments would create less restrictive regulations with likely no opposition, they could move forward as fast-track regulations. Suggested amendments were made to *Regulations for Practitioners of the Healing Arts to Sell Controlled Substances* (Attachment A), *Regulations for Collaborative Practice Agreements* (Attachment B), and *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers* (Attachment C). Suggested changes to the *Regulations Governing the Practice of Pharmacy* will be presented at the March 2013 full board meeting.

Regulations for Practitioners of the Healing Arts to Sell Controlled Substances

- 18VAC110-30-20 – amendment suggested to conform language to Code
- 18VAC110-30-90, 18VAC110-30-100, and 18VAC110-30-130 – amendments suggested for consistency with regulations for pharmacies and to recognize allowances which are currently approved under a limited-use license

MOTION:

The Board voted unanimously to adopt the Regulation Committee's recommendation for proposed fast-track regulatory amendments of *Regulations for Practitioners of the Healing Arts to Sell Controlled Substances* (18VAC110-30-20, 18VAC110-30-90, 18VAC110-30-100, and 18VAC110-30-130) as presented by staff.

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Regulations for Collaborative Practice Agreements

- 18VAC110-40-10- consistent with the definition of "collaborative agreement" in §54.1-3300, a definition of "alternate practitioner" is suggested to clarify that a licensed nurse practitioner or physician assistant who is authorized in a practice agreement with a Virginia-licensed doctor of medicine, osteopathy, or podiatry may participate in a collaborative practice agreement

MOTION:

The Board voted unanimously to adopt the Regulation Committee's recommendation for proposed fast-track regulatory amendments of *Regulations for Collaborative Practice Agreements* (18VAC110-40-10 and 18VAC110-40-20) as presented by staff.

Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers

- 18VAC110-50-70 – amendment suggested to clarify who must provide a social security number or control number as currently indicated in Guidance Document 110-34
- 18VAC110-50-40 and 18VAC110-50-80 – amendments to clarify intent of regulations

MOTION:

The Board voted unanimously to adopt the Regulation Committee's recommendation for proposed fast-track regulatory amendments of *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers* (18VAC110-50-40, 18VAC110-50-70, and 18VAC110-50-80) as presented by staff.

UPDATE ON ACTION ITEMS:

- Discussion of "authorized generics"

Ms. Juran gave an overview of the research that she obtained at the Board's request during the October 1, 2012 full board meeting concerning "authorized generics". While surveying states to determine how they address authorized generics, she was provided an excerpt from a newsletter posted by the Kentucky Board of Pharmacy which referenced the preface of the FDA Orange Book which states, "Any drug product in the List repackaged and/or distributed by other than the application holder is considered to be therapeutically equivalent to the application holder's drug product even if the application holder's drug product is single source or coded as non-equivalent (e.g., BN). Also, distributors or repackagers of an application holder's drug product are considered to have the same code as the application holder." Thus, it appears FDA considers authorized generics to be therapeutically equivalent to branded products.

MOTION:

The Board voted unanimously to adopt a guidance document that deems "authorized generics" as being therapeutically equivalent to branded products as stated in the 32nd edition of the FDA Orange Book and have staff reference this information in the next

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newsletter. (motion by Warriner, second by Shinaberry)

ADDTION TO AGENDA:

The Board approved an additional item to the agenda, ethics training offered by Board counsel, after the consideration of consent orders.

MISCELLANEOUS:

- Update on actions taken regarding pharmacies performing sterile compounding, staff request for additional guidance:

Ms. Juran gave the Board an update of actions taken by staff since the October 1, 2012 full board meeting to address recent concerns for sterile compounding pharmacies located in Virginia or registered with the Board as non-resident pharmacies. The nonresident pharmacy registration held by the New England Compounding Center (NECC) was mandatorily suspended on October 5, 2012. Staff had numerous communications with FDA, CDC, and VDH state epidemiologists to receive updates on NECC and Ameridose, posted updates on board's website, and responded to numerous media inquiries. Board staff worked collaboratively with the Enforcement Division to identify pharmacies located in Virginia that perform sterile compounding and increased efforts to perform routine inspections of these pharmacies. Ms. Juran reminded the members that it has been a longstanding policy to perform routine unannounced pharmacy inspections approximately every two years. Additionally, in an effort to identify the nonresident pharmacies that are shipping compounded sterile products (CSP) into Virginia, staff mailed on November 27, 2012, with the Chairman's approval, a written request to all nonresident pharmacies registered in Virginia. The request seeks confirmation if the pharmacy is shipping CSP into Virginia and requires submission of documents indicating compliance with sterile compounding standards listed in USP Chapter 797. The Chairman will appoint an ad hoc committee of the Board to assist staff in reviewing the submitted documents. A submission deadline of December 28, 2012 was provided. Staff also recently responded to two Congressional committee requests sent to all boards of pharmacy to determine each state's oversight on sterile compounding. Ms. Juran reported that she and Mr. Casway will attend a 50 state intergovernmental meeting hosted by the FDA on December 19, 2012 in Silver Spring, MD. Staff has reviewed the number of pharmacy inspectors currently employed and has received approval to hire one additional pharmacy inspector. A second hiring request for board staff will be submitted as well for consideration. All state hiring requests must be approved by the Chief of Staff. Staff is recommending the Board review Guidance Document 110-9 to determine if any deficiencies related to sterile compounding should be revised since they were implemented over a year ago. Staff obtained a free 42-module of continuing education for staff and members regarding USP standards. Staff has been and will continue to stay abreast of NABP's efforts to address sterile compounding. Many of NABP's efforts were determined at the recently held Executive Officer Forum which Ms. Juran attended.

- Consideration of possible legislative amendments regarding licensure and renewal process of non-

Staff is aware that legislators and/or stakeholders may be contemplating legislation to address sterile compounding concerns. Staff provided members with possible statutory amendments which could be considered by legislators and sought a reaction from the members. The Board also

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resident pharmacies and compounding:

received public comment from several practicing pharmacists on the issue of sterile compounding. Cheri Garvin with Leesburg Pharmacy stated that states should continue to regulate compounding, but that uniform national standards such as PCAB accreditation are necessary. She indicated that a myriad of drugs are compounded for office-use and therefore, did not support elimination of compounding for office-use. She expressed concern for non-resident pharmacies that appear to ship compounded drugs for resale when Virginia law prohibits it.

Baylor Rice from South River Compounding Pharmacy addressed the Board stating that the compounding pharmacies in Virginia have not had any major issues and that he believes the legislation that is currently in place is adequate. Mr. Rice serves as a board member for the International Academy of Compounding Pharmacists and suggested the members reference its position paper. Mr. Rice and Ms. Garvin indicated they would be willing to assist the board as necessary. Sonny Currin representing Rx3 Compounding Pharmacy discussed his concerns and expressed value for the positive service that compounding pharmacies offer patients. He expressed concern for non-resident pharmacies that ship CSP into Virginia for office-use.

In discussing whether possible legislative amendments are necessary, the Board expressed some concern for eliminating the ability to compound for office-use since this may impact patient access to needed drugs and further review of the subject would be warranted. There was positive feedback for holding nonresident pharmacies to similar standards as resident pharmacies by requiring a current inspection report to be taken within the last 6 months prior to the issuance of a nonresident pharmacy registration, a requirement for submission of a current inspection report from nonresident pharmacies upon renewal in even years with the report having been taken within the last 2 years, and clarification that inspection reports for nonresident pharmacies shall indicate compliance with USP 797 standards. Additionally, there was positive feedback for requiring all healthcare professionals who perform sterile compounding to comply with USP standards.

- Adoption of amendments to guidance document 110-9

Mr. Johnson gave the Board an overview of the proposed amendments made to Guidance Document 110-9 that refers to inspection deficiencies. The changes made to the Guidance Document reflected primarily around sterile compounding.

MOTION:

The Board voted unanimously to adopt the proposed amendments to Major deficiency 20 with additional changes made to the wording under section 20a by omitting "checking" and adding "final verification" and to section 20b by omitting "checking" and adding "final verification". (motion by Rhodes, second by Allen)

MOTION:

The Board voted unanimously to adopt the proposed amendment to Major deficiency 21 to increase the monetary penalty to $10,000. (motion by Munden, second by Allen)

MOTION:

The Board voted unanimously to adopt the proposed amendments to

Major deficiencies 22 and 23 and added the wording to Major 22 under conditions "Review 2 most recent reports". (motion by Allen, second by Munden)

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiencies 25, 25a, 25b, and 25c. (motion by Adams, second by Rhodes)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiencies 26 and 26a. (motion by Allen, second by Adams)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Major deficiency 33. (motion by Munden, second by Rhodes)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Minor deficiencies 30 and 30a, and adding under law/regulation citations "54.1-3410.2". (motion by Rhodes, second by Adams)**

MOTION: **The Board voted unanimously to adopt the proposed amendments to Minor deficiencies 31 and 32. (motion by Munden, second by Allen)**

REPORTS:

- Report on Board of Health Professions:

Mr. Rhodes gave an update to the Board regarding previous and upcoming meetings with the Board of Health Professions. The full board met on October 2, 2012. It was reported that the Perfusionist study is moving forward and the next step is for the Committee to receive public comment on the profession. The Pharmacy Scope of Practice & Team Delivery study is being continued in deference to the General Assembly's action on potential legislation under development by the Virginia Pharmacist Association and Medical Society of Virginia. The Committee was not privy to specific language under consideration at that time. A request to regulate medical assistants has been sent back to the Regulatory Research Committee to obtain additional information regarding the study. BHP staff will be coordinating on the development of a draft website for DHP dedicated to providing information relative to military service member, military spouses, and veterans. There will be information on relevant statutes and licensure requirements and links to the key Commonwealth websites for services and information relating to educational, training, employment, and other issues of significance. The Regulatory Research Committee met on October 2, 2012 and Dr. Carter reported that the Board of Pharmacy' comments were positive concerning the recommendations for collaborative practice put forward by the Virginia Pharmacists Association (VPhA) in response to the Committee's review. The Committee agreed that the Pharmacy Scope of Practice & Team Delivery study should continue after the General Assembly has had the opportunity to address the anticipated 2013 legislation. BHP staff will continue to prepare information on the pharmacy technician scope of practice for presentation at the next meeting scheduled for February 5, 2013. The Regulatory Research Committee held a public hearing on perfusionists on December 3, 2012.

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- Report on Licensure Program:

Mr. Johnson reported that the Board issued 1,047 licenses and registrations for the period of September 1, 2012 through November 30, 2012, including 148 pharmacists, 299 pharmacy interns, and 457 pharmacy technicians. Inspectors conducted 251 facility inspections including 72 routine inspections of pharmacies: 23 resulted in no deficiency, 9 with deficiencies, and 40 with deficiencies and a consent order. One innovative (pilot) program for the utilization of the InstyMeds automated dispensing device in an immediate care center was approved by an informal conference committee.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of March 12, 2012; June 8, 2012; September 28, 2012; and December 11, 2012. For the final date, open cases are 72 at the investigation stage; 66 at the probable cause stage; 11 at the administrative proceedings division stage; 15 at the informal stage; three at the formal stage; and 39 at the pending closure stage.

- Executive Director's Report:

Ms. Juran presented the members with the Board's revenue and expenditures summary report and asked if they would like a copy provided to them at each board meeting. She stated that the Board's expenses are relatively steady and that is has been in good financial standing for several years. She reported that Leo Ross, former Board member, attended the International Pharmaceutical Federation Centennial Congress in Amsterdam in October. Board members Cynthia Warriner, Crady Adams, Ellen Shinaberry and Robbie Rhodes attended the NABP District 1&2 meeting in SkyTop, Pennsylvania with Ms. Juran in mid-October. There was much discussion at the meeting regarding collaborative practice agreements and possible expansion of pharmacist allowances under these agreements. An informative presentation was given by the Assistant Surgeon General of the U.S., Scott Giberson, who is also a pharmacist. District II discussed the bylaws associated with becoming a 501c and passed a resolution that NABP needs to encourage state boards to require accreditation of pharmacies that perform sterile compounding. Another resolution discussed was to prohibit pharmacies acting as a wholesale distributor under the 5% allowance, except for emergencies since this appears to be creating gray market concerns. Ms. Juran also attended the first Tri-Regulator meeting in Washington, DC, which is a meeting of the NABP, National Council of State Boards of Nursing, and the Federation of State Medical Boards.

CONSIDERATION OF CONSENT ORDERS:

MOTION FOR CLOSED MEETING:

The Board voted unanimously to enter into a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia for the purpose of deliberation to reach a decision regarding a Consent Order. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, Howard Casway, Sammy Johnson and Heather Hurley attend the closed meeting because their presence was deemed necessary and would aid the Board in its deliberation. (motion by Allen, second by Adams)

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MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:	**The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements and only such public business matters as were identified in the motion for a closed meeting were heard, discussed, or considered during the closed session just concluded. (motion by Allen, second by Adams)**
MOTION:	**The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Brian Burns, Pharmacy Technician (motion by Warriner, second by Munden)**
MOTION:	**The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of William Wimbish, Jr. , Pharmacist (motion by Warriner, second by Allen)**
REPORT FROM ENFORCEMENT DIVISION:	Faye Lemon, Director of the Enforcement Division, updated the Board on the inspection process, and what procedures were taking place for inspecting pharmacies performing sterile compounding in Virginia. Ms. Lemon reported there are currently three full time pharmacists, one part-time pharmacist, and that interviews for the Northern Virginia pharmacy inspector will be taking place this Friday. Ms. Lemon is also anticipating a fifth pharmacy inspector to be hired in the near future who will serve as a floater inspector to assist with all regions, primarily Northern Virginia.
PRESENTATION BY BOARD COUNCIL REGARDING BOARD MEMBER ETHICS:	Howard Casway, Board Council, reviewed with the Board a power-point presentation of possible conflicts of interests that the members could have while serving on the Board and situations to avoid.
ADJOURN:	With all business concluded, the meeting adjourned at 3:32 pm.

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David C. Kozera, Board Chairman

Caroline D. Juran, Executive Director

Date

Date

Attachment A

Commonwealth of Virginia

VIRGINIA BOARD OF PHARMACY

REGULATIONS

FOR

PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

Title of Regulations: 18 VAC 110-30-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

STAFF RECOMMENDATIONS

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1464
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Phone: 804-367-4456
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Project 3497 – Fast-track (Reg Reform)

BOARD OF PHARMACY

Regulatory review changes

Part II

Licensure Requirements

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine or podiatry issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice ~~medicine~~ shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

C. For good cause shown, the board may issue a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. The license to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice; and

2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than ~~60~~40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for the storage, preparation, and dispensing~~, and record-keeping~~ Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within the immediate vicinity of the selling and storage area; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

18VAC110-30-100. Access to selling area.

Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the licensee shall not be through the selling and storage area. The selling and storage area may be in an office that is exclusively used by the licensee and to which only the licensee has access provided ~~the portion of~~ the office ~~used exclusively for controlled substances storage and preparation~~ is at least ~~60~~40 square feet; provided the drugs are stored in a cabinet, closet or other lockable area which can be locked when the practitioner is using the office for purposes other than dispensing; and provided the office meets all other requirements of 18VAC110-30-90, 18VAC110-30-120, and 18VAC110-30-130.

18VAC110-30-130. Selling area enclosures.

A. The controlled substance selling and storage area of the licensee shall be provided with enclosures subject to the following conditions:

1. The enclosure shall be ~~construed~~ constructed in such a manner that it protects the controlled substance stock from unauthorized entry and from pilferage at all times whether or not the licensee is on duty;

~~2. The enclosure shall be of sufficient height as to prevent anyone from reaching over to gain access to the controlled substances;~~

~~3. Entrances to the enclosed area must have a door which extends from the floor and which is at least as high as the adjacent counters or adjoining partitions; and~~

~~4. Doors to the area must have locking devices which will prevent entry in the absence of the licensee.~~

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

3. The enclosure shall be capable of being locked in a secure manner at any time the licensee on duty is not present in the storage and selling area.

B. The door keys or other means of entry and alarm access code to the selling and storage area shall be ~~subject to the following requirements~~ restricted to the licensee with the following exceptions:

1. ~~Only the licensee shall be in possession of the alarm access code and any keys or other means of entry to the locking device on the door to such enclosure~~ Other persons authorized to assist the licensee in the selling and storage area may possess a key or other means of entry into a locked area only when the licensee is on duty. Such key or other means of entry shall not allow entry when the licensee is not on duty; and

2. ~~The selling and storage area must be locked when the licensee is not present and engaged in preparation or selling of drugs; and~~

~~3.~~ The licensee may place a key or other means of opening the locking device and the alarm access code in a sealed envelope or other sealed container with the licensee's signature across the seal in a safe or vault within the office or other secured place for use by another licensee for emergency access. In lieu of the licensee's signature across a seal, the executive director for the board may approve other methods of securing the emergency keys or access codes to the enclosed area.

C. The controlled substance selling and storage area is restricted to the licensee and one person designated by the licensee. The designated person may be present in the selling and storage area only during the hours when the licensee is on duty to render personal supervision.

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

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

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

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

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

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:

1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;

2. Alternate pharmacist coverage cannot immediately be obtained;

3. The technician is accompanied by a member of the pharmacy's management or administration; and

4. All requirements of subsection E of this section are met.

Attachment B

Commonwealth of Virginia

Virginia Board of Pharmacy
Virginia Board of Medicine

REGULATIONS

FOR

COLLABORATIVE PRACTICE AGREEMENTS

Title of Regulations: 18 VAC 110-40-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Staff recommendations

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1464
email: pharmbd@dhp.virginia.gov

Phone: 804-367-4456
Fax: 804-527-4472

18VAC110-40-10. Definitions.

The following words and terms when used in this chapter shall have the following meanings~~,~~ unless the context clearly indicates otherwise:

"Agreement" means a collaborative practice agreement by which practitioners of medicine, osteopathy or podiatry and pharmacists enter into voluntary, written agreements to improve outcomes for their mutual patients using drug therapies, laboratory tests, and medical devices, pursuant to the provisions of §54.1-3300.1 of the Code of Virginia.

"Alternate practitioner" means a doctor of medicine, osteopathy, or podiatry or a licensed nurse practitioner or physician assistant with an active license to practice in Virginia who is authorized in a practice agreement with a Virginia-licensed doctor of medicine, osteopathy or podiatry to participate in a collaborative agreement.

"Committee" means an Informal Conference Committee, comprised of two members of the Board of Pharmacy and two members of the Board of Medicine.

"Pharmacist" means a pharmacist who holds an active license to practice pharmacy from the Virginia Board of Pharmacy.

"Practitioner" means~~, notwithstanding the definition in §54.1-3401 of the Code of Virginia,~~ a doctor of medicine, osteopathy, or podiatry or an alternate practitioners who writes the order and is directly and ultimately responsible for the care of a patient being treated under an agreement and who holds an active license to practice ~~from the Virginia Board of Medicine~~.

18VAC110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner of medicine, osteopathy, or podiatry involved directly in patient care and a pharmacist involved directly in patient care. ~~The~~ Within the collaborative agreement, the practitioner may designate alternate practitioners, and the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. Documented informed consent from the patient shall be obtained by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement.

1. The patient may decline to participate or withdraw from participation at any time.

2. Prior to giving consent to participate, the patient shall be informed by the practitioner or the pharmacist of the cooperative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.

3. As part of the informed consent, the practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

18VAC110-40-30. Approval of protocols outside the standard of care.

Attachment C

Commonwealth of Virginia

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-50-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

STAFF RECOMMENDATIONS

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1464

Phone: 804-367-4456
Fax: 804-527-4472

email: pharmbd@dhp.virginia.gov

18VAC110-50-40. Safeguards against diversion of drugs.

A. The holder of the license as a wholesale distributor or permit as a manufacturer or warehouser shall restrict all areas in which prescription drugs are stored or kept for sale to only those persons specifically designated as necessary for the manufacture, receipt, storage, distribution or quality control of the controlled substance inventory, and shall provide reasonable security measures to include appropriate locking devices on all access doors to these areas and adequate lighting both inside and outside the facility to deter unauthorized entry and diversion.

B. The holder of the license or permit, except for those distributors of only medical gases other than nitrous oxide, shall install an operable device for the detection of breaking subject to the following conditions:

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

2. The installation shall be hard-wired and both the installation and device shall be based on accepted burglar alarm industry standards.

3. The device shall be operable, centrally-monitored, and have an auxiliary source of power.

4. The device shall fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated.

5. Access to the alarm system shall be restricted to the person named on the application as the responsible party, or to persons specifically designated in writing in a policy and procedure manual.

6. The system shall be activated whenever the drug storage areas are closed for business.

C. Distribution or delivery of prescription drugs shall be accomplished in a manner to prevent diversion or possession of drugs by unauthorized persons.

1. The holder of the license or permit shall only deliver prescription drugs to a person authorized to possess such drugs at a location where the person is authorized to possess such drugs, and only at a time when someone authorized to possess such drugs is in attendance.

2. The holder of the license or permit shall affirmatively verify that the person to whom prescription drugs are delivered is authorized by law to receive such drugs.

3. Prescriptions drugs may be transferred to an authorized agent of a person who may lawfully possess prescription drugs, provided the transfer occurs on the premises of the wholesale distributor, manufacturer, or warehouser, and provided the identity and authorization of the agent is verified, and such transfer is only used to meet the immediate needs of a patient or patients.

Part II. Wholesale Distributors.

18VAC110-50-70. Minimum required information.

A. The application form for a new license or for registration as a non-resident wholesale distributor, or any change of ownership shall include at least the following information:

1. The name, full business address, and telephone number of the applicant or licensee and name and telephone number of a designated contact person;

2. All trade or business names used by the applicant or licensee;

3. The federal employer identification number of the applicant or licensee;

4. The type of ownership and name(s) of the owner of the entity, including:

a. If an individual: the name, address, social security number or control number;

b. If a partnership: the name, address, and social security number or control number of each partner who is specifically responsible for the operations of the facility listed on the application, and the name of the partnership and federal employer identification number;

c. If a corporation:

(1) The name and address of the corporation, federal employer identification number, state of incorporation, the name and address of the resident agent of the corporation;

(2) The name, address, social security number or control number, and title of each corporate officer and director who is specifically responsible for the operations of the facility listed on the application;

(3) For non-publicly held corporations, the name and address of each shareholder that owns ten (10) percent or more of the outstanding stock of the corporation.

(4) The name, federal employer identification number, and state of incorporation of the parent company.

d. If a sole proprietorship: the full name, address, and social security number or control number of the sole proprietor and the name and federal employer identification number of the business entity;

e. If a limited liability company, the name and address of each member, the name and address of each manager, the name of the limited liability company and federal employer identification number, the name and address of the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized;

5. Name, business address and telephone number, and social security number or control number, and documentation of required qualifications as stated in 18VAC110-50-80 of the person who will serve as the responsible party;

6. A list of all states in which the entity is licensed to purchase, possess and distribute prescription drugs, and into which it ships prescription drugs;

7. A list of all disciplinary actions, to include date of action and parties to the action, imposed against the entity by state or federal regulatory bodies, including any such actions against the responsible party, principals, owners, directors, or officers over the last seven years;

8. A full description, for non-resident wholesale distributors, including the address, square footage, security and alarm system description, temperature and humidity control, and other relevant information of the facility or warehouse space used for prescription drug storage and distribution; and

9. An attestation providing a complete disclosure of any past criminal convictions and violations of the state and federal laws regarding drugs or devices or an affirmation and attestation that the applicant has not been involved in, or convicted of, any criminal or prohibited acts. Such attestation shall include the responsible party, principals, directors, officers, or any shareholder who owns 10% or more of outstanding stock in any non-publicly held corporation.

B. An applicant or licensee shall notify the board of any changes to the information required in this section within 30 days of such change.

18VAC110-50-80. Minimum qualifications, eligibility, and responsible party.

A. The board shall use the following factors in determining the eligibility for licensure of wholesale distributors:

1. The existence of grounds to deny an application as set forth in §54.1-3435.1 of the Code of Virginia;

2. The applicant's past experience in the manufacture or distribution of drugs or devices;

3. Compliance with the recordkeeping requirements;

4. Prior disciplinary action by a regulatory authority, prior criminal convictions, or ongoing investigations related to the manufacturing, distribution, prescribing, or dispensing of drugs by the responsible party or immediate family members of the responsible party, and owners, directors, or officers; and

5. The responsible party's credentials as set forth in subsection B of this section.

B. Requirements for the person named as the responsible party:

1. The responsible party shall be the primary contact person for the board as designated by the wholesale distributor, who shall be responsible for managing the wholesale distribution operations at that location;

2. The responsible party shall have a minimum of two years of verifiable experience in a pharmacy or wholesale distributor licensed in Virginia or another state, where the person's responsibilities included, but were not limited to, managing or supervising the recordkeeping, storage, and shipment for drugs or devices;

3. A person may only serve as the responsible party for one wholesale distributor license at any one time;

4. The responsible party shall be employed full time in a managerial position and actively engaged in daily operations of the wholesale distributor;

5. The responsible party shall be present on a full-time basis at the location of the wholesale distributor during normal business hours, except for time periods when absent due to illness, family illness or death, vacation, or other authorized absence; and

6. The responsible party shall be aware of, and knowledgeable about, all policies and procedures pertaining to the operations of the wholesale distributor and all applicable state and federal laws related to wholesale distribution of prescription drugs.

C. The person named as the responsible party on the application shall submit the following with the application:

1. A passport size and quality photograph taken within 30 days of submission of the application;

2. A resume listing employment, occupations, or offices held for the past seven years including names, addresses, and telephone numbers of the places listed;

3. ~~A sworn statement or affirmation~~ An attestation disclosing whether the person has a criminal conviction or is the subject of any pending criminal charges within or outside the Commonwealth;

4. A criminal history record check through the Central Criminal Records Exchange; and

5. A description of any involvement by the person with any business, including any investments, other than the ownership of stock in publicly traded company or mutual fund, during the past seven years, which manufactured, administered, prescribed, distributed, or stored drugs and devices and any lawsuits, regulatory actions, or criminal convictions related to drug laws or laws concerning wholesale distribution of prescription drugs in which such businesses were named as a party.

D. Responsibilities of the responsible party

1. Ensuring that any employee engaged in operations is adequately trained in the requirements for the lawful and appropriate wholesale distribution of prescription drugs.

2. Requiring any employee who has access to prescription drugs to attest that he has not been convicted of any federal or state drug law or any law relating to the manufacture, distribution or dispensing of prescription drugs.

3. Maintaining current working knowledge of requirements for wholesale distributors and assuring continued training for employees.

4. Maintaining proper security, storage and shipping conditions for all prescription drugs.

5. Maintaining all required records.

E. Each non-resident wholesale distributor shall designate a registered agent in Virginia for service of any notice or other legal document. Any non-resident wholesale distributor that does not so designate a registered agent shall be deemed to have designated the Secretary of the Commonwealth to be its true and lawful agent, upon who may be served all legal process in any action or proceeding against such non-resident wholesale distributor. A copy of any such service of legal documents shall be mailed to the non-resident wholesale distributor by the board by certified mail at the address of record.

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/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, December 18, 2012
Commonwealth Conference Center
Second Floor
Board Room 1

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

CALL TO ORDER:	A meeting of a Special Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.
PRESIDING:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Ellen B. Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
WALTER C. JONES License No. 0202-004975	Walter C. Jones appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the August 21, 2012, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Walter C. Jones. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Mr. Jones.

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

NADER ABEDINZADEH
License No. 0202-011595

Nader Abedinzadeh appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 26, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Nader Abedinzadeh. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Mr. Kozera stated that the Committee concluded that this matter be sent to a formal administrative hearing.

EVERETTE G. RICHARDSON
Registration No. 0230-012179

Everette G. Richardson did not appear at the informal conference. The committee chose to proceed in his absence as the notice was mailed to Mr. Richardson's legal address or record. The committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 16, 2012, Notice.

Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Everette G. Richardson. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Richardson an Order to obtain an evaluation pursuant to § 54.1-2400(15). As provided by law, this decision cannot be appealed.
ADAM D. BAUGESS Registration No. 0230-016990	Adam D. Baugess did not appear at the informal conference. The committee chose to proceed in his absence as the notice was mailed to Mr. Baugess' legal address of record. The committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 26, 2012, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Adam D. Baugess. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order with his license being placed on suspension with said suspension stayed upon Mr. Baugess' participating with the Health Practitioners Monitoring Program.
JASON A. GREEN Registration No. 0230-018817	Jason A. Green did not appear at the informal conference. The committee chose to proceed in his absence as the notice was mailed to Mr. Green's legal address or record. The committee discussed that he may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 27, 2012, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Jason A. Green. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Mr. Green a Consent Order for the indefinite suspension of his pharmacy technician registration for a period of not less than two years.

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

David C. Kozera
Committee Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, January 14, 2013

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 10:25 a.m., on January 14, 2013, to consider the summary restriction of the license of Christopher K. Currin to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Dinny Li
Empsy Munden
Ellen B. Shinaberry

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

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

CHRISTOPHER K. CURRIN
License No. 0202 011727

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

Upon a motion by Ms. Allen and duly seconded by Ms. Shinaberry, the Board 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 Christopher K. Currin. Additionally, she moved that Caroline Juran, Cathy Reiniers-Day, Eusebia Joyner and Howard Casway attend the closed meeting.

At approximately, 12:50 p.m., Ms. Juran departed.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Munden and duly seconded by Mr. Adams, the Board unanimously voted 6-0 that, with the evidence presented, the practice as a pharmacist by Christopher K. Currin poses a substantial danger to the public; and therefore, said license to practice pharmacy in the Commonwealth of Virginia be and hereby is Restricted.

Upon a motion by Ms. Allen and seconded by Ms. Shinaberry, the Board voted that a Consent Order for a stay of the restriction with certain terms and conditions be offered to Mr. Currin.

ADJOURN:

With all business concluded, the meeting adjourned at 1:10 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

David C. Kozera, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, January 22, 2013
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 11:00 a.m.

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Robert M. Rhodes
Ellen B. Shinaberry
Cynthia Warriner

STAFF PRESENT:
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
Shevaun Roukous, DHP Adjudication Specialist

QUORUM: With six (6) members of the Board present, a panel was established.

JENNIFER M. CRAIGHEAD
Registration # 0230-010622

A formal hearing was held in the matter of Jennifer M. Craighead following the summary suspension of her pharmacy technician registration on December 3, 2012, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians in Virginia.

Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Shevaun Roukous, DHP Adjudication Specialist.

Diana Gallion, Kroger Theft and Loss Prevention, testified by telephone; and Jennifer E. Baker, DHP Regional Enforcement Manager, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Ms. Allen and duly seconded by Ms. Shinaberry, 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 Jennifer M. Craighead. Additionally, she moved that Cathy Reiniers-Day, Eusebia Joyner and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Warriner and duly seconded by Ms. Rhodes, the panel voted 6-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Mr. Casway.

Upon a motion by Mr. Rhodes and duly seconded by Mr. Mr. Adams, the panel voted 6-0 that Ms. Craighead's registration to practice as a pharmacy technician shall be revoked.

Adjourn:

With all business concluded, the meeting adjourned at 12:45 p.m.

Cathy M. Reiniers-Day
Deputy Executive Director

David C. Kozera, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY

MINUTES OF EXAMINATION COMMITTEE

January 22, 2013
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:40 p.m.

PRESIDING: Robert M. Rhodes, Committee Chairman

MEMBERS PRESENT: Empsy Munden
Jody H. Allen

STAFF PRESENT: J. Samuel Johnson, Jr., Deputy Executive Director
Cathy Reiniers-Day, Deputy Executive Director

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

The Examination Committee met to discuss proposals submitted in response to a Request for Proposal for the Virginia Pharmacy Technician Examination.

CLOSED MEETING:

Upon a motion by Ms. Allen, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(29) of the Code of Virginia, for the purpose of discussion of the award of a public contract involving the expenditure of public funds, including interviews of bidders or offerors, and discussion of the terms or scope of such contract, where discussion in an open session would adversely affect the bargaining position or negotiating strategy of the public body. Additionally, she moved that J. Samuel Johnson, Jr., and Cathy Reiniers-Day 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.

ADJOURN: With all business concluded, the meeting adjourned at 4:00 p.m..

Robert M. Rhodes
Committee Chairman

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF PILOT INFORMAL CONFERENCE COMMITTEE

Thursday, January 31, 2013
Commonwealth Conference Center
Second Floor
Training Room 1

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

CALL TO ORDER:	A meeting of a Pilot Informal Conference Committee of the Board of Pharmacy was called to order at 1:45 p.m.
PRESIDING:	David C. Kozera, Committee Chairman
MEMBERS PRESENT:	Jody H. Allen, Committee Member
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Jr., Deputy Executive Director
Omnicare t/a Williamson's Pharmacy; Neighborcare - Richmond	David Barrington, pharmacist, William J. Hancock, pharmacist, J. E. Hill Hopper, pharmacist, Michelle L. Lincoln, pharmacist, and Michael J. Szesco, with Omnicare, Inc., were present to discuss the application received on November 13, 2012, for approval of an innovative (pilot) program wherein Omnicare t/a Williamson's Pharmacy and Neighborcare - Richmond intends to utilize the Auto Label Verify (AVL) Robotic Verification Process to dispense prescriptions to patients of a long-term care facility. Omnicare t/a Williamson's Pharmacy; Neighborcare - Richmond is requesting a waiver of Board Regulations 18 VAC 110-20-10 regarding the definition of "unit dose package" and unit dose system" and 18 VAC 110-20-425 regarding the regulations that relate to robotic pharmacy systems.
Closed Meeting:	Upon a motion by Ms. Allen, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter Omnicare t/a Williamson's Pharmacy; Neighborcare - Richmond Additionally, she moved that Caroline D. Juran, and J. Samuel Johnson, Jr. 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:

After consideration of the application and statements concerning the innovative (pilot) program, Mr. Kozera stated the Committee shall offer a consent order that approves the innovative (pilot) program for a period of three years from the date of implementation by Omnicare t/a Williamson's Pharmacy; Neighborcare - Richmond with terms and conditions.
(This Consent Order shall be effective upon endorsement by Omnicare t/a Williamson's Pharmacy; Neighborcare - Richmond and the Board).

ADJOURN:

With all business concluded, the meeting adjourned at 4:00 p.m.

David C. Kozera, Chair

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE FOR NONRESIDENT PHARMACY STERILE COMPOUNDING SURVEYS

Friday, February 1, 2013
Commonwealth Conference Center
Second Floor
Training Room 1

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

CALL TO ORDER: A meeting of an Ad Hoc Committee for Nonresident Pharmacy Sterile Compounding Surveys of the Board of Pharmacy was called to order at 1:45 p.m.

PRESIDING: Ellen B. Shinaberry, Committee Chairman

MEMBERS PRESENT:
Jody H. Allen
David C. Kozera
R. Crady Adams
Empsy Munden

STAFF PRESENT:
Caroline D. Juran, Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Paul Dalby, Deputy Director of Enforcement
Vicki Gwaltney Garrison, Pharmacist Inspector
Nan Dunaway, Pharmacist Inspector
Don Jackson, Pharmacist Inspector
Susan Beckman, Pharmacist Inspector
Laura Rothrock, Administrative Assistant

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

NONRESIDENT PHARMACY STERILE COMPOUNDING SURVEYS

Sammy Johnson provided an overview of the letters sent to all nonresident pharmacies requesting information to demonstrate compliance with USP standards for those performing sterile compounding. Of the 509 nonresident pharmacies, 176 indicated they ship compounded sterile products into Virginia. Two hundred ninety-nine indicated they do not ship sterile compounded products into Virginia. The remaining nonresident pharmacies either did not respond to the survey or provided incomplete information, and therefore, staff is in communication with them to complete the request. The committee then began reviewing the submitted documentation for each nonresident pharmacy that indicated they perform sterile compounding. The committee completed the review of the confidential information for approximately 120

nonresident pharmacies. Staff is to continue the review process and take additional steps which may involve communicating with the pharmacy for additional information or clarification of the submitted information.

ADJOURN: With all business concluded, the meeting adjourned at 5:10 p.m.

Ellen B. Shinaberry, Chairman

Caroline D. Juran
Executive Director

Date

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, February 4, 2013

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 4, 2013, to consider the summary suspension of the registration of Ajani Moore to practice as a pharmacy technician and the license of Russell S. Gates to practice as a pharmacist in the Commonwealth of Virginia.

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT:
R. Crady Adams
Dinny Li
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury

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
Wayne T. Halbleib, Senior Assistant Attorney General
Shevaun Roukous, DHP Adjudication Specialist

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 two possible summary suspension cases. The Board members stated that they would not have been able to attend.

With eight (8) members participating and two (2) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

AJANI MOORE
Registration No. 0230-014090

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

Upon a motion by Ms. Stelly and duly seconded by Mr. Rhodes, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Ajani Moore poses a substantial danger to the public; and therefore, the registration of

Mr. Moore to practice as a pharmacy technician be summarily suspended; and that with a Notice of Hearing, a Consent Order be offered to Mr. Moore for the revocation of his registration in lieu of a hearing.

Mr. Kozera departed at 10:48 a.m.

PRESIDING:

Ms. Shinaberry presided over the following matter.

RUSSELL S. GATES
License No. 0202 009066

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

Upon a motion by Ms. Stelly and duly seconded by Mr. Adams, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by Russell S. Gates poses a substantial danger to the public; and therefore, the right to renew his pharmacist license be summarily suspended; and that, with a Notice of Hearing, a Consent Order be offered for the revocation of his right to renew his license to practice pharmacy.

ADJOURN:

With all business concluded, the conference call adjourned at 11:00 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

David C. Kozera, Chair

Ellen B. Shinaberry, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, February 12, 2013
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 9:30 a.m.
PRESIDING:	David C. Kozera, Committee Chair
MEMBERS PRESENT:	Ellen B. Shinaberry, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
GENNIFER L. BARKER Registration No. 0230-012649	Gennifer L. Barker appeared with Leonard A. Paris, her attorney, and Josephine Barker, her grandmother, to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the September 26, 2012, Notice.
Closed Meeting:	The Committee referred the matter to a Formal Hearing before the Board of Pharmacy.
PHILIP D. RICHARD Pharmacist Reinstatement Applicant License No. 0202 004237	Philip D. Richard appeared 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 December 21, 2012, Notice.
Closed Meeting:	Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Philip D. Richard. Additionally, she moved that Cathy Reiniers-Day and Mykl D. Egan attend the closed meeting

because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order reinstating Mr. Richard's pharmacist license once he complies with certain conditions.

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

ROY L. GARRETT
License No. 0202 003642

Roy L. Garrett appeared with Eleanor Garrett, his wife, to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the December 11, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Roy L. Garrett. Additionally, she moved that Cathy Reiniers-Day and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Mr. Garrett an Order with a reprimand.

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

NOTE:

Pratt P. Stelly arrived to serve as the additional Committee Member for the following case. Ms. Shinaberry chaired the conference and Mr. Kozera recused himself from this matter. Further, Shevaun Roukous, DHP Adjudication Specialist, staffed this conference.

AMANDA OVERSTREET
Registration No. 0230-007538

Amanda Overstreet did not appear at the informal conference. The Committee chose to proceed in her absence as the notice was mailed to Ms. Overstreet's legal address of record. The Committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 26, 2012, Notice.

Closed Meeting:

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

matter of Amanda Overstreet. Additionally, she moved that Cathy Reiniers-Day and Shevaun Roukous attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Overstreet a Consent Order for the indefinite suspension of her right to renew her pharmacy technician registration.

NOTE:

Ms. Stelly departed and Mr. Kozera returned to chair the remaining conferences. Further, Mr. Egan returned to staff the remaining conferences.

JAMES V. ETTARE, II
Pharmacist Reinstatement Applicant
License No. 0202 205862

James V. Ettare appeared with Jody Ettare, his wife and a pharmacist; and J. Buckley Warden, 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 February 1, 2013, Notice.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of James V. Ettare. Additionally, she moved that Cathy Reiniers-Day and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order reinstating Mr. Ettare's pharmacist license once he complies with certain conditions.

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

RUTH L. GREEN
License No. 0202-207618

Ruth L. Green did not appear at the informal conference. The Committee chose to proceed in her absence as the notice was mailed to Ms. Green's legal address of record. The Committee discussed that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the December 21, 2012, Notice.

Closed Meeting:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(28) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Ruth L. Green. Additionally, she moved that Cathy Reiniers-Day and Mykl D. Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Shinaberry, and duly seconded by Mr. Kozera, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue Ms. Green an Order to continue her pharmacist license on probation with terms and conditions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Green, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Green 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 4:30 p.m.

David C. Kozera, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Ellen B. Shinaberry, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, February 25, 2013

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on February 25, 2013, at 9:00 a.m., to consider the summary suspensions of the licenses of Elizabeth S. Pence and Russell T. Lederhouse to practice as pharmacists in the Commonwealth of Virginia.

PRESIDING: David C. Kozera, Chair

MEMBERS PRESENT:
R. Crady Adams
Jody H. Allen
Empsy Munden
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Mykl Egan, DHP Adjudication Specialist
Howard Casway, Senior Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
James T. Schliessmann, Senior Assistant Attorney General
Vicki G. Garrison, DHP Pharmacy Inspector
Nan Dunaway, DHP Pharmacy Inspector

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 eight (8) members participating and two (2) members unable to participate, it was established that a quorum could not have been convened in a regular meeting to consider this matter.

ELIZABETH S. PENCE
License No. 0202 010751

James E. Schliessmann presented a summary of the evidence in this case.

Upon a motion by Ms. Stelly and duly seconded by Ms. Allen, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by Elizabeth S. Pence poses a substantial danger to the public; and therefore, the license of Ms. Pence shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Pence for the indefinite suspension of her license for a period of not less than two years.

RUSSELL T. LEDERHOUSE
License No. 0202 207604

Wayne T. Halbleib presented a summary of the evidence in this case. Further, Vicki G. Garrison and Nan Dunaway, answered questions from the Board members.

At approximately, 10:03 a.m., Ms. Allen departed.

Upon a motion by Ms. Shinaberry and duly seconded by Ms. Warriner, the Board voted 8-0, to convene a closed meeting pursuant to § 2.2-3711(A) (27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Russell T. Lederhouse. Additionally, she moved that Caroline Juran, Cathy Reiniers-Day, Eusebia Joyner and Howard Casway attend the closed meeting.

Reconvene:

Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Board re-convened in open meeting and announced the decision.

Decision:

Upon a motion by Ms. Warriner and duly seconded by Ms. Shinaberry, the Board unanimously voted 8-0 that, with the evidence presented, the practice as a pharmacist by Russell T. Lederhouse poses a substantial danger to the public; and therefore, the license of Mr. Lederhouse shall be summarily suspended pending a Formal Hearing.

ADJOURN: With all business concluded, the meeting adjourned at 11:30 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

David C. Kozera, Chair

Date

Report of the 2013 General Assembly
(All bills have passed; duplicate bills not included in list)

Board of Pharmacy

HB 1422 Interchangeable biosimilar biological products; permits pharmacists to dispense, etc.

Chief patron: O'Bannon

Dispensing of interchangeable biosimilar biological products. Permits pharmacists to dispense a biosimilar that has been licensed by the U.S. Food and Drug Administration as interchangeable with a prescribed biological product unless the prescriber indicates such substitution is not authorized or the patient insists on dispensing of the prescribed biological product. The bill requires any pharmacist who dispenses an interchangeable biosimilar to inform the patient prior to dispensing the biosimilar, provide notification of the substitution to the prescriber, record the brand name or the product name and name of the manufacturer of the biosimilar on the record of dispensing and the prescription label, and provide retail cost information for both the prescribed biological product and the interchangeable biosimilar to the patient.

HB 1444 Medications; administration by certain employees or contract service providers.

Chief patron: O'Bannon

Administration of medications by employees or contract service providers of providers licensed by the Department of Behavioral Health and Developmental Services. Provides that employees of or persons providing services pursuant to a contract with a provider licensed by the Department of Behavioral Health and Developmental Services may administer insulin, glucagon, and epinephrine pursuant to a written order issued by a prescriber in certain circumstances. The bill provides protection from liability for certain acts related to such administration and requires the Board of Nursing to promulgate regulations governing training in the administration of epinephrine and glucagon by persons authorized to administer epinephrine and glucagon.

HB 1499 Emergency medical services personnel; administration of medications.

Chief patron: Stolle

Administration of medications. Clarifies the circumstances under which emergency medical services personnel may administer medications and provides that emergency medical services personnel may administer medications pursuant to an oral or written order or standing protocol. This bill is identical to SB 773.

HB 1501 Pharmacy; collaborative agreements.

Chief patron: O'Bannon

Pharmacy; collaborative agreements. Clarifies parties with whom a pharmacist may enter into a collaborative agreement; provides that a patient who does not wish to participate in a collaborative procedure must notify the prescriber of his decision; and provides that a prescriber may elect to have a patient not participate in a collaborative agreement by contacting the pharmacist or his designated alternative pharmacist or by documenting his decision on the patient's prescription. The bill also clarifies that collaborative agreements may be in writing or in electronic form.

HB 1564 Drugs; administration by a person to a child in private school.

Chief patron: Orrock

Administration of drugs; private schools. Allows the administration of drugs by a person to a child in a private school that is accredited by the Virginia Council for Private Education and exempt from licensure by the Board of Social Services, or in a private school that is accredited by the Virginia Council for Private Education in accordance with standards prescribed by the Board of Education, provided the person has completed an approved training program, obtained written authorization of the parent, and administers drugs dispensed from a pharmacy and maintained in the original labeled container only to the child identified on the prescription label and in accordance with the prescriber's instructions. This bill is identical to SB 807.

HB 1672 Naloxone; administration by unlicensed individual in cases of opiate overdose.

Chief patron: O'Bannon

Naloxone; administration in cases of opiate overdose. Within the context of a pilot program, allows a person to obtain a prescription for and to possess and administer naloxone to a family member or friend for the purpose of counteracting the effects of opiate overdose. The bill also requires the Department of Behavioral Health and Developmental Services to work together with the Department of Health, Department of Health Professions, law-enforcement agencies, substance abuse recovery support organizations, and other stakeholders to conduct pilot programs on the administration of naloxone to counteract the effects of opiate overdose. The bill requires the Department of Behavioral Health and Developmental Services to report on such pilot programs to the General Assembly by December 1, 2014.

HB 1704 Prescription Monitoring Program; disclosure of information to local chief law enforcement officer.

Chief patron: Stolle

Prescription Monitoring Program; disclosure of information to local law enforcement. Adds an agent designated by the chief law-enforcement officer of any county or city to the list of individuals to whom the Department of Health Professions must disclose information relevant to a specific investigation of a specific recipient, dispenser, or prescriber upon request, and provides that agents designated by the superintendent of the Department of State Police or the chief law-enforcement officer of a county or city to receive information relevant to a specific investigation of a specific recipient, dispenser, or prescriber shall have completed the Virginia State Police Drug Diversion School. The bill also provides that the Department may disclose information relating to prescriptions for covered substances issued by a specific prescriber to that prescriber.

HB 1791 Practitioners; suspension of license, etc., by health regulatory agency.

Chief patron: Garrett

Suspension of license, registration, or certificate by a health regulatory agency; practice pending appeal. Prohibits a practitioner of the healing arts whose license, certificate, registration, or permit has been suspended or revoked by a health regulatory board from engaging in practice pending appeal of the board's order.

HB 1941 Cannabinoids, research chemicals, synthetic; penalties. Emergency.

Chief patron: Garrett

Synthetic cannabinoids; research chemicals; penalties. Amends provisions added to the Code in previous years regarding the criminalization of synthetic cannabinoids and chemicals known as "research chemicals" (previously referred to as "bath salts") to add newly identified chemical compounds and structural classes. In addition to adding new chemical compounds as synthetic cannabinoids, the bill adds newly identified structural classes of synthetic cannabinoids so that new chemical compounds that fit within the structural class will nevertheless be considered synthetic cannabinoids without the precise chemical compound having to be added to the Code. The bill contains an emergency clause and incorporates HB 1843.

HB 2136 Methasterone and prostanozol; added to list of Schedule III controlled substances.

Chief patron: Hodges

Adding methasterone and prostanozol to Schedule III. Adds methasterone and prostanozol to Schedule III.

HB 2161 Nurses; authority to possess and administer oxygen to treat emergency medical conditions.

Chief patron: O'Bannon

Nurses; authority to possess and administer oxygen to treat emergency medical conditions. Provides that a prescriber may authorize registered nurses and licensed practical nurses to possess oxygen for administration in treatment of emergency medical conditions.

HB 2181 Medical equipment suppliers; delivery of sterile water and saline.

Chief patron: Hodges

Medical equipment suppliers; delivery of sterile water and saline. Adds sterile water and saline to the list of prescription drugs and devices that a permitted medical equipment supplier may receive, store, and distribute to a consumer.

HB 2312 Pharmacies; clarifies definition of compounding, etc.

Compounding pharmacies. Clarifies the definition of "compounding" and adds a requirement for a current inspection report for registration or renewal of a registration for a nonresident pharmacy.

SB 898 Practitioners; Board of Medicine to revoke license of certain (Twomey bill).

Chief patron: Reeves

Board of Medicine; license revocation (Twomey bill). Provides that a practitioner whose license has been revoked due to engaging in sexual contact with a patient under certain circumstances may not apply for reinstatement of such license until five years have passed since revocation. Under current law, the person may apply for reinstatement after three years.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3401, 54.1-3434.1, and 54.1-3457 of the Code of Virginia and to amend the Code of Virginia by adding a section numbered 54.1-3408.04, relating to dispensing of interchangeable biosimilar biological products.

[H 1422]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3434.1, and 54.1-3457 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding a section numbered 54.1-3408.04 as follows:

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a single preparation and includes the mixing, assembling, packaging, or labeling of a drug or device (i) by

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

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

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; ~~or~~ (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii)*; or (v) a biological product*. "Drug" does not include devices or their components, parts, or accessories.

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

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

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

"FDA" means the ~~United States~~ *U.S.* Food and Drug Administration.

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

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

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

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

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

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

"Manufacturer" means every person who manufactures.

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

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

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

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

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

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

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

provided then on an official form provided for that purpose by the Board of Pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

known as the "Orange Book."

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

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

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

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

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

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

§ 54.1-3408.04. Dispensing of interchangeable biosimilars permitted.

A. A pharmacist may dispense a biosimilar that has been licensed by the U.S. Food and Drug Administration as interchangeable with the prescribed product unless (i) the prescriber indicates such substitute is not authorized by specifying on the prescription "brand medically necessary" or (ii) the patient insists on the dispensing of the prescribed biological product. In the case of an oral prescription, the prescriber's oral dispensing instructions regarding dispensing of an interchangeable biosimilar shall be followed. No pharmacist shall dispense a biosimilar in place of a prescribed biological product unless the biosimilar has been licensed as interchangeable with the prescribed biological product by the U.S. Food and Drug Administration.

B. When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall inform the patient prior to dispensing the interchangeable biosimilar. The pharmacist or his designee shall also indicate, unless otherwise directed by the prescriber, on both the record of dispensing and the prescription label, the brand name or, in the case of an interchangeable biosimilar, the product name and the name of the manufacturer or distributor of the interchangeable biosimilar. Whenever a pharmacist substitutes an interchangeable biosimilar pursuant to a prescription written for a brand-name product, the pharmacist or his designee shall label the drug with the name of the interchangeable biosimilar followed by the words "Substituted for" and the name of the biological product for which the prescription was written. Records of substitutions of interchangeable biosimilars shall be maintained by the pharmacist and the prescriber for a period of not less than two years from the date of dispensing.

C. When a pharmacist dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall provide electronic, written, or telephonic notification of the substitution to the prescriber or his staff within five business days of dispensing the interchangeable biosimilar or as set forth in a collaborative agreement as defined in § 54.1-3300.

D. Whenever a pharmacist or his designee dispenses an interchangeable biosimilar in the place of a prescribed biological product, the pharmacist or his designee shall provide the patient with retail cost information for both the prescribed biological product and the interchangeable biosimilar. For the purposes of this subsection, "retail cost" means the actual cost to be paid by a retail purchaser to a pharmacy for a drug at the prescribed dosage and amount.

§ 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.

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

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

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

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

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

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

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

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

§ 54.1-3457. Prohibited acts.

The following acts shall be prohibited:

1. The manufacture, sale, ~~or~~ delivery, holding, or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded.

2. The adulteration or misbranding of any drug, device, or cosmetic.

3. The receipt in commerce of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

4. The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of § 54.1-3421.

5. The dissemination of any false advertisement.

6. The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record.

7. The giving of a false guaranty or undertaking.

8. The removal or disposal of a detained article in violation of § 54.1-3459.

9. The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a drug, device, or cosmetic, if such act is done

while such article is held for sale and results in such article being adulterated or misbranded.

10. The forging, counterfeiting, simulating, or falsely representing, or without proper authority using *of* any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of this chapter or of the federal act.

11. The using by any person to his own advantage, or revealing, other than to the Board or its authorized representative or to the courts when relevant in any judicial proceeding under this chapter of any information acquired under authority of this chapter concerning any method or process which as a trade secret is entitled to protection.

12. The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under § 54.1-3421, or that such drug complies with the provisions of such section.

13. In the case of a drug distributed or offered for sale in this Commonwealth, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. This subdivision shall not be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.

14. Placing or causing to be placed upon any drug or device or container, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or selling, dispensing, disposing of, or causing to be sold, dispensed, or disposed of, or concealing or keeping in possession, control, or custody, with intent to sell, dispense, or dispose of, any drug, device, or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by this section or making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

15. The doing of any act ~~which~~ *that* causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing, of a counterfeit drug.

16. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the permission of the person ordering or prescribing, except as provided in § 54.1-3408.03 relating to dispensing of therapeutically equivalent drugs.

17. Dispensing or causing to be dispensed a biosimilar in place of a prescribed biological product or brand of biological product, except as provided in § 54.1-3408.04 related to dispensing of interchangeable biosimilars.

2. That the provisions of subsections C and D of § 54.1-3408.04 as added by this act shall expire on July 1, 2015.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-3300 and 54.1-3300.1 of the Code of Virginia, relating to pharmacy; collaborative agreements.

[H 1501]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3300 and 54.1-3300.1 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-3300. Definitions.

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

"Board" means the Board of Pharmacy.

"Collaborative agreement" means a voluntary, written, *or electronic* arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a *single physical* location where patients receive services and ~~a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners~~ *(i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900,* involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling, or compounding necessary to prepare the substance for delivery.

"Pharmacist" means a person holding a license issued by the Board to practice pharmacy.

"Pharmacy" means every establishment or institution in which drugs, medicines, or medicinal chemicals are dispensed or offered for sale, or a sign is displayed bearing the word or words "pharmacist," "pharmacy," "apothecary," "drugstore," "druggist," "drugs," "medicine store," "drug sundries," "prescriptions filled," or any similar words intended to indicate that the practice of pharmacy is being conducted.

"Pharmacy intern" means a student currently enrolled in or a graduate of an approved school of pharmacy who is registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

"Pharmacy technician" means a person registered with the Board to assist a pharmacist under the pharmacist's supervision.

"Practice of pharmacy" means the personal health service that is concerned with the art and science of selecting, procuring, recommending, administering, preparing, compounding, packaging, and dispensing of drugs, medicines, and devices used in the diagnosis, treatment, or prevention of disease, whether compounded or dispensed on a prescription or otherwise legally dispensed or distributed, and shall include the proper and safe storage and distribution of drugs; the maintenance of proper records; the responsibility of providing information concerning drugs and medicines and their therapeutic values and uses in the treatment and prevention of disease; and the management of patient care under the terms of a collaborative agreement as defined in this section.

"Supervision" means the direction and control by a pharmacist of the activities of a pharmacy intern or a pharmacy technician whereby the supervising pharmacist is physically present in the pharmacy or in the facility in which the pharmacy is located when the intern or technician is performing duties restricted to a pharmacy intern or technician, respectively, and is available for immediate oral communication.

Other terms used in the context of this chapter shall be defined as provided in Chapter 34 (§ 54.1-3400 et seq.) ~~of this title~~ unless the context requires a different meaning.

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the

Boards of Medicine and Pharmacy.

A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with ~~a practitioner of medicine, osteopathy, or podiatry and his designated alternate practitioners~~ *(i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided such collaborative agreement is signed by each physician participating in the collaborative practice agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working as part of a patient care team as defined in § 54.1-2900,* involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions ~~and/or~~ *or* limitations, for the purpose of improving patient outcomes. *However, no person licensed to practice medicine, osteopathy, or podiatry shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.*

No patient shall be required to participate in a collaborative procedure without such patient's consent. *A patient who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.*

Collaborative agreements may include the *implementation,* modification, continuation, or discontinuation of drug therapy pursuant to written~~, patient specific~~ *or electronic* protocols, *provided implementation of drug therapy occurs following diagnosis by the prescriber*; the ordering of laboratory tests; or other patient care management measures related to monitoring or improving the outcomes of drug or device therapy. No such collaborative agreement shall exceed the scope of practice of the respective parties. Any pharmacist who deviates from or practices in a manner inconsistent with the terms of a collaborative agreement shall be in violation of § 54.1-2902; such violation shall constitute grounds for disciplinary action pursuant to §§ 54.1-2400 and 54.1-3316.

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

ENROLLED

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 54.1-2408.1, 54.1-3401, 54.1-3410.2, 54.1-3434.1, and 54.1-3434.2 of the Code of Virginia, relating to compounding pharmacies.

[H 2312]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-2408.1, 54.1-3401, 54.1-3410.2, 54.1-3434.1, and 54.1-3434.2 of the Code of Virginia are amended and reenacted as follows:

§ 54.1-2408.1. Summary action against licenses, certificates, registrations, or multistate licensure privilege; allegations to be in writing.

A. Any health regulatory board may suspend the license, certificate, registration, *permit,* or multistate licensure privilege of any person holding a license, certificate, registration, *permit,* or licensure privilege issued by it without a hearing simultaneously with the institution of proceedings for a hearing, if the relevant board finds that there is a substantial danger to the public health or safety which warrants this action. A board may meet by telephone conference call when summarily suspending a license, certificate, registration, *permit,* or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. Institution of proceedings for a hearing shall be provided simultaneously with the summary suspension. The hearing shall be scheduled within a reasonable time of the date of the summary suspension.

B. Any health regulatory board may restrict the license, certificate, registration, *permit,* or multistate licensure privilege of any person holding a license, certificate, registration, *permit,* or licensure privilege issued by it without proceeding simultaneously with notification of an informal conference pursuant to §§ 2.2-4019 and 54.1-2400, if the relevant board finds that there is a substantial danger to the public health or safety that warrants this action. A board may meet by telephone conference call when summarily restricting a license, certificate, registration, *permit,* or licensure privilege if a good faith effort to assemble a quorum of the board has failed and, in the judgment of a majority of the members of the board, the continued practice by the individual constitutes a substantial danger to the public health or safety. The informal conference shall be scheduled within a reasonable time of the date of the summary restriction.

C. Allegations of violations of this title shall be made in writing to the relevant health regulatory board.

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

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

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

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; or (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii) or (iii). "Drug" does not include devices or their components, parts or accessories.

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

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

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

"FDA" means the United States Food and Drug Administration.

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

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

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

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

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

"Manufacturer" means every person who manufactures.

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

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

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

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

conditions.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

A pharmacist may also provide compounded products to practitioners of medicine, osteopathy, podiatry, dentistry, or veterinary medicine to administer to their patients in the course of their professional practice, either personally or under their direct and immediate supervision.

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

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

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

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

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary

monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

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

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

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

H. Pharmacists shall not engage in the following:

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

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

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

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

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

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

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

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

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

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a non-resident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver

a sterile compounded drug product into the Commonwealth. Upon renewal, a pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 or Chapter 34 of this title. The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

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

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

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

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

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

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

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

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

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

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

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

container of drugs dispensed to patients in the Commonwealth.

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

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

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

§ 54.1-3434.2. Permit to be issued.

The Board shall only register nonresident pharmacies that maintain a current unrestricted license, certificate, permit, or registration as a pharmacy in a jurisdiction within the United States, or within another jurisdiction that may lawfully deliver prescription drugs directly or indirectly to consumers within the United States.

Applications for a nonresident pharmacy registration, under this section, shall be made on a form furnished by the Board. The Board may require such information as it deems is necessary to carry out the purpose of the section.

The permit or nonresident pharmacy registration shall be renewed annually on a date determined by the Board in regulation. Renewal is contingent upon the nonresident pharmacy providing documentation of *a current inspection report in accordance with subdivision A 3 of § 54.1-3434.1;* continuing current, unrestricted licensure in the resident jurisdiction; and continuing certification if required in subdivision A 4 of § 54.1-3434.1.

Report of the Status of Regulatory Actions
(As of February 26, 2013)

Board of Pharmacy

Chapter	Action / Stage Information
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Addressing hours of continuous work by pharmacists Stage: NOIRA - *Register Date: 9/10/12* *Proposed adopted 12/12; DPB review in progress*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Administrative fees for duplicate licenses and verification Stage: Proposed - *At Secretary's Office for 572 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: NEW Less restrictive and burdensome record-keeping for on-hold prescriptions Stage: Proposed - *At Governor's Office for 284 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: NEW Modifications to requirements for automated dispensing devices for less burdensome process Stage: Proposed - *At Governor's Office for 119 days*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: Continuous quality improvement programs Stage: Proposed - *DPB Review in progress*
Virginia Board of Pharmacy Regulations [18 VAC 110 - 20]	Action: NEW Change to run-dry requirement for automated counting devices Stage: Fast-Track - *At Secretary's Office for 85 days*
Regulations for Practitioners of the Healing Arts to Sell Controlled Substances [18 VAC 110 - 30]	Action: NEW Regulatory reform Stage: Fast-Track - *DPB Review in progress*
Regulations Governing Wholesale Distributors, Manufacturers and Warehousers [18 VAC 110 - 50]	Action: NEW Regulatory reform Stage: Fast-Track - *DPB Review in progress*

COMMONWEALTH of VIRGINIA

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

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MEMORANDUM

TO: Members, Board of Pharmacy

FROM: Dianne L. Reynolds-Cane, M.D.

DATE: February 27, 2013

SUBJECT Revenue, Expenditures, & Cash Balance Analysis

Virginia law requires that an analysis of revenues and expenditures of each regulatory board be conducted at least biennially. If revenues and expenditures for a given board are more than 10% apart, the Board is required by law to adjust fees so that the fees are sufficient, but not excessive, to cover expenses. The action by the Board can be a fee increase, a fee decrease, or it can maintain the current fees.

The Board of Pharmacy ended the 2010 - 2012 biennium (July 1, 2010, through June 30, 2012) with a cash balance of $1,932,721. Current projections indicate that revenue for the 2012 - 2014 biennium (July 1, 2012, through June 30, 2014) will exceed expenditures by approximately $522,405. When combined with the Board's $1,932,721 cash balance as of June 30, 2012, the Board of Pharmacy projected cash balance on June 30, 2014, is $2,455,126.

We recommend no action to change license fees be taken at this time. Please note that these projections are based on internal agency assumptions and are, therefore, subject to change based on actions by some other state agencies, the Governor and\or the General Assembly.

We are grateful for continued support and cooperation as we work together to manage the fiscal affairs of the Board and the Department.

Please do not hesitate to call me if you have questions.

CC: Caroline Juran, Executive Director
Arne Owens, Chief Deputy Director
Mark Monson, Deputy Director of Administration
Charles Giles, Budget Manager
Elaine Yeatts, Senior Policy Analyst

FREE CLINIC
OF FRANKLIN COUNTY, INC.

490 South Main Street
P.O. Box 764
Rocky Mount, VA 24151
Phone: 540-489-7500 Fax: 540-489-7502

Virginia Board of Pharmacy
9960 Mayland Drive #300
Henrico, Virginia 23233

October 28, 2012

Attention: Cathy Reiniers-Day, Deputy Executive Director
Subject: Free Clinic of Franklin County, Inc. (FCFC)

Dear Ms. Reiniers-Day:

We ask the Pharmacy Board's consultation and help in addressing the issues of providing free prescriptions to the uninsured poor of Franklin County.

As you know, free clinics provide primary health care to the uninsured, poor of their communities. If the person is poor enough to qualify for *free* services, they certainly do not have money for the (expensive) prescriptions needed for treatment. To operate without the capability of providing prescriptions to support the patient's treatment plan is like one hand clapping. Nothing happens; and we have deluded ourselves if we think we are helping the less fortunate to achieve better health. For people who are uninsured or underinsured the cost of their prescription(s) may be a serious barrier preventing them from taking medication as directed by their doctor. The result is that patients are sicker, access to the healthcare system is more often (i.e. ER visits and hospitalizations), there are unnecessary (sometimes permanent) complications due to inadequate treatment, and there are overall higher healthcare costs for everyone. The health of the entire community is affected. Free clinics with pharmacies are in a unique position to help the poor to attain and maintain health.

In order for free clinics to address the primary health care needs of the uninsured, they sometimes need special consideration with regards to daily operations. For instance: Because of a critical need for help in free clinics, the Board of Medicine provides volunteer physicians with a temporary license to work in a free clinic within five days vs. a six-month licensing process; and the Board of Medicine has provided a special continuing waiver for our physician assistant to work in our rural clinic, full-time. Both of these considerations have limitations, but they have enabled our Clinic to remain open and continue to provide primary health care services to the uninsured poor of the county.

It is conceivable that Free Clinics (and FCFC, specifically) are unique facilities and -- because of their societal impact -- should not be held to the same standards as a commercial/retail pharmacy. For instance:

- FCFC is 501(c) 3 organization. The Clinic is totally supported by volunteers, grants, monetary, and in-kind community donations;

- All patients receiving prescriptions are registered at Clinic and are below 200% of the Federal Poverty Guidelines. Both primary healthcare and prescriptions are provided at *no* charge to the patient;

- Most drugs are donated through the RxP and TPC Programs. The Clinic purchases a limited number of generic drugs that cannot be obtained through donations -- and which are required for the appropriate treatment of our registered patients. All drugs and prescriptions are documented in our QS1 Computer Program and reported monthly to the programs that supply the medications;

- Except for packaging medications, the pharmacy does not even resemble a commercial pharmacy (no patient access, limited hours of operation, no charge for prescriptions, drugs are donated for dispensing, etc.);

- Since there are no charges to the patients for the drugs, FCFC earns no income from the medications we dispense.

- Some free clinics are staffed by volunteers. Because of our MUA and HPSA status, local volunteers are not available and pharmacist staff travel 80 mile roundtrip to provide services. Although paid staff adds to the cost of services, it adds a high level of accountability to the service;

- We have a severely limited formulary (i.e. 1-2 drugs/category). The FCFC formulary addresses very basic primary health care services and contains no Schedule II-V drugs.

- Patients receiving medications at FCFC are treated only by *our* providers for services rendered within the Clinic. A prescription is written and maintained in the patient's chart and in the pharmacy.

- We receive a large amount of donated drugs for individuals through the MAP Program. These must be stored in a closet until a pharmacist is available. No room in the facility is as secure as the pharmacy with its security alarm system. It is the only room in the building that cleaners do not have access and patients do not enter.

Importantly, free clinics operate to the degree possible on the use of volunteers and donations. It is primarily volunteerism and donations-in-kind that allow the clinic to provide health care services to large numbers of those who would, otherwise, not have access to continuing health care. Conflicting with volunteerism, some counties (i.e. Franklin County) are designated as medically underserved (MUA) and a Health Care Professional Shortage Area (HPSA) so that it is virtually impossible to find qualified personnel to volunteer. Paid staff is not only the most expensive component of providing services, but it decreases funds that could be used for care. We are proud that every dollar donated to the Free Clinic of Franklin County, Inc., the Clinic provides $7.45 in services. Unfortunately, the Clinic has had to pay our pharmacist, not only an hourly fee, but mileage to commute from Vinton to Rocky Mount. This is becoming unsustainable in today's economic market; when we need to further maximize every dollar donated to the Clinic.

In thinking about our situation and reviewing the Virginia Board of Pharmacy regulation, it became clear that the Board of Pharmacy has levels of licensure for atypical pharmacies or special needs. For instance, there are regulations for:

- Hospitals

- Long-term Care Facilities

- Correctional Facilities
- Drug donation site(s) which allows a pharmacy that specifically registers with the board for the purpose of receiving or re-dispensing eligible donated prescription drugs
- Nuclear pharmacy allows a pharmacy to provide limited services (i.e. a dio-pharmaceutical services)
- Physicians are allowed to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available
- "Special use permit" is issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation
- Drugs in infirmaries/first aid rooms which allows for administering (? dispensing) to those persons served by that facility. Access to the drugs is by a staff member who is under the direction and supervision of a *practitioner*
- Humane Society permit. (Does a veterinarian have a pharmacy license?)
- Manufacturing: FCFC does not manufacture or compound medications
- Wholesaling: where "stock" prescription drugs are *distributed*

I understand these categories don't necessarily apply to free clinics; however, it is obvious the Board has addressed special situations -- *and that is my appeal* – that a special consideration, waivers, or a category be considered for free clinics based on our uniqueness and societal effect.

For instance, 18VAC110-20-120, provides for special or limited-use pharmacy permits in situations where the scope, degree or type of pharmacy practice or service to be provided is of a "special, limited or unusual nature *as compared to a regular pharmacy service"*. This permit is issued based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. For instance, I understand, "For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190". The pharmacy regulation addresses PIC absentism, supervision, and patient access to prescriptions and records. These elements, obviously, do not apply to free clinics. It appears the regulations were written for commercial/retail pharmacies; and free clinics – with specialized attributes and needs -- have developed subsequently.

Pharmacy services are constantly evolving. For instance, since the emergence of modern clinical pharmacy, "ambulatory care pharmacy practice" is becoming a unique pharmacy practice setting. This new category is based primarily on pharmacotherapy services that a pharmacist provides in a clinic setting. Is it possible to consider our clinic practice in a different light (i.e. an ambulatory care clinic pharmacy) other than that of a Walgreen, CVS, or Kroger Pharmacy – or, even, as a free clinic with limited waiver(s)?

I am, therefore, requesting the Board of Pharmacy to consider viewing free clinics as highly specialized service which does not meet the criteria of a commercial/retail pharmacy. Can you help us maximize our donations by allowing licensed (employee) providers (MD, PA, FNP) to directly supervise pharmacy activities under the general supervision of a pharmacist, who will be onsite at least once weekly? This would allow us to prepare prescriptions for the pharmacist's review and maximize the hourly rate of this individual with staff who are already in the Clinic. Prescriptions would only be prepared by a certified pharmacy technician (employee) in a secured area – not accessible by non-licensed/non-pharmacy personnel or patients. Another proposed option could be to allow the pharmacy technician to begin preparing the medication 1-2 hours before the pharmacist arrives to supervise and approve the preparation of medications before dispensing them. The pharmacist's time would be maximized and our costs would be reduced.

If our request cannot be entertained, could you help us in any way to accomplish our pharmacy service to the uninsured patient using donations to the maximum benefit?

I realize I am requesting a unique solution to a unique problem; however, I believe the Board of Pharmacy is sensitive to the plight of uninsured patients and the services free clinics provide. Free clinics can provide a better health care safety net to the uninsured by minimizing costs, maximizing donations, and working together to accomplish the goals and objectives of the clinics and agencies that supervise and regulate them.

We appreciate your consideration of our request.

Sincerely,

Lois B. Macdonald
Executive Director

CC: Duane Lenart, PIC
John Merten, Medical Director
Audrey Matherly, Board Chair
File

Virginia Board of Pharmacy
Guidance for Free Clinic Pharmacy Applicants

Free clinics applying for a pharmacy permit which do not have a need for a full service pharmacy should apply for a special or limited-use permit as described in section 18 VAC 10-20-120 of the Virginia Board of Pharmacy Regulations and submit the required information with the application and fee. While waivers are granted by the Board on an individual case basis after considering the merit of each such request, the Board will normally waive certain provisions of the below regulation for free clinic pharmacies:

18 VAC 110-20-150-Physical Standards

- the size requirement of 240 square feet provided there is adequate room inside the enclosure for both storage of drug inventory, equipment, and records and for working space.

- the sink being inside the pharmacy provided there is a sink with hot and cold running water in close proximity which is not a bathroom sink.

The Board typically requires that the provisions of 18 VAC 110-20-180 concerning the burglar alarm system and 18 VAC 110-20-190 concerning enclosures be met. A free clinic pharmacy may request a waiver of 18 VAC 110-20-190 (C) for the purpose of securing a drug order in the pharmacy if it is absolutely necessary that drugs be delivered in the absence of a pharmacist or for the purpose of repairing or upgrading essential pharmacy equipment when those repairs or upgrades cannot be reasonably performed while a pharmacist is present. A request for this waiver will be very closely scrutinized and granted at the discretion of the Board, if deemed necessary and appropriate, and only then under the specific conditions of 18 VAC 110-20-120 (B).

18VAC110-20-120. Special or limited-use pharmacy permits.

A. For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.

3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the following conditions:

1. The access is only for the purpose of repairing or upgrading essential equipment or for the purpose of securing a delivered drug order in the pharmacy.

2. The PIC shall be notified prior to each entry and give permission for the designated, specific individuals to enter.

3. If entry is by a nonpharmacist, two persons must enter together, one of whom must be an employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician assistant. Both persons must remain in the pharmacy the entire time that access is required.

4. The key or other means of unlocking the pharmacy and the alarm access code shall be maintained in a secure location within the facility in a sealed envelope or other container with the name of the "sealing" pharmacist written across the seal. If a nonpharmacist accesses the pharmacy, this means of access may be used, and the licensed health professional, as set forth in subdivision 3 of this subsection, is responsible for resealing the means of access and writing his name across the seal. The PIC shall ensure that the alarm access code is changed within 48 hours. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

5. A log must be maintained of each nonpharmacist entry showing date and time of entry, names of the two persons entering, purpose for entry, and notation that permission was granted by the pharmacist-in-charge and the date it was granted. Such log shall be maintained on premises for one year.

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

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

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

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

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

B. The keys or other means of entry into a locked prescription department and the alarm access code shall be restricted to pharmacists practicing at the pharmacy and authorized by the PIC with the following exceptions:

1. The PIC or a pharmacist on duty, for emergency access, may place a key or other means of unlocking the prescription department and the alarm access code in a sealed envelope or other container with the pharmacist's signature across the seal in a safe or vault or other secured place within the pharmacy. This means of emergency access shall only be used to allow entrance to the prescription department by other pharmacists, or by a pharmacy technician in accordance with subsection D of this section. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.

2. Pharmacy interns, pharmacy technicians, and other persons authorized by the PIC or pharmacist on duty may possess a key or other means of entry into a locked prescription department only when a pharmacist is on duty. Such key or other means of entry shall not allow entry when a pharmacist is not on duty.

C. The prescription department is restricted to pharmacists who are practicing at the pharmacy. Pharmacy interns, pharmacy technicians, and other persons designated by the pharmacist on duty may be allowed access by the pharmacist but only when the pharmacist is on duty. Each pharmacist while on duty shall be responsible for the security of the pharmacy, including provisions for effective control against theft or diversion of prescription drugs and devices.

D. Upon a request by a patient to obtain an already-dispensed prescription, a pharmacy technician may enter the pharmacy for the sole purpose of retrieving filled prescriptions that have already been reviewed and certified for accuracy by a pharmacist and deemed ready for delivery to the patient if:

1. There is an unforeseen, unplanned absence of a pharmacist scheduled to work during regular prescription department hours;

2. Alternate pharmacist coverage cannot immediately be obtained;

3. The technician is accompanied by a member of the pharmacy's management or administration; and

4. All requirements of subsection E of this section are met.

E. Requirements for entry into the prescription department in the absence of a pharmacist.

1. The requirements for prescriptions awaiting delivery in subsection A of 18VAC110-20-200 are followed.

2. Prior to entry into the prescription department, the pharmacy technician shall obtain verbal permission from the PIC or another pharmacist regularly employed by that pharmacy to obtain and use the emergency key or other access and alarm access code and enter the pharmacy.

3. A record shall be made by the pharmacy technician of the entry to include the date and time of entry; the name and signature of the pharmacy technician; the name, title, and signature of the person accompanying the pharmacy technician; the pharmacist's name granting permission to enter and telephone number where the pharmacist was reached; the name of the patient initially requesting needed medication and the nature of the emergency; a listing of all prescriptions retrieved during that entry; and the time of exit and re-securing of the prescription department.

4. The pharmacy technician shall reseal the key and alarm access code after the pharmacy is re-secured, and the PIC shall have the alarm access code changed within 48 hours of such an entry and shall document that this has been accomplished on the record of entry.

5. All records related to entry by a pharmacy technician shall be maintained for a period of one year on premises.

"annual" and "semiannual" be defined to mean every twelve and six months, respectively. Additionally, she indicated that the information in the document was somewhat outdated and the other suggested changes as presented in the draft document were to simply update the information.

MOTION:

The Board voted unanimously to adopt the amended Guidance Document 110-36 as presented.
(motion by Rhodes, second by Munden)

- Establish threshold for compliance in guidance document 110-9

The Board discussed whether a threshold was appropriate when determining compliance with annual and semiannual requirements for media fill testing found in Major Deficiencies 25 and 26 in Guidance Document 110-9. Mr. Adams believed a 60-day threshold was too long.

MOTION:

A motion was made to accept the suggested changes to Major Deficiencies 25 and 26 as presented within Guidance Document 110-9, but without the suggested 60-day threshold. (motion by Adams, died for lack of second)

MOTION:

A new motion was made to accept the suggested changes to Major Deficiencies 25 and 26 as presented within Guidance Document 110-9 which included the suggested 60-day threshold. (motion by Yi, died for lack of second)

MOTION:

The Board voted unanimously to amend Major Deficiencies 25 and 26 in Guidance Document 110-9 to include the following thresholds when determining compliance:

- **Major Deficiency 25 = 14-day threshold added, i.e., inspector will not cite deficiency until 15 days after the required due date of the semi-annual media fill testing for high-risk level CSPs;**
- **Major Deficiency 26 = 30-day threshold added, i.e., inspector will not cite deficiency until 31 days after the required due date of the annual media fill testing for low and medium-risk levels. (motion by Rhodes, second by Adams)**

- Evaluation and revision of Sanction Reference Point System:

Neal Kauder presented to the Board a slide presentation reviewing the suggested evaluation and revision process of the Sanction Reference Point System (SRPS). The Board adopted the SRPS in guidance document 110-21 in September 2007 and he recommended that it may be time to evaluate its effectiveness and determine if it remains consistent with Board policies. He stated that other boards such as Medicine and Nursing have recently concluded this evaluation process which did result in some changes.

MOTION:

The Board voted unanimously that the Board of Health Professions evaluate the effectiveness of the Board of Pharmacy's Sanction Reference Point System. (motion by Kozera, second by Yi)

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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

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.	18VAC110-20-180		250
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
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200		250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V	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	54.1-3434 and 18VAC110-20-240		500
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240		250
16. Theft/unusual 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 (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
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 or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	10% threshold	250
20a. Pharmacist not documenting final verification of non-sterile compounding	54.1-3410.2, 18VAC110-20-355		500
20b. Pharmacist not documenting final verification of sterile compounding	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2		10000
22. Certification of the direct compounding area (DCA) for CSPs indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; *certification must be performed no later than the last day of the sixth month from the previous certification*	3000
23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.	54.1-3410.2	Review 2 most recent reports; *certification must be performed no later than the last day of the sixth month from the previous certification*	1000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
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 high risk CSPs assigned inappropriate beyond use date (BUD)	54.1-3410.2		5000 per incident up to 3 incidents; schedule for IFC for > 3 incidents
25a. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level CSPs	54.1-3410.2		5000
25b. High-risk drugs intended for use are improperly stored	54.1-3410.2		5000 per incident up to 3 incidents; schedule for IFC for > 3 incidents
25c. 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	54.1-3410.2		5000 per incident up to 3 incidents; schedule for IFC for > 3 incidents
26. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level CSPs	54.1-3410.2		500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
26a. ~~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~~ *Documentation that a person who failed a media-fill test has performed low or medium risk level CSPs after receipt of the negative test result and prior to retraining and receipt of passing 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
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk CSPs assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports	*18VAC110-20-418*	*20% threshold*	*250*
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	*18VAC110-20-395*		*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. Repealed 6/2011		
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, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on label of returned drug, mixing lot numbers in stock container)	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold

Minor Deficiency	Law/Regulation Cite	Conditions
10. Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
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, 54.1-3434 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. 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
17. Minor 17 combined with Minor 16 – 6/2011		
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, 18VAC110-20-255,18VAC110-20-310, 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	

Minor Deficiency	Law/Regulation Cite	Conditions
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	
24. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
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 Review 25 prescriptions
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	54.1-3410.2	
30a. Compounded products not properly labeled	54.1-3410.2	
31. Required "other documents" for USP 797 listed on inspection report are not appropriately maintained	54.1-3410.2	
32. Personnel performing CSPs do not comply with cleansing and garbing requirements	54.1-3410.2	

Minor Deficiency	Law/Regulation Cite	Conditions
33. Compounding facilities and equipment used in performing non-sterile compounds not in compliance	54.1-3410.2	
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	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
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	

Minor Deficiency	Law/Regulation Cite	Conditions
42. *Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance*	*18VAC110-20-418*	

§ 54.1-3300. Definitions.

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

"Dispense" means to deliver a drug to an ultimate user or research subject by or pursuant to the lawful order of a practitioner, including the prescribing and administering, packaging, labeling or compounding necessary to prepare the substance for delivery.

§ 54.1-3302. Restrictions on practitioners of the healing arts.

A practitioner of the healing arts shall not sell or dispense controlled substances except as provided in §§ 54.1-2914 and 54.1-3304.1. Such exceptions shall extend only to his own patients unless he is licensed to practice pharmacy.

§ 54.1-3304. Licensing of physicians to dispense drugs; renewals.

For good cause shown, the Board may grant a license to any physician licensed under the laws of Virginia authorizing such physician to dispense drugs to persons to whom a pharmaceutical service is not reasonably available. This license may be renewed annually. Any physician or osteopath so licensed shall be governed by the regulations of the Board of Pharmacy when applicable.

§ 54.1-3401. Definitions.

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

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

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

Virgina Department of Health Professions
Cash Balance
As of January 31, 2013

	107- Pharmacy
Board Cash Balance as of June 30, 2012	$ 1,932,721
YTD FY13 Revenue	1,853,635
Less: YTD FY13 Direct and In-Direct Expenditures	1,590,888
Cash Balance as of January 31, 2013	2,195,467

Virginia Dept. of Health Professions
Revenue and Expenditures Summary
July 1, 2012 through January 31, 2013

	107- Pharmacy			
	Jul '12 - Jan 13	Budget	$ Over Budget	% of Budget
Revenue				
2400 · Fee Revenue				
2401 · Application Fee	187,255.00	299,010.00	-111,755.00	62.63%
2402 · Examination Fee	0.00			
2406 · License & Renewal Fee	1,602,030.00	2,336,295.00	-734,265.00	68.57%
2407 · Dup. License Certificate Fee	0.00	100.00	-100.00	0.0%
2408 · Board Endorsement - In	0.00			
2409 · Board Endorsement - Out	0.00			
2421 · Monetary Penalty & Late Fees	15,630.00	6,220.00	9,410.00	251.29%
2430 · Board Changes Fee	36,850.00	42,500.00	-5,650.00	86.71%
2432 · Misc. Fee (Bad Check Fee)	35.00	175.00	-140.00	20.0%
Total 2400 · Fee Revenue	1,841,800.00	2,684,300.00	-842,500.00	68.61%
3000 · Sales of Prop. & Commodities				
3002 · Overpayments	0.00			
3007 · Sales of Goods/Svces to State	0.00			
3020 · Misc. Sales-Dishonored Payments	-60.00			
Total 3000 · Sales of Prop. & Commodities	-60.00			
9000 · Other Revenue				
9060 · Miscellaneous Revenue	10,534.05	750.00	9,784.05	1,404.54%
9084 · Refund- Prior Yr Disb	1,360.46			
Total 9000 · Other Revenue	11,894.51	750.00	11,144.51	1,585.94%
Total Revenue	1,853,634.51	2,685,050.00	-831,415.49	69.04%
Expenditures				
1100 · Personal Services				
1110 · Employee Benefits				
1111 · Employer Retirement Contrib.	24,481.00	39,831.00	-15,350.00	61.46%
1112 · Fed Old-Age Ins- Sal St Emp	21,525.14	35,363.00	-13,837.86	60.87%
1113 · Fed Old-Age Ins- Wage Earners	2,655.71	5,544.00	-2,888.29	47.9%
1114 · Group Insurance	3,349.53	5,411.00	-2,061.47	61.9%
1115 · Medical/Hospitalization Ins.	39,586.00	60,852.00	-21,266.00	65.05%
1116 · Retiree Medical/Hospitalizatn	2,839.86	4,547.00	-1,707.14	62.46%
1117 · Long term Disability Ins	1,371.59	2,138.00	-766.41	64.15%
Total 1110 · Employee Benefits	95,808.83	153,686.00	-57,877.17	62.34%
1120 · Salaries				
1123 · Salaries, Classified	284,177.70	454,685.00	-170,507.30	62.5%
1125 · Salaries, Overtime	0.00			
Total 1120 · Salaries	284,177.70	454,685.00	-170,507.30	62.5%
1130 · Special Payments				
1131 · Bonuses and Incentives	13,640.00	13,641.00	-1.00	99.99%
1138 · Deferred Compnstn Match Pmts	1,650.00	3,360.00	-1,710.00	49.11%
Total 1130 · Special Payments	15,290.00	17,001.00	-1,711.00	89.94%
1140 · Wages				

Virginia Dept. of Health Professions
Revenue and Expenditures Summary
July 1, 2012 through January 31, 2013

	107- Pharmacy			
	Jul '12 - Jan 13	Budget	$ Over Budget	% of Budget
1141 · Wages, General	34,684.28	72,458.00	-37,773.72	47.87%
1143 · Wages, Overtime	30.79			
Total 1140 · Wages	34,715.07	72,458.00	-37,742.93	47.91%
1150 · Disability Benefits				
1153 · Short-trm Disability Benefits	0.00			
Total 1150 · Disability Benefits	0.00			
1160 · Terminatn Personal Svce Costs				
1162 · Salaries, Annual Leave Balanc	0.00			
1165 · Employee Retirement Contributio	0.00	0.00	0.00	0.0%
Total 1160 · Terminatn Personal Svce Costs	0.00	0.00	0.00	0.0%
Total 1100 · Personal Services	429,991.60	697,830.00	-267,838.40	61.62%
1200 · Contractual Services				
1210 · Communication Services				
1211 · Express Services	0.00	172.00	-172.00	0.0%
1212 · Outbound Freight Services	0.00	0.00	0.00	0.0%
1213 · Messenger Services	0.00			
1214 · Postal Services	22,797.56	34,904.00	-12,106.44	65.32%
1215 · Printing Services	173.84	301.00	-127.16	57.75%
1216 · Telecommunications Svcs (DIT)	3,799.45	7,200.00	-3,400.55	52.77%
1219 · Inbound Freight Services	0.00			
Total 1210 · Communication Services	26,770.85	42,577.00	-15,806.15	62.88%
1220 · Employee Development Services				
1221 · Organization Memberships	0.00	805.00	-805.00	0.0%
1222 · Publication Subscriptions	295.00	1,005.00	-710.00	29.35%
1224 · Emp Trning Courses, Wkshp & Cnf	2,968.74	0.00	2,968.74	100.0%
1225 · Employee Tuition Reimbursement	0.00			
1227 · Emp Trning- Trns, Ldgng & Meals	0.00			
Total 1220 · Employee Development Services	3,263.74	1,810.00	1,453.74	180.32%
1230 · Health Services				
1236 · X-ray and Laboratory Services	221.36	258.00	-36.64	85.8%
Total 1230 · Health Services	221.36	258.00	-36.64	85.8%
1240 · Mgmnt and Informational Svcs				
1242 · Fiscal Services	21,227.42	36,580.00	-15,352.58	58.03%
1243 · Attorney Services	0.00			
1244 · Management Services	51.14	40.00	11.14	127.85%
1246 · Public Infrmtnl & Relation Svcs	150.00	180.00	-30.00	83.33%
1247 · Legal Services	525.00	515.00	10.00	101.94%
1248 · Media Services	145.60	0.00	145.60	100.0%
1249 · Recruitment Services	0.00			
Total 1240 · Mgmnt and Informational Svcs	22,099.16	37,315.00	-15,215.84	59.22%
1250 · Repair and Maintenance Svcs				
1252 · Electrical Rep & Maintenance	0.00			

Virginia Dept. of Health Professions
Revenue and Expenditures Summary
July 1, 2012 through January 31, 2013

	107- Pharmacy			
	Jul '12 - Jan 13	Budget	$ Over Budget	% of Budget
1253 · Equip Repair & Maintenance	0.00	0.00	0.00	0.0%
1256 · Mechanical Rep & Maint Svcs	0.00			
1257 · Plant Rep & Maintenance Svcs	0.00	700.00	-700.00	0.0%
Total 1250 · Repair and Maintenance Svcs	0.00	700.00	-700.00	0.0%
1260 · Support Services				
1263 · Clerical Services	0.00			
1264 · Food & Dietary Services	1,449.96	2,453.00	-1,003.04	59.11%
1266 · Manual Labor Services	3,015.05	6,050.00	-3,034.95	49.84%
1267 · Production Services	15,812.49	23,695.00	-7,882.51	66.73%
1268 · Skilled Services	61,413.75	137,954.00	-76,540.25	44.52%
Total 1260 · Support Services	81,691.25	170,152.00	-88,460.75	48.01%
1280 · Transportation Services				
1282 · Travel, Personal Vehicle	5,849.27	4,978.00	871.27	117.5%
1283 · Travel, Public Carriers	269.90	0.00	269.90	100.0%
1284 · Travel, State Vehicles	7.69			
1285 · Travel, Subsistence & Lodging	3,041.36	2,152.00	889.36	141.33%
1288 · Trvl, Meal Reimb- Not Rprtble	1,355.25	996.00	359.25	136.07%
Total 1280 · Transportation Services	10,523.47	8,126.00	2,397.47	129.5%
1297 · Late Payment Penalties	0.00			
Total 1200 · Contractual Services	144,569.83	260,938.00	-116,368.17	55.4%
1300 · Supplies And Materials				
Personal Care Supplies	0.00	156.00	-156.00	0.0%
1310 · Administrative Supplies				
1311 · Apparel Supplies	29.94	29.00	0.94	103.24%
1312 · Office Supplies	999.33	3,574.00	-2,574.67	27.96%
1313 · Stationery and Forms	87.69	1,728.00	-1,640.31	5.08%
Total 1310 · Administrative Supplies	1,116.96	5,331.00	-4,214.04	20.95%
1320 · Energy Supplies				
1323 · Gasoline	0.00			
Total 1320 · Energy Supplies	0.00			
1330 · Manufctrng and Merch Supplies				
1335 · Packaging and Shipping Suppl	23.36			
Total 1330 · Manufctrng and Merch Supplies	23.36			
1350 · Repair and Maint. Supplies				
1352 · Custodial Rep & Maint Mat'ls	0.00			
1353 · Electrical Repair and Maint	0.00			
Total 1350 · Repair and Maint. Supplies	0.00			
1360 · Residential Supplies				
1362 · Food and Dietary Supplies	0.00	75.00	-75.00	0.0%
1363 · Food Service Supplies	4.66	229.00	-224.34	2.04%
1364 · Laundry and Linen Supplies	0.00	8.00	-8.00	0.0%
Total 1360 · Residential Supplies	4.66	312.00	-307.34	1.49%

Virginia Dept. of Health Professions
Revenue and Expenditures Summary
July 1, 2012 through January 31, 2013

	107- Pharmacy			
	Jul '12 - Jan 13	Budget	$ Over Budget	% of Budget
1370 · Specific Use Supplies				
1373 · Computer Operating Supplies	45.76	229.00	-183.24	19.98%
Total 1370 · Specific Use Supplies	45.76	229.00	-183.24	19.98%
Total 1300 · Supplies And Materials	1,190.74	6,028.00	-4,837.26	19.75%
1400 · Transfer Payments				
1410 · Awards, Contrib., and Claims				
1413 · Premiums	120.00	0.00	120.00	100.0%
1415 · Unemployment Compnsatn Reimb	0.00	0.00	0.00	0.0%
Total 1410 · Awards, Contrib., and Claims	120.00	0.00	120.00	100.0%
Total 1400 · Transfer Payments	120.00	0.00	120.00	100.0%
1500 · Continuous Charges				
S Purch Ch. Card Check Fee	0.00			
1510 · Insurance-Fixed Assets				
1512 · Automobile Liability	0.00			
1516 · Property Insurance	177.51	0.00	177.51	100.0%
Total 1510 · Insurance-Fixed Assets	177.51	0.00	177.51	100.0%
1530 · Operating Lease Payments				
1534 · Equipment Rentals	1,903.44	3,264.00	-1,360.56	58.32%
1535 · Building Rentals	0.00			
1539 · Building Rentals - Non State	24,884.18	45,230.00	-20,345.82	55.02%
Total 1530 · Operating Lease Payments	26,787.62	48,494.00	-21,706.38	55.24%
1550 · Insurance-Operations				
1551 · General Liability Insurance	637.14	0.00	637.14	100.0%
1554 · Surety Bonds	37.59	0.00	37.59	100.0%
Total 1550 · Insurance-Operations	674.73	0.00	674.73	100.0%
Total 1500 · Continuous Charges	27,639.86	48,494.00	-20,854.14	57.0%
2200 · Equipment Expenditures				
Electronic & Photo Equip Impr	0.00			
2210 · Computer Equipment				
2217 · Other Computer Equipment	10.75			
2218 · Computer Software Purchases	0.00			
Total 2210 · Computer Equipment	10.75			
2220 · Educational & Cultural Equip				
2224 · Reference Equipment	116.46	285.00	-168.54	40.86%
2228 · Educational & Cultural Equip Im	69.95			
Total 2220 · Educational & Cultural Equip	186.41	285.00	-98.59	65.41%
2230 · Electrnc & Photographic Equip				
2233 · Voice & Data Transmissn Equip	0.00	0.00	0.00	0.0%
2238 · Electrnc & Phtgrphc Equip Imprv	0.00			

Virginia Dept. of Health Professions
Revenue and Expenditures Summary
July 1, 2012 through January 31, 2013

	107- Pharmacy			
	Jul '12 - Jan 13	Budget	$ Over Budget	% of Budget
Total 2230 · Electrnc & Photographic Equip	0.00	0.00	0.00	0.0%
2260 · Office Equipment				
2261 · Office Appurtenances	0.00	0.00	0.00	0.0%
2262 · Office Furniture	0.00	508.00	-508.00	0.0%
2263 · Office Incidentals	92.43	12.00	80.43	770.25%
2264 · Office Machines	0.00	0.00	0.00	0.0%
2268 · Office Equipment Improvements	0.00	6.00	-6.00	0.0%
Total 2260 · Office Equipment	92.43	526.00	-433.57	17.57%
2270 · Specific Use Equipment				
2271 · Household Equipment	0.00	46.00	-46.00	0.0%
Total 2270 · Specific Use Equipment	0.00	46.00	-46.00	0.0%
Total 2200 · Equipment Expenditures	289.59	857.00	-567.41	33.79%
Total Expenditures	603,801.62	1,014,147.00	-410,345.38	59.54%
9001 · Allocated Expenditures				
9201 · Behavioral Science Exec	0.00			
9202 · Opt\VM\ASLP Exec Dir	0.00			
9204 · Nursing / Nurse Aid	0.00			
9206 · Funeral\LTCA\PT	0.00			
9301 · DP Operations & Equipment	232,758.73	487,765.80	-255,007.07	47.72%
9302 · Human Resources	30,307.43	44,108.99	-13,801.56	68.71%
9303 · Finance	77,728.11	125,566.56	-47,838.45	61.9%
9304 · Director's Office	64,454.60	72,479.40	-8,024.80	88.93%
9305 · Enforcement	427,417.80	562,039.32	-134,621.52	76.05%
9306 · Administrative Proceedings	70,007.20	90,554.53	-20,547.33	77.31%
9307 · Impaired Practitioners	3,967.58	7,211.64	-3,244.06	55.02%
9308 · Attorney General	30,789.12	32,246.76	-1,457.64	95.48%
9309 · Board of Health Professions	29,968.58	51,528.72	-21,560.14	58.16%
9311 · Moving Costs	0.00	1,306.07	-1,306.07	0.0%
9313 · Emp. Recognition Program	133.72	1,281.00	-1,147.28	10.44%
9314 · Conference Center	241.38	845.76	-604.38	28.54%
9315 · Pgm Devlpmnt & Implmentn	18,878.07	30,510.24	-11,632.17	61.88%
987900 · Cash Trsfr Out- Appr Act Pt. 3	433.73	5,400.24	-4,966.51	8.03%
Total 9001 · Allocated Expenditures	987,086.05	1,512,845.03	-525,758.98	65.25%
Total Direct and Allocated Expenditures	1,590,887.67	2,526,992.03	-936,104.36	62.96%
Net Cash Surplus\Shortfall	**262,746.84**	**158,057.97**	**104,688.87**	**166.23%**