COMMONWEALTH OF VIRGINIA

Meeting of the Board of Pharmacy

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

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

Tentative Agenda of Meeting

March 26, 2014

9:00AM

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: David Brown, DC

Regulatory Actions: Elaine Yeatts

- Legislative Update — 40-44
- Regulatory Update — 45
  - Adoption of Final Regulations for CQI — 46-58
  - Reconsideration of Regulation 18VAC110-20-500 regarding EMS- *Chairman has Referred Issue to Regulation Committee* — 59-76
  - Request from Department of Corrections to Amend 18VAC110-20-590 to Allow Floor Stock of Certain Drugs — 76A – 76B
- Action on Petition for Rulemaking – Pharmacy Coupons — 77-88

Miscellaneous: Caroline D. Juran

- Request from Containment Technologies Group, Inc. (CTG) to amend Guidance Document 110-36
  - Letter from Hank Rahe, Director Technology, CTG — 89-97
  - Draft Guidance Document 110-36 containing Staff's Suggested Amendments — 98-106
- Request from Accreditation Commission for Health Care (ACHC) and LDT Health Solutions to Accept their Accreditation or Assessment in lieu of Inspection Report from Regulatory or Licensing Agency of the Jurisdiction - *Chairman has Referred Issue to Ad Hoc Inspection Committee* — 107-111
- DEA Open Public Comment Period for Proposed Rules to Move Hydrocodone Combination Products to Schedule II — 112-129
- Ad Hoc Committee Report on Guidance for Suggested Disciplinary Action and Monetary Penalties Resulting from Routine Inspections of Physicians Licensed to Dispense
  - Draft Guidance Document containing Committee's Recommendations — 130-137
- Board Member Request to Consider Providing 24-hour Advanced Notice of Routine Inspections
- Staff Request to Amend Guidance Document 110-9 to Include Deficiency Regarding Gloved Fingertip Sampling - *Chairman has Referred Issue to Ad Hoc Inspection Committee*
- 2015 Possible Legislative Proposals – *Chairman has Referred Issue to Regulation Committee*

Reports:

- Report on Board of Health Professions – Robert M. Rhodes
- Report on Planning of NABP/AACP District 1 and 2 Meeting – Cindy Warriner
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day
- Executive Director's Report - Caroline D. Juran

Consideration of Consent Orders (if any)

New Business:

Adjourn

* The Board will have a working lunch at approximately 12pm.
* Following adjournment of the business portion of the meeting, a one-hour conflict of interest training will be shown. *

DRAFT/FINAL

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR REGULATIONS 18 VAC 110-20-10- CONTINUOUS QUALITY IMPROVEMENT PROGRAMS

December 12, 2013
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:15 AM.

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT:
Crady R. Adams
David C. Kozera
Empsy Munden
Robert M. Rhodes
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

MEMBERS NOT PRESENT: Dinny Li

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

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

CALL FOR COMMENT: Ms. Allen called for public comment on the proposed regulations for continuous quality improvement programs. There was no public comment received at this time.

Ms. Allen stated that written comments may be submitted to Town Hall or to Caroline Juran, Executive Director, Board of Pharmacy, until January 17, 2014. Final regulations will be considered for adoption at the March 26, 2014 full board meeting.

ADJOURN: The public hearing adjourned at 9:20 am.

Jody H. Allen, Board Chairman

Date

Caroline D. Juran, Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

December 12, 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 9:20am.

PRESIDING: Jody Allen, Chairman

MEMBERS PRESENT:
Ellen B. Shinaberry, Vice-Chairman
Crady R. Adams
David Kozera
Empsy Munden
Robert M. Rhodes
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner
Dinny Li - arrived at 9:30am

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Dianne Reynolds-Cane, Director, DHP – arrived 11:30am
Arne Owens, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
Heather Hurley, Administrative Assistant
Wayne Halbleib, Assistant Attorney General- arrived 12:45pm
Carrie Mitchell, Assistant Attorney General- arrived 12:45 p.m.
Allyson Tysinger, Assistant Attorney General-arrived 12:45pm
Mykl Egan, Ajudication Specialist

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

APPROVAL OF AGENDA: An amended agenda was provided and approved as presented.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the September 9, 2013 (Regulation Committee regarding Emergency Medical Services Agencies), September 10, 2013 (Full Board Meeting), October 7, 2013 (Informal Conference Committee), October 15, 2013 (Panel Formal Hearing), October 17, 2013 (Special Conference Committee and Informal Conference Committee), November 7, 2013 (Telephone Conference Committee), November 12, 2013 (Special Conference Committee and Informal Conference Committee), November 25, 2013 (Regulation Committee), and November 25, 2013 (Ad Hoc Committee on Guidance for Suggested Disciplinary Action Resulting from Routine Inspections of Pharmacies and Physicians Licensed to Dispensed). Mr. Adams recommended a correction in the September 10, 2013 Full Board Meeting minutes under the subject of

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possible disciplinary action against PICs following documented drug loss. The word "PIC" in the sentence "Mr. Adams stated that during his research, he discovered that in the first six months of the year 2013, only nine disciplinary actions, resulting from drug losses, were taken against a PIC." should be changed to read "pharmacist or pharmacy technician".

MOTION:

The Board voted unanimously to approve the minutes as presented, to include the amendment of the September 10, 2013 Full Board Meeting minutes. (motion by Adams, second by Kozera)

PUBLIC COMMENTS:

No public comments were received at this time.

DHP DIRECTOR'S REPORT:

Due to a conflict, Dr. Cane was unable to attend the meeting at the time the Director's report was provided. Arne Owens, Chief Deputy Director of DHP, provided the Director's report in her absence. Mr. Owens stated that the pan to reduce prescription drug abuse has been submitted to the National Governor's Associations (NGA). Virginia was also awarded another grant by the NGA that will focus on the transition of veterans and active military into the civilian or public sectors of certain healthcare fields. The grant will focus primarily on the occupations of licensed practical nurses, physical therapy assistants, and emergency medical technicians. The study will research the type of licensing, education and credentialing military and veterans will need to transition into these types of positions. The study will last a year and will conclude January of 2015. The first interagency meeting will be held January 8, 2014. Additionally, Delegate Stolle has requested the review of certain professionals transitioning from the military to healthcare. The review includes pharmacy technicians. Ms. Allen expressed appreciation to both Mr. Owens and Dr. Cane for the past four years of their service.

REGULATORY ACTIONS:

Ms. Yeatts reviewed the current status of the proposed regulations as outlined on page 44 of the agenda packet.

REGULATORY UPDATE:

- ADOPTION OF COMMENT TO DEA ON PROPOSAL TO PLACE TRAMADOL INTO SCHEDULE IV:

Ms. Yeatts explained that the DEA had published a notice of proposed rulemaking to place tramadol into Schedule IV and that a public comment period was open until January 3, 2014. She further explained that the Board had supported legislative proposals in Virginia in 2010, 2011, and 2013 to place tramadol into Schedule IV of the Drug Control Act. She then stated a draft of public comment on page 45 of the agenda packet was provided for their consideration.

MOTION:

The Board voted unanimously to approve staff submitting the public comment as presented to the DEA which supports placing tramadol into Schedule IV. (motion by Munden, second by Rhodes)

- ADOPTION OF AMENDED GUIDANCE DOCUMENT

A handout was provided which included a draft version amending Guidance Document 110-17 and a letter from NABP dated 11/27/13

110-17 TO CONFORM WITH NEW MINIMUM SCORE REQUIREMENTS FOR TOEFL IBT:

regarding TOEFL iBT passing standards increase. Ms. Yeatts explained that because NABP recently notified the Board of an increase to the minimum passing score of the TOEFL iBT, the Board would need to amend Guidance Document 110-17 to conform to the new standard. The Board requested staff to research the total score a candidate could receive in each of the four sections and follow up with them in an email.

MOTION:

The Board voted unanimously to amend Guidance Document 110-17 as presented. (motion by Kozera, second by Adams)

- ADOPTION OF AMENDED GUIDANCE DOCUMENT 110-22 TO CONFORM WITH REGULATORY AMENDMENT OF 18VAC 110-20-27:

A handout containing the current Regulation 18VAC110-20-270 and a draft amending Guidance Document 110-22 was provided. Ms. Yeatts explained that the guidance previously captured in Guidance Documents 110-22 regarding which pharmacist to hold responsible for a dispensing error had recently been incorporated into regulations during the last periodic review, effective September 2013. If the Board believes the examples provided in Guidance Document 110-22 are still beneficial, then the Board should amend the document to conform to current regulations. In lieu of the draft language in the introductory paragraph provided in the handout, Ms. Yeatts recommended the following: "To improve compliance with regulations and assist in determining which pharmacist to hold responsible for a dispensing error, the Board offers the following guidance on current dispensing practices and required recordkeeping when more than one pharmacist at the same location assumes responsibility for individual dispensing functions associated with dispensing one prescription product."

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MOTION:

The Board voted unanimously to amend Guidance Document 110-22 as presented with the amended language for the introductory paragraph as suggested by Ms. Yeatts. (motion by Warriner, second by Stelly)

- REPORT FROM THE AD HOC COMMITTEE FOR DRUG DIVERSION AND RESPONSIBILITY OF PHARMACIST-IN-CHARGE TO PROVIDE ADEQUATE SAFEGUARDS:

Ms. Yeatts and Ms. Warriner provided background regarding the Regulation Committee of the Board which met on November 25, 2013 to discuss the responsibility of the pharmacist-in-charge in providing adequate safeguards concerning drug diversion. The recommendations to the Board included entering the name of the pharmacist(s)-in-charge in the finding of facts for those cases that involve drug diversion and also to amend Guidance Document 110-27 to add a new section regarding diversion, theft and loss of controlled substances. The amendments to the guidance document would also include suggestions for best practices for safeguarding against diversion of controlled substances.

MOTION:

As recommended by the Regulation Committee, the Board voted unanimously to list the name of the pharmacist(s)-in-charge in the Finding of Facts in disciplinary cases involving drug diversion. (motion by Regulation Committee, second by Munden)

Ms. Juran indicated staff would correct any typographical errors found in the proposed amendments of Guidance Document 110-27. Mr. Adams

recommended adding as a suggested best practice, "Have full and timely access to all reports relating to inventories, invoices, and audits".

MOTION:

The Board voted unanimously to amend Guidance Document 110-27 as recommended by the Regulation Committee, following the correction of typographical errors, and to include the suggested best practice to "Have full and timely access to all reports relating to inventories, invoices, and audits". (motion by Warriner, second by Munden)

MOTION:

The Board voted unanimously to make an additional amendment to Guidance Document 110-27 to include the Board's new policy to list the name of the pharmacist(s)-in-charge in the Findings of Fact in those disciplinary cases involving drug diversion. (motion by Adams, second by Munden)

MISCELLANEOUS:

- REPORT FROM THE AD HOC COMMITTEE ON GUIDANCE FOR SUGGESTED DISCIPLINARY ACTION RESULTING FROM ROUTINE INSPECTIONS OF PHARMACIES AND PHYSICIANS LICENSED TO DISPENSED:

An Ad Hoc Committee of the Board met on November 25, 2013 to discuss suggested disciplinary action resulting from routine inspections of pharmacies and physicians licensed to dispense. The following recommendations were made by the committee:

- Amend Guidance Document 110-9 as presented in the agenda packet
- To take no action at this time regarding the consideration of suggested penalty for repeat deficiencies
- To take no action at this time regarding the consideration of reduced monetary penalties imposed against free clinic pharmacies, however, to hear more on this subject at the December full board meeting

Regarding the consideration for directing inspectors to provide an expedited pre-hearing consent order to physicians licensed to dispense, following a routine inspection with certain deficiencies, the committee recommended the following:

- To implement a process similar to the process used for routine pharmacy inspections
- To reconvene the ad hoc committee prior to the March full board meeting to develop a guidance document similar to Guidance Document 110-9 to identify deficiencies and suggested monetary penalties for routine inspections of physician licensed to dispense
- Issuing pre-hearing consent orders against the individual physician licensed to dispense. If a common stock of drugs is maintained, then it is recommended that the pre-hearing consent order is issued to the designated responsible practitioner for that practice.

Mr. Johnson briefly reviewed the numerous recommended amendments to Guidance Document 110-9.

MOTION:

The Board voted unanimously to amend Guidance Documents 110-9 as recommended by the ad hoc committee, effective December 12, 2013. (motion by Stelly, second by Adams)

Based upon the ad hoc committee's recommendations, the Board did not take any action concerning disciplinary sanctions for repeat deficiencies.

MOTION:

The Board voted unanimously to reconvene the ad hoc committee prior to the March full board meeting to develop a guidance document similar to Guidance Document 110-9 which will list suggested monetary penalties for certain deficiencies, following a routine inspection of physicians licensed to dispense. (motion by Warriner, second by Rhodes)

- REQUEST FROM FREE CLINICS FOR REDUCED MONETARY PENALTIES RESULTING FROM ROUTINE PHARMACY INSPECTIONS:

Linda Wilkinson, Executive Director of the Virginia Association of Free Clinics and Amy Yarcich, Executive Director of Rx Partnership, discussed with the Board the impact of the current monetary penalties against free clinic pharmacies. Ms. Wilkinson stated that there are 60 free clinics in Virginia and 26 of those clinics have pharmacies. Out of the 26 clinics, 9 were cited during a routine inspection and sanctioned with a monetary penalty. At least 4 of those free clinic pharmacies did not have a backup system for the pharmacy alarm. Ms. Yarcich requested that the Board consider lowering the monetary penalty for free clinic pharmacies since all services rendered to patients are free and they have a difficult time getting funding. She also stated that education from the inspector or Board would be welcomed so that they would be able to comply for future inspections.

The Board expressed appreciation for the services provided by the free clinics; however, there was consensus that all dispensing locations should be held to the same standard. Additionally, the Board reminded Ms. Wilkinson and Ms. Yarcich that any pharmacy may refuse to pay the suggested monetary penalty imposed by the inspector and may request an informal conference with the Board for further consideration of the matter. If mitigating circumstances exist, it is the committee's prerogative to adjust the suggested sanction. The Board concluded the discussion that no action should be taken at this time to reduce the monetary penalties imposed against a free clinic pharmacy following a routine pharmacy inspection wherein certain deficiencies were cited.

OLD BUSINESS:

- REQUEST FROM VPHA TO RECONVENE AD HOC COMMITTEE ON

Ms. Juran stated that she had shared the public comment provided at the September full board meeting by Loyd V. Allen, Jr., Ph.D., R.Ph., Editor-in-Chief for the *International Journal of Pharmaceutical Compounding* and Remington: The Science and Practice of Pharmacy, with Rick

STERILE COMPOUNDING:

Schnatz, Manager Compounding and Healthcare Standards for the U.S. Pharmacopeial Convention (USP). Ms. Juran then reviewed the response provided by Mr. Schnatz, and found in the agenda packet, which indicates USP posted an Accelerated Revision on November 22, 2013 to clarify chapter <795>. The intent of the revision was to clarify that the beyond-use date in the table "BUD by Type of Formulation" is specific for nonsterile preparations and users should refer to General Chapter <797> *Pharmaceutical Compounding- Sterile Preparation* for standards on sterile compounding. Ms. Juran also shared that Mr. Schnatz indicated that Dr. Allen had resigned from the USP expert committee for personal and professional reasons.

The Accelerated Revision appeared to negate Dr. Allen's concern with question #4 in Guidance Document 110-36. The comments expressed by Dr. Allen for questions number 2, 6, and 16 within Guidance Document 110-36 appeared commentary in nature. The Board stated that if USP amends its chapters on these subjects, then it could certainly consider amending its guidance at that time. For these reasons, the Board reached consensus that it did not need to reconvene the ad hoc committee on compounding at this time.

REPORTS:

- CHAIRMAN'S REPORT

Ms. Allen recognized two students of the VCU School of Pharmacy in the audience and encouraged other students to attend future Board meetings.

- BOARD OF HEALTH PROFESSIONS

Mr. Rhodes indicated the last meeting had been cancelled and that there was nothing to report at this time.

- NABP/AACP DISTRICT 1 AND 2 MEETING

Ms. Warriner reported on the attendance at the NABP/AACP District 1 and 2 meeting held in October in Maine. She reviewed the information provided on pages 83-86 in the agenda packet, to include the resolutions passed at the meeting.

- LICENSURE PROGRAM

Mr. Johnson reported that the Board issued 907 licenses and registrations for the period of September 1, 2013 through November 30, 2013, including 152 pharmacists, 178 pharmacy interns, and 460 pharmacy technicians. Mr. Johnson also reviewed the number of current active licenses, certifications, and registrations. Inspectors conducted 422 facility inspections including 195 routine inspections of pharmacies: 69 resulted in no deficiency, 47 with deficiencies, and 79 with deficiencies and a consent order. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies.

- 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 8, 2013; June 14, 2013; September 9, 2013; and December 10, 2013. For the final date, open cases are five at the entry stage; 71 at the investigation stage; 85 at the probable cause stage; 9 at the administrative proceedings division stage; 12 at the informal stage; five at the formal

stage; and 137 at the pending closure stage.

Further, Ms. Reiniers-Day provided the Board with the agency's Patient Care Disciplinary Case Processing Times for the Quarterly Performance Measurement for the First Quarter 2014. Specific to the Board of Pharmacy, the clearance rate was 116%, the Pending Caseload older than 250 days was 13%; and the percent closed within 250 business days was 98%.

- EXECUTIVE DIRECTOR'S REPORT

Ms. Juran reported that the executive officer forum hosted by NABP in September was excellent. She served as a panelist and provided a presentation regarding actions Virginia has taken to address compounding. The NASCSA meeting held in October was informative. Discussion topics included prescription monitoring programs (PMP), synthetic cannabinoids, research chemicals (bath salts), increased access to naloxone for overdose treatment. Additionally, Ralph Orr, Director of the VA PMP was elected President. Ms. Juran reported that Mr. Johnson and Mr. Orr attended a prescription drug forum in Tennessee hosted by the US Attorneys General. Mr. Johnson also presented in October at the Virginia Society of Health Systems Pharmacists annual meeting. Ms. Beckman will attend the NABP inspector forum later this month. Attendees for most of these meetings received travel grants to offset expenses. Also, Ms. Juran stated she had provided a presentation in October to a visiting Chinese delegation interested in learning about regulatory oversight of drugs. Ms. Juran provided an update on the planning for the 2014 NABP/AACP District 1 and 2 meeting which will be held at the Williamsburg Lodge October 5-7, 2014. She provided current statistics for the PMP requests processed to date and reported that Virginia is now interoperable with 14 other states. Ms. Juran reminded board members to participate in the Tri-Regulator Webinar Series on compounding. Eric Kastango and Kate Douglass are the presenters. The tri-regulators include members of the National Association of Boards of Pharmacy, the Federation of State Medical Boards, and the National Council of State Boards of Nursing. Lastly, she reported that she was seeking travel approval to serve as a panelist at the upcoming educational conference hosted by the International Academy of Compounding Pharmacists.

NEW BUSINESS:

Mr. Adams suggested that staff mail the newly revised Guidance Document 110-27 to all current pharmacists-in-charge (PICs) in Virginia. After some discussion, the Board concluded it would be appropriate to mail this particular guidance document to all PICs.

MOTION:

The Board voted unanimously to direct staff to mail the newly revised Guidance Document 110-27 to all pharmacists-in-charge in Virginia. (motion by Adams, second by Rhodes)

CONSIDERATION OF CONSENT ORDERS:

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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 Consent Orders. Additionally, it was moved that Caroline Juran, Cathy Reiniers-Day, 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 Shinaberry, second by Warriner)

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 Shinaberry, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of Jennifer Wild Hoerrner, Pharmacist (motion by Kozera, second by Warriner)

MOTION:

The Board voted unanimously to accept the Consent Order as presented by Ms. Reiniers-Day in the matter of David J. Franza, Pharmacy Technician (motion by Kozera, second by Warriner)

SUMMARY SUSPENSION:

DOUGLAS A. HARRIS
Pharmacist
License Number:
0202-006176

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

MOTION FOR CLOSED MEETING:

The Board voted unanimously to convene a closed meeting pursuant to § 2.2-3711.A.27 of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of a possible summary suspension and that Caroline D. Juran, Cathy Reiniers-Day, and Eusebia Joyner attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations. (motion by Shinaberry, second by Warriner)

MOTION TO CERTIFY THE PURPOSE OF THE CLOSED MEETING:

The Board voted unanimously that only public business matters lawfully exempted from open meeting requirements under the Virginia Freedom of Information Act and only such public business matters as were identified in the motion for closed meeting were heard, discussed or considered during the closed meeting. (motion by Shinaberry, second by Warriner)

MOTION:

The Board voted unanimously in favor of the motion that, according to the evidence presented, the continued practice by Douglas A. Harris as a pharmacist poses a substantial danger to the public; and therefore, the license of Douglas A. Harris to practice as a pharmacist shall be summarily suspended and that a Consent Order be offered to

Mr. Harris for the revocation of his license in lieu of a hearing. (motion by Stelly, second by Rhoades)

ADJOURN: With all business concluded, the Board adjourned at 4:30 p.m.

Jody H. Allen, Chairman

Date: _____

Caroline D. Juran, Executive Director

Date: _____

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Thursday, December 12, 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 2:35 p.m.

PRESIDING: Jody H. Allen, Chair

MEMBERS PRESENT:
David C. Kozera
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
Charis Mitchell, Assistant Attorney General
Allyson Tysinger, Senior Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With five (5) members of the Board present, a panel was established.

BENNETT'S CREEK PHARMACY
Permit No. 0201-002252

A formal hearing was held in the matter of Bennett's Creek Pharmacy. S. Christopher Jones, Pharmacist-in-Charge, appeared on behalf of Bennett's Creek Pharmacy to review allegations governing the conduct of pharmacy in Virginia.

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

Nan Dunaway, DHP Senior Inspector, testified on behalf of the Commonwealth.

Mr. Jones testified on behalf of Bennett's Creek Pharmacy.

Closed Meeting:

Upon a motion by Mr. Kozera, and duly seconded by Ms. Warriner, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Bennett's Creek Pharmacy. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner, Charis Mitchell and Allyson Tysinger attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Mr. Kozera, and duly seconded by Ms. Stelly, the panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Ms. Mitchell.

Upon a motion by Mr. Kozera and duly seconded by Ms. Warriner, the panel determined that an Order shall be entered to include Findings of Fact and Conclusions of Law with no sanction being imposed.

Adjourn:

With all business concluded, the meeting adjourned at 3:55 p.m.

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, December 17, 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 10:00 a.m.
PRESIDING:	Ellen B. Shinaberry, Committee Chair
MEMBERS PRESENT:	Pratt P. Stelly, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Sammy Johnson, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
HELEN M. SIMMONS Pharmacy Technician Registration No. 0230-002166	Helen M. Simmons appeared with Holly K. Morris, Phamacist-in-Charge; Jan Joseph Skibinski, Staff Pharmacist and Hunter Jamerson, her attorney, to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the November 8, 2013, 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 Helen M. Simmons. Additionally, she moved that Cathy Reiniers-Day, Sammy Johnson and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and determined that an Order shall be issued to Ms. Simmons for a reprimand.

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

JAN JOSEPH SKIBINSKI
Pharmacist
License No. 0202-004735

Jan Joseph Skibinski appeared with Holly K. Morris, Pharmacist-in-Charge; Helen M. Simmons, Pharmacy Technician and Hunter Jamerson, his attorney, to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 8, 2013, 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 Jan Joseph Skibinski. Additionally, she moved that Cathy Reiniers-Day, Sammy Johnson and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and determined that an Order shall be issued to Mr. Skibinski for a reprimand and a monetary penalty of Two Hundred Fifty Dollars ($250.00).

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

Mr. Skibinski 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.

HOLLY K. MORRIS
Pharmacist
License No. 0202-011792

Holly K. Morris appeared with Jan Joseph Skibinski, Staff Pharmacist; Helen M. Simmons, Pharmacy Technician and Hunter Jamerson, her attorney, to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 8, 2013, 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 Holly K. Morris. Additionally, she moved that Cathy Reiniers-Day, Sammy Johnson and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and determined that an Order shall be issued to Ms. Morris for a reprimand and a monetary penalty of One Thousand Dollars ($1,000).

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

MATTHEW P. GARNER Pharmacist License No. 0202-208043	Matthew P. Garner appeared to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 8, 2013, 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 Candice D. Rattan. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, the Committee determined that an Order shall be issued to Mr. Garner that includes Findings of Fact and Conclusions of Law with no sanction being imposed.
RIANNA L. HODGEN Pharmacy Technician Registration No. 0230-019341	Rianna L. Hodgen did not appear, however the committee chose to proceed in her absence as the notice was mailed to Ms. Hodgen'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 September 20, 2013, 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 Rianna L. Hodgen. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Stelly, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Hodgen a Consent Order for the indefinite suspension of her pharmacy technician registration for a period of not less than two years.
ADJOURN:	With all business concluded, the meeting adjourned at 2:15 p.m.

Ellen B. Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL & INFORMAL CONFERENCE COMMITTEE

Tuesday, January 21, 2014
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER: A meeting of a Special and Informal Conference Committee of the Board of Pharmacy was called to order at 9:30 a.m.

PRESIDING: Ellen B. Shinaberry, Committee Chair

MEMBERS PRESENT: Robert M. Rhodes, Committee Member

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

FARM FRESH PHARMACY #6267/360
Permit Number 0201-003684

M. Ray Holt, Pharmacist-in-Charge, appeared with Hunter Jamerson, their attorney, on behalf of Farm Fresh Pharmacy #6267/360 to review allegations that Farm Fresh Pharmacy #6267/360 may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 7, 2014, Notice.

Closed Meeting: Upon a motion by Mr. Rhodes, 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 Farm Fresh Pharmacy #6267/360. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

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

Decision: Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Farm Fresh Pharmacy #6267/360, for a monetary penalty in the amount of $14,600.

(This Consent Order shall be effective upon endorsement by Farm Fresh Pharmacy #6267/360 and the Board of the findings of fact, conclusions of law, and terms of the Order).

KENNETH L. BURGESS
Pharmacist
License No. 0202-011980

Kenneth L. Burgess appeared with Thomas Burgess, his father, to review allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the November 8, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Rhodes, 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 Kenneth L. Burgess. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee unanimously voted to close this case with no violation.

WESTBURY PHARMACY
Permit No. 0201-002508

Faiz A. Oley, Jr., Pharmacist-in-Charge; and Joseph Oley, Pharmacist, appeared with Hunter Jamerson, their attorney, on behalf of Westbury Pharmacy to review allegations that Westbury Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the December 31, 2013, Notice.

Closed Meeting:

Upon a motion by Mr. Rhodes, 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 Westbury Pharmacy. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed

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

Reconvene:

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

Decision:

Upon a motion by Mr. Rhodes, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Westbury Pharmacy for a monetary penalty in the amount of $7,750.

(This Consent Order shall be effective upon endorsement by Westbury Pharmacy and the Board of the findings of fact, conclusions of law, and terms of the Order).

EVERETTE G. RICHARDSON
Pharmacy Technician
Registration No. 0230-012179

Everette G. Richardson did not appear at the informal conference.

The Committee referred the matter to a formal administrative hearing.

ADJOURN:

With all business concluded, the meeting adjourned at 3:30 p.m.

Ellen B. Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Monday, January 27, 2014

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

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

TIME & PURPOSE:

Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on January 27, 2014, at 9:00 a.m., to consider the summary suspension of the registration of Amber Kristin Shorter to practice as a pharmacy technician in the Commonwealth of Virginia.

PRESIDING:

Jody H. Allen, Chair

MEMBERS PRESENT:

R. Crady Adams
David C. Kozera
Ellen B. Shinaberry
Pratt P. Stelly
Rebecca Thornbury

STAFF PRESENT:

Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Eusebia L. Joyner, Disciplinary Program Specialist
Mykl Egan, DHP Adjudication Specialist
Wayne T. Halbleib, Senior Assistant Attorney General
Erin Barrett, Assistant Attorney General

POLL OF MEMBERS:

The Board members were polled as to whether they could have attended a regular meeting at the office in a timely manner for the purpose of hearing evidence in a possible summary suspension cases. 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.

AMBER KRISTIN SHORTER
Registration No. 0230-023408

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

Upon a motion by Ms. Stelly and duly seconded by Mr. Kozera, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Amber Kristin Shorter poses a substantial danger to the public; and therefore, the registration of Ms. Shorter shall be summarily suspended. Further, with the Notice of Hearing, a Consent Order shall be offered to Ms. Shorter for the indefinite suspension of her registration for a period of not less than two years with the suspension stayed upon her entry into and compliance with the Health Practitioners Monitoring Program.

ADJOURN: With all business concluded, the meeting adjourned at 9:30 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Jody H. Allen, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL & INFORMAL CONFERENCE COMMITTEE

Wednesday, February 5, 2014
Commonwealth Conference Center
Second Floor
Board Room 2

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

CALL TO ORDER:	A meeting of a Special and Informal Conference Committee of the Board of Pharmacy was called to order at 9:45 a.m.
PRESIDING:	Ellen B. Shinaberry, Committee Chair
MEMBERS PRESENT:	David C. Kozera, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
BREMO PHARMACY Permit Number 0201-002887	Sandra W. Michael, Pharmacist-in-Charge, and Katherine Cary, Owner, appeared on behalf of Bremo Pharmacy to review allegations that Bremo Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 9, 2014, Notice.
Closed Meeting:	Upon a motion by Mr. Kozera, 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 Bremo Pharmacy. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Mr. Kozera, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer a Consent Order to Bremo Pharmacy with certain Findings of Fact and Conclusions of Law and a monetary penalty in the amount of $13,550.

(This Consent Order shall be effective upon endorsement by Bremo Pharmacy and the Board of the findings of fact, conclusions of law, and terms of the Order).

SUSAN L. WINDSOR
Pharmacist
License No. 0202-004750

Susan L. Windsor appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the January 31, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Kozera, 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 Susan L. Windsor. Additionally, he moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

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

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Windsor, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Windsor 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 2:45 p.m.

Ellen B. Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF TELEPHONE CONFERENCE CALL

Tuesday, February 18, 2014

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

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

TIME & PURPOSE: Pursuant to § 54.1-2400(13) of the Code of Virginia, a telephone conference call of the Virginia Board of Pharmacy ("TCC") was held on February 18, 2014, at 10:15 a.m., to consider the summary suspensions of the license of David M. Fedorko to practice as a pharmacist and the registrations of Samika Haymore, Tania K. Dominique and Marchee Jones-Anderson to practice as pharmacy technicians in the Commonwealth of Virginia.

PRESIDING: Ellen B. Shinaberry, Chair

MEMBERS PRESENT:
R. Crady Adams
Dinny Li
Empsy Munden
Pratt P. Stelly
Rebecca Thornbury
Cynthia Warriner

MEMBERS ABSENT:
Jody H. Allen
David C. Kozera
Robert M. Rhodes

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
Corie Tillman Wolf, Assistant Attorney General
James E. Schliessmann, Senior Assistant Attorney General
Erin Barrett, Assistant Attorney General

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

With seven (7) members participating and three (3) members unable to participate, it was established that a

quorum could not have been convened in a regular meeting to consider this matter.

DAVID M. FEDORKO
License No. 0202-010693

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

Upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacist by David M. Fedorko poses a substantial danger to the public; and therefore, Mr. Fedorko's right to renew his license to practice pharmacy shall be summarily suspended.

Further, upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Mr. Fedorko for the revocation of his right to renew his license to practice pharmacy.

SAMIKA HAYMORE
Registration No. 0230-023067

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

Upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Samika Haymore poses a substantial danger to the public; and therefore, the registration of Ms. Haymore shall be summarily suspended.

Further, upon a motion by Ms. Warriner and duly seconded by Ms. Munden, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Ms. Haymore for the revocation of her registration to practice as a pharmacy technician.

TANIA K. DOMINIQUE
0230-019822

James E. Schliessmann 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 pharmacy technician by Tania K. Dominique poses a substantial danger to the public; and therefore, the registration of Ms. Dominique shall be summarily suspended.

Further, upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Ms. Dominique for the indefinite suspension of her registration for a period of not less than two years.

MARCHEE JONES-ANDERSON
Registration No. 0230-018364

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

Upon a motion by Ms. Stelly and duly seconded by Ms. Warriner, the Board unanimously voted that, with the evidence presented, the practice as a pharmacy technician by Marchee Jones-Anderson poses a substantial danger to the public; and therefore, Ms. Jones-Anderson's right to renew her registration shall be summarily suspended to practice as a pharmacy technician.

Further, upon a motion by Ms. Stelly and duly seconded by Ms. Munden, the Board unanimously voted that, with the Notice of Hearing, a Consent Order shall be offered to Ms. Jones-Anderson for the indefinite suspension of her right to renew her pharmacy technician registration for a period of not less than two years.

ADJOURN:

With all business concluded, the meeting adjourned at 10:45 a.m.

Cathy M. Reiniers-Day
Deputy Executive Director

Eusebia L. Joyner
Disciplinary Program Specialist

Ellen B. Shinaberry, Chair

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
INFORMAL CONFERENCE COMMITTEE MINUTES

Thursday, February 20, 2014
Commonwealth Conference Center
Second Floor
Board Room 3

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

CALL TO ORDER:	A meeting of an Informal Conference Committee of the Board of Pharmacy was called to order at 9:00 a.m.
PRESIDING:	Empsy Munden, Committee Chair
MEMBERS PRESENT:	R. Crady Adams, Committee Member
STAFF PRESENT:	J. Samuel Johnson, Jr., Deputy Executive Director Brittany Taylor, Administrative Assistant Mykl D. Egan, DHP Adjudication Specialist
Bierer's Pharmacy Permit No. 0201-000041	Mamita Gurung, Pharmacist-in-Charge, appeared on behalf of Bierer's Pharmacy to review allegations that Bierer's Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 24, 2014, Notice.
Closed Meeting:	Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Bierer's Pharmacy. Additionally, he moved that Sammy Johnson, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting.
Decision:	Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to close this case as no

violation.

Fisburne & Son Pharmacy
Permit No. 0201-005210

David Garber, Pharmacist-in-Charge, appeared on behalf of Fishburne & Son Pharmacy to review allegations that Fishburne & Son Pharmacy may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 24, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Fishburne & Son Pharmacy. Additionally, he moved that Sammy Johnson, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

Reconvene:

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

Decision:

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

This Consent Order shall be effective upon endorsement by Fishburne & Son Pharmacy and the Board of the findings of fact, conclusions of law, and terms of the Order.

Free Clinic of Culpeper
Permit No. 0201-003121

Eugene Triplett, Pharmacist-in-Charge, and Norma Dunwiddie, Executive Director, appeared on behalf of Free Clinic of Culpeper to review allegations that Free Clinic of Culpeper may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 24, 2014, Notice.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-

3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Free Clinic of Culpeper. Additionally, he moved that Sammy Johnson, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

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

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

This Consent Order shall be effective upon endorsement by Free Clinic of Culpeper and the Board of the findings of fact, conclusions of law, and terms of the Order.

Charlottesville Free Clinic
Permit No. 0201-003106

Aaron Howell, Pharmacist-in-Charge, and Chris Hicks, pharmacy coordinator, appeared on behalf of Charlottesville Free Clinic to review allegations that Charlottesville Free Clinic may have violated certain laws and regulations governing the conduct of pharmacy as stated in the January 24, 2014, Notice.

Closed Meeting: Upon a motion by Mr. Adams, and duly seconded by Ms. Munden, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711.A(27) of the Code of Virginia, for the purpose of deliberation to reach a decision in the matter of Charlottesville Free Clinic. Additionally, he moved that Sammy Johnson, Brittany Taylor, and Mykl Egan attend the closed meeting because their presence in the closed meeting would aid the Committee in its deliberations.

Reconvene: Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened

in open meeting.

Decision:

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

This Consent Order shall be effective upon endorsement by Charlottesville Free Clinic and the Board of the findings of fact, conclusions of law, and terms of the Order.

Adjourn:

With all business concluded, the meeting adjourned at 11:41 a.m.

Empsy Munden
Chair

J. Samuel Johnson, Jr.
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Wednesday, February 26, 2014
Commonwealth Conference Center
Second Floor
Board Room 1

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 9:40 a.m.

PRESIDING: Jody H. Allen, Chair

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

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

Ellen B. Shinaberry departed at 9:45 a.m.

QUORUM: With five (5) members of the Board present, a panel was established.

GENNIFER L. BARKER
Registration No. 0230-012649

A formal hearing was held in the matter of Gennifer L. Barker 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 Mykl Egan, DHP Adjudication Specialist.

Randy Hall, Loss Prevention Regional Office Manager, CVS/pharmacy; Rebecca Lovelace, Pharmacist-in-Charge, CVS/pharmacy #1994; and Andrea P. Christian, DHP Senior Investigator, testified on behalf of the Commonwealth.

Ms. Barker was represented by Leonard A Paris, Esquire.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Ms. Stelly, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Gennifer L. Barker. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner, and Charis Mitchell attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Adams, the panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Ms. Mitchell.

Upon a motion by Ms. Stelly and duly seconded by Mr. Rhodes, the panel voted 4-1 that Ms. Barker's registration to practice as a pharmacy technician be placed on probation under certain terms and conditions as read by Ms. Reiniers-Day.

AMBER KRISTIN SHORTER
Registration No. 0230-023408

A formal hearing was held in the matter of Amber Kristin Shorter, following the summary suspension of her pharmacy technician registration on January 29, 2014, to discuss allegations governing the practice of pharmacy technicians in Virginia.

Mr. Shorter was not present at the hearing. The Board proceeded with the hearing in Ms. Shorter's absence as the Notice of Hearing dated January 29, 2014, was mailed to her legal address of record, both by regular and certified mail. Ms. Allen ruled that adequate notice was provided to Ms. Shorter.

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

Stephen Rudder, District Pharmacy Supervisor, CVS/pharmacy, and Jeremy McNeil, DHP Senior Investigator, testified on behalf of the Commonwealth.

Closed Meeting:

Upon a motion by Mr. Adams, and duly seconded by Mr. Rhodes, the panel voted 5-0, to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Amber Kristin Shorter. Additionally, he moved that Cathy Reiniers-Day, Caroline Juran, Eusebia Joyner, and Charis Mitchell attend the closed meeting.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Ms. Li, the panel voted 5-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the panel and read by Ms. Mitchell.

Upon a motion by Ms. Stelly and duly seconded by Ms. Li, the panel voted 5-0 to revoke Ms. Shorter's registration to practice as a pharmacy technician.

Adjourn:

With all business concluded, the meeting adjourned at 2:40 p.m.

Jody H. Allen, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF SPECIAL CONFERENCE COMMITTEE

Tuesday, March 11, 2014
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:	Robert M. Rhodes, Committee Chair
MEMBERS PRESENT:	Pratt P. Stelly, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
CASEY R. FRICK Pharmacy Technician Registration No. 0230-013699	Casey R. Frick appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the January 9, 2014, Notice.
Closed Meeting:	Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, 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 Casey R. Frick. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the Committee re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to offer Ms. Frick a Consent Order for the indefinite suspension on her pharmacy technician registration for a period of not less than two years.

VIRGINIA P. TARRER
Pharmacist
License No. 0202-005544

Virginia P. Tarrer appeared to review allegations that she may have violated certain laws and regulations governing the practice of pharmacy as stated in the February 12, 2014, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, 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 Virginia P. Tarrer. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to reprimand Ms. Tarrer.

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

CANDICE D. RATTAN
Pharmacy Technician
Registration No. 0230-010415

Candice D. Rattan did not appear at the informal conference. The Committee chose to proceed in her absence as the notice was mailed to Ms. Rattan'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 8, 2013, Notice.

Closed Meeting:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, 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 Candice D. Rattan. Additionally, she moved that Cathy Reiniers-Day and Mykl Egan attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Committee in its deliberations.

Reconvene:

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

Decision:

Upon a motion by Ms. Stelly, and duly seconded by Mr. Rhodes, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue a Consent Order to Ms. Rattan for the revocation of her right to renew her pharmacy technician registration.

ADJOURN:

With all business concluded, the meeting adjourned at 11:55 a.m.

_____

Robert M. Rhodes, Chair

_____

Cathy M. Reiniers-Day
Deputy Executive Director

_____

Date

DRAFT – CORRECTION NEEDED

VIRGINIA BOARD OF PHARMACY
MINUTES OF AD HOC COMMITTEE ON GUIDANCE FOR SUGGESTED DISCIPLINARY ACTION RESULTING FROM ROUTINE INSPECTIONS OF PHARMACIES AND PHYSICIANS LICENSED TO DISPENSE

November 25, 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 11:10AM.

PRESIDING: Ellen Shinaberry, Committee Chairman

MEMBERS PRESENT:
R. Crady Adams
Jody Allen
Empsy Munden
Cynthia Warriner
Rebecca Thornbury (left at 2:30pm)

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

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

DISCUSSION: Ms. Juran provided an overview of the agenda packet and feedback she has informally received regarding the process used for disciplinary action following a routine pharmacy inspection. While many pharmacists have indicated they appreciate the transparency which Guidance Document 110-9 provides, some independent pharmacy owners have indicated they do not like the issuance of a public document against the pharmacy permit when a monetary penalty is imposed. Prior to beginning its discussions, the committee received public comment from Ron Davis, President of the Virginia Pharmacists Association (VPhA). ~~He indicated that VPhA is not happy with the routine pharmacy inspection process and that it has decayed the relationship between VPhA and the Board.~~ Speaking as an individual, Mr. Davis stated that he is currently not happy with the routine pharmacy inspection process and he feels that it has decayed the relationship between Virginia pharmacists and the Board. He stated the Board should deal with major offensives, but not impose monetary penalties for minor offensives. He encouraged voluntary compliance with minor offensives. He supported the idea of sanctioning for repeat violations.

The committee also received comment from Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA). He indicated VPhA supports all dispensers being held to the same standard. He stated one of the biggest concerns with the inspection process is the public record against the pharmacy permit which results when monetary penalties are imposed. He recommended the Board focus on the immediate impact on public health when considering disciplinary action

for specific deficiencies; he provided a handout with suggested amendments to Guidance Document 110-9 (Attachment 1).

The committee discussed each major and minor deficiency within Guidance Document 110-9, taking into consideration how often it has been cited in the past and the suggested changes provided by VPhA. The committee offered suggestions for amending certain deficiencies and thresholds, which determine when deficiencies will be cited. Additionally, it discussed increasing the number of minor deficiencies that must be cited prior to imposing a monetary penalty. The committee discussed possible disciplinary action which could be imposed on a pharmacy that is cited the same deficiency in subsequent inspections. The committee recommended no action on this issue at this time. Ms. Juran indicated she was aware that representatives associated with free clinic pharmacies wish the Board to consider reducing monetary penalties imposed against these pharmacies following a routine pharmacy inspection. She reported that a legislator had also recently called staff expressing concern for a monetary penalty imposed against a free clinic pharmacy. The committee recommended no action on this issue at this time, but expressed a desire to hear more on this subject at the December full board meeting. The committee concluded it will recommend to the full Board to implement a similar process for handling deficiencies cited during routine inspections of physicians licensed to dispense drugs. Time did not permit the committee to begin drafting a guidance document similar to 110-9. The committee expressed desire to reconvene prior to the March 2014 full board meeting for the purpose of drafting guidance which would identify specific deficiencies and associated monetary penalties to be imposed following a routine inspection of physicians licensed to dispense.

MOTION:

The Committee voted unanimously to recommend the following to the full board for its consideration:

- **amendments to Guidance Document 110-9 as indicated in Attachment 2; and,**
- **implementation of a similar process for handling disciplinary action resulted from deficiencies cited during routine inspections of physicians licensed to dispense drugs; that the pre-hearing consent order be issued against the individual licensed to dispense or the responsible designated practitioner, when a common stock of drug is maintained; and, reconvene, prior to the March 2014 full board meeting, the ad hoc committee to develop guidance similar to Guidance Document 110-9 to identify deficiencies and suggested monetary penalties. (motion by Warriner, second by Allen, Thornbury absent for vote)**

ADJOURN: With all business concluded, the meeting adjourned at 4:50PM.

Ellen Shinaberry, Committee Chairman

Caroline D. Juran, Executive Director

Date

Date

Attachment 1 - Provided by VPhA

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. COL or remodel without application or Board approval ***MOVE TO MINOR***	18VAC110-20-140	must submit an application and fee	250
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. ***(Suggest reconsidering the definition of prescription department)***	18VAC110-20-180		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~~ ***250***
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~~ ***250***
15. 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) ***MOVE TO MINOR***	54.1-3404 and 18VAC110-20-240		250
20b. Pharmacist not documenting final verification of sterile compounding	54.1-3410.2, 18VAC110-20-355		~~5000~~ ***1000***
16. 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~~ ***1500***

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
17. 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~~ ***1500***
18. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level CSPs or high risk CSPs assigned inappropriate beyond use date (BUD) ***(VPhA still questions the determination the Board is using for BUDs)***	54.1-3410.2		~~5000~~ ***1000*** 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~~ ***1000***
25b. High-risk drugs intended for use are improperly stored	54.1-3410.2		~~5000~~ ***1000*** per incident up to 3 incidents; schedule for IFC for > 3 incidents
19. 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~~ ***250***
27. Compounding using ingredients in violation ***(Clarification?)***	54.1-3410.2		1000
28. Low or medium-risk CSPs assigned inappropriate beyond use date (BUD) ***(VPhA still questions the determination the Board is using for BUDs)***	54.1-3410.2		~~1000~~ ***750***

Minor Deficiencies

Minor Deficiency	Law/Regulation Cite	Conditions
1. Decreased hours of operation without public/Board notice ***REMOVE***	18VAC110-20-135	
5. Current dispensing reference not maintained ***REMOVE***	18VAC110-20-170	
6. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured ***REMOVE***	18VAC110-20-440	
7. Policies and procedures for drug therapy reviews not maintained or followed ***REMOVE***	18VAC110-20-440	

Additional Comments:

1. LTC pharmacies have been cited in the past year for not having a process in place, or a record maintained for pharmacists to check drugs being used to replenish drugs utilized from the stat boxes/emergency boxes. The inspectors have cited 18VAC110-20-460/540 and 550 when citing these deficiencies.
   a. 18VAC110-20-460 is listed as a hospital regulation pertaining to floor stock. Although 540 and 550 are the Long Term Care regulations pertaining to stat boxes and emergency boxes, there is no mention in those regulations regarding replenishment procedures/record of pharmacist checking drugs being replenished for those boxes.
   b. This needs to be clarified in Minor #40.
2. Consideration of a separate PIC for Sterile Compounding if a pharmacy chooses to appoint an additional PIC

Report of the 2014 General Assembly

Board of Pharmacy

HB 190 Athletic trainers; possession and administration of oxygen.

Chief patron: Bell, Richard P.

Summary as introduced:
Athletic trainers; possession and administration of oxygen. Provides that prescribers may authorize licensed athletic trainers to possess and administer oxygen for use in emergency situations.

03/06/14 House: Bill text as passed House and Senate (HB190ER)

HB 505 Dextromethorphan Distribution Act; penalty for distributing or selling Dextromethorphan to a minor.

Chief patron: Hodges

Summary as passed:

Dextromethorphan Distribution Act; penalty. Provides that no pharmacy or retail distributor may knowingly or intentionally sell or distribute a product containing dextromethorphan (a cough suppressant found in many over-the-counter medications) to a minor and that no minor may knowingly and intentionally purchase such product. A violation is punishable by a $25 civil penalty. Additionally, a pharmacy or retail distributor shall not sell or distribute a product containing dextromethorphan unless the purchaser presents a government-issued photo-ID showing proof of age or the purchaser appears to be at least 25 years old. Upon a first violation, the pharmacy or retail distributor shall receive a notice of noncompliance, and any subsequent violation is punishable by a $25 civil penalty. The bill also provides that a person who distributes or possesses with the intent to distribute unfinished dextromethorphan is guilty of a Class 1 misdemeanor. The bill has a delayed effective date of January 1, 2015, and is identical to SB 213.

03/03/14 Governor: Approved by Governor-Chapter 101 (effective 1/1/15)

HB 539 Prescription Monitoring Program; delegation of authority.

Chief patron: Hodges

Summary as introduced:
Prescription Monitoring Program; delegation of authority. Authorizes dispensers who are authorized to access the information in the possession of the Prescription Monitoring Program to delegate this authority to certain health care professionals employed at the same facility and under their direct supervision. The bill also changes the requirements for individuals to whom such authority may be delegated by prescribers or dispensers, to include health care professionals licensed, registered, or

certified by a health regulatory board in another state and employed at the same facility and under their direct supervision.

03/03/14 Governor: Approved by Governor-Chapter 72 (effective 7/1/14)

HB 575 Perampanel and Lorcaserin; added to Schedules III and IV, respectively.

Chief patron: O'Bannon

Summary as passed House:

Schedule III and Schedule IV drugs. Adds lorcaserin to the list of Schedule IV drugs and adds perampanel to the list of Schedule III drugs.

03/03/14 Governor: Approved by Governor-Chapter 74 (effective 7/1/14)

HB 611 Health regulatory boards; denial or suspension of a license, certificate or registration, exception.

Chief patron: Robinson

Summary as introduced:

Health regulatory boards; denial or suspension of a license, certificate or registration; exception. Creates an exception to the requirement that health regulatory boards within the Department of Health Professions shall refuse to issue a license, certificate, or registration to an applicant if the candidate or applicant has had his license, certificate, or registration to practice the profession or occupation revoked or suspended in another jurisdiction and shall suspend the license, registration, or certification of a person licensed, registered, or certified in the Commonwealth if his license, registration, or certification has been suspended or revoked or accepted for surrender in lieu of disciplinary action in another jurisdiction for cases in which the revocation or suspension in the other jurisdiction is the result of nonrenewal of the license, registration, or certification.

03/03/14 Governor: Approved by Governor-Chapter 76 (effective 7/1/14)

HB 661 Falsifying patient records; statute of limitation on prosecutions increased.

Chief patron: Bell, Robert B.

Summary as passed:

Limitation of prosecutions; falsifying patient records. Increases from one year to three years the statute of limitations on prosecutions for the misdemeanor of falsifying patient records with the intent to defraud.

03/05/14 Governor: Approved by Governor-Chapter 169 (effective 7/1/14)

HB 855 Health regulatory boards; reinstatement of licensure.

Chief patron: Garrett

Summary as introduced:

Health regulatory boards; reinstatement of licensure. Provides that an applicant for reinstatement of a certificate, registration, or license that has been revoked bears the burden of proof to show to the appropriate health regulatory board by clear and convincing evidence that he is safe and competent to practice.

02/20/14 Governor: Acts of Assembly Chapter text (CHAP0011)

HB 874 Drugs; designation and reporting those of concern.

Chief patron: Yost

Summary as passed:

Designation and reporting of drugs of concern. Authorizes the Board of Pharmacy to identify "drugs of concern" and requires such drugs of concern to be reported to the Prescription Monitoring Program.

03/03/14 House: Signed by Speaker
03/06/14 Senate: Signed by President

HB 891 Health regulatory boards; powers and duties, special conference committees.

Chief patron: Peace

Summary as introduced:

Powers and duties of health regulatory boards; special conference committees. Provides that special conference committees may consider applications for a license, certificate, registration, permit, or issuance of a multistate licensure privilege and may grant or deny the application or issue a restricted license, certification, registration, permit, or multistate licensure privilege. The bill also provides that special conference committees may hear cases in which a holder of a permit issued by a health regulatory board is reported to be the subject of disciplinary action.

02/26/14 House: Signed by Speaker
02/28/14 Senate: Signed by President

HB 923 Prescription Monitoring Program; disclosure method of information to recipient.

Chief patron: Peace

Summary as introduced:

Prescription Monitoring Program; disclosure method. Specifies that when the Director, in his discretion, discloses information that is in the possession of the program concerning a recipient who is over the age of 18 to that recipient, the information shall be mailed to the street or mailing address indicated on the recipient request form.

02/20/14 Governor: Approved by Governor-Chapter 12 (effective 7/1/14)

HB 1032 Pharmacy, Board of; automatic review of certain case decisions.

Chief patron: Orrock

Summary as passed House:

Board of Pharmacy; automatic review of certain case decisions. Provides that, in cases in which a monetary fine may be imposed for a violation of the Drug Control Act relating to the practice of pharmacy and the pharmacy subject to the fine is affiliated with a free clinic that receives state or local funds, the Board of Pharmacy shall ascertain the factual basis of the case through informal conference or consultation proceedings, unless the named party and the Board agree to resolve the matter through a consent order or the named party consents to waive such conference or proceeding to go directly to a formal hearing.

02/26/14 House: Signed by Speaker
02/28/14 Senate: Signed by President

HB 1035 Veterinarians; dispensing compounded drug products, report.

Chief patron: Orrock

Summary as passed House:

Veterinarians; dispensing compounded drug products. Provides that a veterinarian may dispense a 72-hour supply of a compounded drug product for a companion animal that is his patient when the compounded drug product is dispensed to treat an emergent condition and timely access to a compounding pharmacy is not available. The bill requires pharmacists to label compounded drug products dispensed to veterinarians with the name and strength of the drug product or list of the active ingredients and strengths, the facility's control number, a beyond-use date, the name and address of the pharmacy, and the quantity dispensed. The bill also requires the Board of Pharmacy to convene a work group to explore and clarify issues related to the compounding of drugs for human and animal use.

03/05/14 Governor: Approved by Governor-Chapter 147 (effective 7/1/14)

HB 1112 Controlled substance analogs; regulation by Board of Pharmacy, synthetic cannabinoids, penalties.

Chief patron: Garrett

Summary as passed House:

Cannabimimetic agents; regulation by Board of Pharmacy; penalties. Substitutes the term "cannabimimetic agents" for the term "synthetic cannabinoids" to describe certain substances that are unlawful to possess, sell, give, distribute, or manufacture. The bill raises from a Class 6 felony to a Class 5 felony the penalty for selling, giving, distributing, or possessing with the intent to sell, give, or distribute such substances. The bill authorizes the Board of Pharmacy to add a substance into the list of controlled substances found in Schedule I or II or to the list of cannabimimetic agents via an expedited regulatory process. A substance added via this process is removed from such list after 18 months unless a general law is enacted adding the substance to such list. The bill also adds five new compounds to the list of cannabimimetic agents and one new research chemical to Schedule I.

02/28/14 House: Conference report agreed to by House (88-Y 10-N)
03/03/14 Senate: Conference report agreed to by Senate (40-Y 0-N)

HB 1249 Prescription Monitoring Program; registration with Program for prescriber treating human patients.

Chief patron: Hodges

Summary as passed House:

Prescription Monitoring Program; prescriber requirements. Requires prescribers to be registered with the Prescription Monitoring Program by the Department of Health Professions upon filing an application for licensure or renewal of a license, if the prescriber has not already registered. The bill requires prescribers to request information from the Director of the Department of Health Professions to determine what, if any, other covered substances are currently being prescribed to any patient for whom the prescriber is initiating a new course of treatment that includes the prescribing of benzodiazepine or an opiate, when such course of treatment is anticipated to last more than 90 consecutive days and for which a treatment agreement is entered into, except when the prescriber's course of treatment arises from pain management relating to dialysis or cancer treatment. The bill also authorizes the Secretary of Health and Human Resources to identify and publish a list of benzodiazepines or opiates that have a low potential for abuse by human patients, the prescription of which shall not require the prescriber to request and obtain information from the Prescription Monitoring Program. This bill has a delayed effective date of July 1, 2015. This bill is identical to SB 294.

03/03/14 Governor: Approved by Governor-Chapter 93 (effective 7/1/15)

Status of Regulatory Actions

Board of Pharmacy

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Administrative fees for duplicate licenses and verification [Action 3444] Proposed - *At Governor's Office for 55 days (negative recommendation from Secretary's office)*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Continuous quality improvement programs [Action 3496] Proposed - *Register Date: 11/18/13* *Comment period ended 1/17/14*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Secretary's Office for 301 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Modifications to requirements for automated dispensing devices for less burdensome process [Action 3578] Final - *Register Date: 1/13/14* *Effective: 2/27/14*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Less restrictive and burdensome record-keeping for on-hold prescriptions [Action 3451] Final - *Register Date: 1/13/14* *Effective: 2/27/14*
[18 VAC 110 - 40]	Regulations Governing Collaborative Practice Agreements	Conformity to changes in the Code [Action 4101] Final - *Register Date: 3/24/14* *Effective: 4/23/14*

Agenda Item: Adoption of Final Regulations

Replacement of Emergency Regulations for <u>Continuous Quality Improvement Programs</u>

Included in your agenda package are:

A copy of Proposed Regulations replacing emergency regulations which were in effect from 10/1/12 to 9/30/13 (request for extension was never approved)

A copy of comment on the proposed regulations

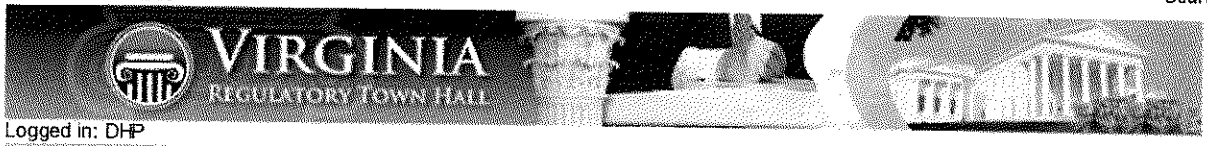
Staff note:

There was a comment period on the proposed regulations which ended 1/17/14. At the public hearing on 12/12/13, there was no public comment.

Board action:

Consideration of the comment on proposed regulations

Adoption of final amendments to replace emergency regulations



Logged in: DHP

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action	**Continuous quality improvement programs**
Stage	**Proposed**
Comment Period	Ends 1/17/2014

Back to List of Comments

Commenter: Virginia Hospital & Healthcare Association *

1/7/14 12:50 pm

Continuous Quallity Improvement Programs

The Virginia Hospital & Healthcare Association submits these public comments in response to the Virginia Board of Pharmacy regulation at 18 VAC110-20, published in the Virginia Register, Volume: 30 Issue: 6, starting at page 753. The definition of "actively reports" should be modified to be consistent with federal regulations promulgated under the Patient Safety and Quality Improvement Act of 2005 (Pub. L. 109-41) (the "Act"). The Board of Pharmacy defines "actively reports" to mean "reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error." However, the Agency for Healthcare Research and Quality regulations do not require information to be reported to a PSO in order to qualify for protections under the Act nor do they specify a timeframe for reporting patient safety work product. In issuing final regulations under the Act, AHRQ clarified that "information documented as collected within a patient safety evaluation system by a provider shall be protected as patient safety work product" and "would become patient safety work product upon collection." *See* 73 Fed. Reg. 70741. Accordingly, federal regulations do not require reporting in order for information to be protected as patient safety work product. There are several reasons why a provider would not report patient safety work product to a PSO within (30) days and the flexibility in the federal regulations was designed, in part, to avoid unintended consequences associated with a "race to report" and the need to develop dual systems for handling patient safety information. *Id.* Under the federal regulations, the act of documenting and collecting the information is sufficient.

One possible solution to address the apparent discrepancy between the Board's proposed regulations and the federal regulations would be to change the definition of "actively reports" to mean "documenting as collected for reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error." This approach balances the need to encourage a timely process for identifying and analyzing errors with the need to extend the reporting timeframe beyond 30 days and is consistent with the federal regulations.

Thank you for this opportunity to comment. Please contact R. Brent Rawlings with any questions regarding these public comments by calling (804) 965-1228 or by email at brawlings@vhha.com.

* Nonregistered public user

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Proposed Regulations

Comment Period from November 18, 2013 to January 17, 2014

BOARD OF PHARMACY

Continuous quality improvement programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of 50% 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; or (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.

"Actively reports" means reporting all dispensing errors and analyses of such errors to a patient safety organization as soon as practical or at least within 30 days of identifying the error.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Analysis" means a review of the findings collected and documented on each dispensing error, assessment of the cause and any factors contributing to the dispensing error, and any recommendation for remedial action to improve pharmacy systems and workflow processes to prevent or reduce future errors.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Dispensing error" means one or more of the following discovered after the final verification by the pharmacist:

1. Variation from the prescriber's prescription drug order, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form;

d. Incorrect patient; or

e. Inadequate or incorrect packaging, labeling, or directions.

2. Failure to exercise professional judgment in identifying and managing:

a. Known therapeutic duplication;

b. Known drug-disease contraindications;

c. Known drug-drug interactions;

d. Incorrect drug dosage or duration of drug treatment;

e. Known drug-allergy interactions;

f. A clinically significant, avoidable delay in therapy; or

g. Any other significant, actual, or potential problem with a patient's drug therapy.

3. Delivery of a drug to the incorrect patient.

4. Variation in bulk repackaging or filling of automated devices, including, but not limited to:

a. Incorrect drug;

b. Incorrect drug strength;

c. Incorrect dosage form; or

d. Inadequate or incorrect packaging or labeling.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

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

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

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

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"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Patient safety organization" means an organization that has as its primary mission continuous quality improvement under the Patient Safety and Quality Improvement Act of 2005 (P.L. 109-41) and is credentialed by the Agency for Healthcare Research and Quality.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive 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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

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

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-418. Continuous quality improvement programs.

A. Notwithstanding practices constituting unprofessional practice indicated in 18VAC110-20-25, any pharmacy that actively reports dispensing errors and the analysis of such errors to a

patient safety organization consistent with § 54.1-3434.03 of the Code of Virginia and 18VAC110-20-10 shall be deemed in compliance with this section. A record indicating the date a report was submitted to a patient safety organization shall be maintained for 12 months from the date of reporting. If no dispensing errors have occurred within the past 30 days, a zero report with date shall be recorded on the record.

B. Pharmacies not actively reporting to patient safety organizations, consistent with § 54.1-3434.03 Code of Virginia and 18VAC110-20-10, shall implement a program for continuous quality improvement in compliance with this section.

1. Notification requirements:

a. A pharmacy intern or pharmacy technician who identifies or learns of a dispensing error shall immediately notify a pharmacist on-duty of the dispensing error.

b. A pharmacist on-duty shall appropriately respond to the dispensing error in a manner that protects the health and safety of the patient.

c. A pharmacist on-duty shall immediately notify the patient or the person responsible for administration of the drug to the patient and communicate steps to avoid injury or mitigate the error if the patient is in receipt of a drug involving a dispensing error which may cause patient harm or affect the efficacy of the drug therapy. Additionally, reasonable efforts shall be made to determine if the patient self-administered or was administered the drug involving the dispensing error. If it is known or reasonable to believe the patient self-administered or was administered the drug involving the dispensing error, the pharmacist shall immediately assure that the prescriber is notified.

2. Documentation and record requirements; remedial action:

a. Documentation of the dispensing error must be initiated as soon as practical, not to exceed three days from identifying the error. Documentation shall include, at a minimum, a description of the event that is sufficient to allow further investigation, categorization and analysis of the event.

b. The pharmacist-in-charge or designee shall perform a systematic, ongoing analysis, as defined in 18VAC110-20-10, of dispensing errors. An analysis of each dispensing error shall be performed within 30 days of identifying the error.

c. The pharmacist-in-charge shall inform pharmacy personnel of changes made to pharmacy policies, procedures, systems, or processes as a result of the analysis.

d. Documentation associated with the dispensing error need only to be maintained until the systematic analysis has been completed. Prescriptions, dispensing information, and other records required by federal or state law shall be maintained accordingly.

e. A separate record shall be maintained and available for inspection to ensure compliance with this section for 12 months from the date of the analysis of dispensing errors and shall include the following information:

(1) Dates the analysis was initiated and completed;

(2) Names of the participants in the analysis;

(3) General description of remedial action taken to prevent or reduce future errors; and

(4) A zero report with date shall be recorded on the record if no dispensing errors have occurred within the past 30 days.

Agenda Item: Re-consideration of a fast-track action on EMS Regulations

Staff Note:

There have been requests to re-consider provisions of section 500, subsection B

Included in your packet:

A draft of fast-track regulations previously adopted but not yet submitted for Executive branch review

Board action:

Consideration of request to amend the previous action.

From: Melinda Duncan [mailto:melinda@vaems.org]
Sent: Thursday, December 12, 2013 2:54 PM
To: Juran, Caroline (DHP)
Cc: Rauch, Greg (Greg.Rauch@fairfaxva.gov); Collins, Jennie L.; Berg, Michael (VDH); Winston, Scott (VDH); Brown, Gary (VDH)
Subject: Meeting Request

Hello Ms. Juran,

I see that you were copied on several emails concerning the proposed changes to regulations about drug exchanges by EMS personnel. Could you please fill me in on the proposed timeline for these changes?

It is my understanding that the Board of Pharmacy has put these changes on a "fast track" schedule. If at all possible, we would like to meet with you (in Northern Virginia) and any other members from the Board of Pharmacy prior to the changes reaching the Town Hall status. We would invite our local pharmacists, operational medical directors, and EMS operations people to this meeting so that they could discuss their concerns with you.

Please let me know if this is agreeable to you and we will make it happen.

Thanks so much,
Melinda

Melinda Duncan, Executive Director
Northern Virginia EMS Council
7250 Heritage Village Plaza, Suite 102
Gainesville, VA 20155
877-261-3550 (office)
703-505-8419 (cell)
melinda@vaems.org
http://www.northern.vaems.org

Sent: Friday, January 17, 2014 4:50 PM
To: Bob Montminy (wmontminy@pwcgov.org); Brian Hricik (brian.hricik@alexandriava.gov); Byron Andrews (bandr3@aol.com); Darren Stevens (darren.stevens@fauquiercounty.gov); Dustin Rice (Dustin.Rice@Fairfaxcounty.gov); Greg Rauch (greg.rauch@fairfaxva.gov); James Bonzano (JBonzano@arlingtonva.us); James Soaper (j.soaper@manassasparkva.gov); Jason Bowers (jbowers@manassasva.gov); Jennie Collins (jcollins@pwcgov.org); Joey King (jking@lifecare94.com); Jose Salazar (jose.salazar@loudoun.gov); Kate Passow (kpassow@physicians-transport.com); Kevin Stiles (kevin.stiles@loudoun.gov); Kim Pumphrey (kapumphrey@pwcgov.org); Lisa McAllister (lmcallister@phihelico.com); Lori Knowles (LKnowles@staffordcountyva.gov); Marcia Pescitani; Mark Nary (MNary@manassasva.gov); Mark Smith (mark.smith@fairfaxcounty.gov); Melinda Duncan; Michelle Ludeman; Miguel Serra (Miguel.A.Serra.civ@health.mil); Natasha Randall (Natasha.randall@fauquiercounty.gov); Philip Pommerening (philip.pommerening@fairfaxcounty.gov); Robert Pye (Rpye@arlingtonva.us); Sam Dahl; Scott Legore (Scott.Legore@mwaa.com); Steve Schmid (sschmid@ci.manassas.va.us); Todd Lupton (tlupton@ci.manassas.va.us); William Garrett (william.garrett@fairfaxcounty.gov); Annette Reichenbaugh (annette.reichenbaugh@hcahealthcare.com); Cathleen Cowden (cathleen.cowden@inova.org); Dana Anderson (danderson@virginiahospitalcenter.com); Dayo Akinbi (AXAKINBI@Sentara.com); Gill Abernathy (Gill.Abernathy@inova.org); Jason West (jbwest@novanthealth.org); Michelle Le (michelle.le@inova.org); Nancy Moughon (nbmoughon@novanthealth.org)
Cc: Scott Weir (weirsd@comcast.net); E. Reed Smith (ereed.smith@gmail.com); Berg, Michael (VDH); Harrell, Adam (VDH); Lorenz Dahl
Subject: Meeting to discuss drug exchanges with EMS

All,

We would like to invite you to a meeting with our EMS operations people and our hospital pharmacists to discuss the proposed Board of Pharmacy regulations which may change how EMS exchanges drugs with our local hospitals. Unless we are able to change these proposed regulations, we will NO LONGER be able to do the one-for-one drug exchanges we have done for many years.

The meeting will be held on **Monday, February 3, from 1 pm until 3 pm at Fairfax Station 40, 4621, Legato Road, Fairfax** (Training Room).

It is very important that we develop a plan on how we will address this issue at the next Board of Pharmacy meeting on March 26. Chief Jennie Collins will also discuss this at the State Rules and Regulations Committee meeting on February 6.

We hope to see everyone on February 3rd!

Thanks,
Melinda

Melinda Duncan, Executive Director
No. VA EMS Council
7250 Heritage Village Plaza, Suite 102
Gainesville, VA 20155
877-261-3550 (office)
703-505-8419 (cell)
http://www.northern.vaems.org

Juran, Caroline (DHP)

From: ELLEN B SHINABERRY [EBSHINAB@sentara.com]
Sent: Wednesday, January 22, 2014 11:10 AM
To: Juran, Caroline (DHP)
Subject: Proposed changes to 18 VAC110-20-500 Licensed (EMS) agencies program

Hi Caroline,
I hope your travels to Chicago were timely and uneventful yesterday! I had very little trouble traveling back the Harrisonburg in the snow and it was quite a beautiful drive so all is well.

I would like to share with you some concerns that I have regarding the revised changes the Regulations for Licensed EMS agencies and seek your guidance on how best to proceed. As I recall, the Regulation Committee presented these proposed changes at the September 2013 Board meeting for approval, however, the revisions were not distributed to members in advance for review. Since that time, I have had an opportunity to review the changes in detail and would like to highlight a few of the changes that I believe need to be readdressed below. I am interested in your feedback regarding my concerns and how best to pursue any modifications.

Item 1:
6) Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, or prescriber. Documentation shall be maintained for a period of two years from the date of destruction.

The current process for documenting waste of controlled substances by EMS is between two EMS providers.
The specific concern with #6 above is that in our facility (and I am sure in others as well), nurses are not willing to cosign for wastage of controlled substances by EMS due to the time it takes them away from direct patient care, and also because they are not comfortable signing for something that was administered outside of the facility and for which they cannot verify the contents of at the time of wasting. Additionally, it is un reasonable to expect that Physicians in the ED will stop caring for patients to waste narcotics with EMS personnel – this simply will not happen. This forces the waste to occur between EMS and a pharmacist. Most hospitals do not have pharmacists in the ED, therefore, EMS personnel would need to go to the Pharmacy for a cosigner. This in turn then takes a pharmacist away from patient care and requires them to sign for wastage of a medication that was administered in the field.

Therefore, I would like to suggest an amendment to the wording of #6 to be:
6) Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse~~, or~~ prescriber, ***pharmacy technician, or second EMS provider****. Documentation shall be maintained for a period of two years from the date of destruction.*

Item 2:
10) In lieu of exchange by the hospital pharmacy, the PIC of the hospital may authorize the exchange of the drug kit by the emergency department. Exchange of the drug kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber.

The current process in most hospitals is that the exchange of boxes that do not contain Schedules II, III, IV or V drugs is performed by the EMS personnel. This includes IV start kits and Shock/Trauma boxes. The new regulation effectively prohibits exchange of the these boxes in the ED by EMS personnel.

I would like to suggest an amendment to the working of #10 to be:
10) In lieu of exchange by the hospital pharmacy, the PIC of the hospital may authorize the exchange of the drug kit by the emergency department. Exchange of the drug kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber ***if the kit contents included Schedule II, III, IV or V drugs.***

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Item 3:
10.B.) In lieu of obtaining replacement intravenous fluids, irrigation fluids, heparin flush kits, sterile water and saline, and prescription devices via the exchanging of the drug kit, a licensed EMS agency may obtain a controlled substances registration pursuant to S54.1-3423 D for the purpose of performing a one-to-one exchange of such drugs or devices.

We have an agency that interprets this to mean that they can perform a one-to-one exchange of Schedule II, III, IV and V drugs since they have a "controlled substances" registration. I believe this to be an incorrect interpretation ~ can you clarify this?

Thank you for taking time to review my concerns. Feel free to give me a call to discuss if you prefer. I thought it would be more efficient for me to put this in writing to you initially rather than trying to explain all of the detail via telephone.

Thanks so much!

Ellen
Ellen B. Shinaberry RPH PharmD, Pharmacy IT Manager
RMH Healthcare | 2010 Health Campus Drive, Harrisonburg, VA 22801
540.689.2367 | ebshinab@sentara.com | RMHOnline.com
Get well, Live well
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Sperryville Volunteer Rescue Squad, Inc.

Serving Rappahannock County & Surrounding Communities Since 1969

P.O. Box 178
Sperryville, Virginia 22740
1-540-987-8085

January 22, 2014

Cynthia C. Romero, MD
State Health Commissioner
Virginia Department of Health
P.O. Box 2448
Richmond, VA 23218-2448

Dear Dr. Romero:

As a rural Virginia volunteer EMS agency operating two ALS ambulances, the availability of medications is a crucial aspect of delivering high quality care to our patients. Currently we exchange medications administered to our patients through a 1:1 exchange in the Emergency Room of the receiving hospitals. This quick efficient process is a great help to our volunteer providers and to the community. The advantages we see are:

- Immediate restocking of medications and quick turnaround allows us to keep our ambulances in-service
- Accessibility to medications at all four of the receiving hospitals (about one third of our transports are to a hospital other than our primary hospital)
- Provider familiarity with available medications to minimize medication errors

The elimination of the 1:1 medication exchange is a serious concern to our agency. Our concerns are:

- Limited access to medications. Three of the four hospitals we transport patients to are in other jurisdictions with different OMDs. Therefore, they are unlikely to have the correct drug box set up available.
- A trip to another hospital from our primary hospital would easily add a full hour to the volunteer's time and keep the ambulance out of service for that hour. In our area with limited volunteers and no paid providers the wasted hour is a big deal.
- In addition, the extra trip to our primary hospital would add roughly 50 miles on average to the trip adding substantially to cost for fuel and wear and tear on our ambulances

- Even at our primary hospital, the drug box exchange process is almost certain to be more cumbersome and require additional time. Currently, the 1:1 exchange can almost always be done quickly in the ER. More time would be required to go to the hospital pharmacy and exchange boxes.

We urge you to leave the 1:1 medication exchange system in place. It works well for us and going back to a full box exchange system would be a large step backward in terms of our ability to effectively serve our patients and our community.

Sincerely,

Harold Beebout

Harold Beebout, Chief

cc: Gary Brown, Director, Office of Emergency Medical Services, VDH

Jody H. Allen, Chair, Virginia Board of Pharmacy

Wayne Perry, Executive Director, REMS Council

Project 3870 - none

BOARD OF PHARMACY

Emergency medical services programs

Part I

General Provisions

18VAC110-20-10. Definitions.

In addition to words and terms defined in §§ 54.1-3300 and 54.1-3401 of the Code of Virginia, the following words and terms when used in this chapter shall have the following meanings, unless the context clearly indicates otherwise:

"ACPE" means the Accreditation Council for Pharmacy Education.

"Acquisition" of an existing entity permitted, registered or licensed by the board means (i) the purchase 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 or change in partnership composition; (iii) the acquiring of 50% 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; or (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.

"Alternate delivery site" means a location authorized in 18VAC110-20-275 to receive dispensed prescriptions on behalf of and for further delivery or administration to a patient.

"Beyond-use date" means the date beyond which the integrity of a compounded, repackaged, or dispensed drug can no longer be assured and as such is deemed to be adulterated or misbranded as defined in §§ 54.1-3461 and 54.1-3462 of the Code of Virginia.

"Board" means the Virginia Board of Pharmacy.

"CE" means continuing education as required for renewal of licensure by the Board of Pharmacy.

"CEU" means a continuing education unit awarded for credit as the equivalent of 10 contact hours.

"Chart order" means a lawful order for a drug or device entered on the chart or in a medical record of a patient by a prescriber or his designated agent.

"Compliance packaging" means packaging for dispensed drugs which is comprised of a series of containers for solid oral dosage forms and which is designed to assist the user in administering or self-administering the drugs in accordance with directions for use.

"Contact hour" means the amount of credit awarded for 60 minutes of participation in and successful completion of a continuing education program.

"Correctional facility" means any prison, penitentiary, penal facility, jail, detention unit, or other facility in which persons are incarcerated by government officials.

"DEA" means the United States Drug Enforcement Administration.

"Drug donation site" means a permitted pharmacy that specifically registers with the board for the purpose of receiving or redispensing eligible donated prescription drugs pursuant to § 54.1-3411.1 of the Code of Virginia.

"Electronic prescription" means a written prescription that is generated on an electronic application in accordance with 21 CFR Part 1300 and is transmitted to a pharmacy as an electronic data file.

"EMS" means emergency medical services.

"Expiration date" means that date placed on a drug package by the manufacturer or repacker beyond which the product may not be dispensed or used.

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

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

"Floor stock" means a supply of drugs that have been distributed for the purpose of general administration by a prescriber or other authorized person pursuant to a valid order of a prescriber.

"Foreign school of pharmacy" means a school outside the United States and its territories offering a course of study in basic sciences, pharmacology, and pharmacy of at least four years in duration resulting in a degree that qualifies a person to practice pharmacy in that country.

"Forgery" means a prescription that was falsely created, falsely signed, or altered.

"FPGEC certificate" means the certificate given by the Foreign Pharmacy Equivalency Committee of NABP that certifies that the holder of such certificate has passed the Foreign Pharmacy Equivalency Examination and a credential review of foreign training to establish educational equivalency to board approved schools of pharmacy, and has passed approved examinations establishing proficiency in English.

"Generic drug name" means the nonproprietary name listed in the United States Pharmacopeia-National Formulary (USP-NF) or in the USAN and the USP Dictionary of Drug Names.

"Hospital" or "nursing home" means those facilities as defined in Title 32.1 of the Code of Virginia or as defined in regulations by the Virginia Department of Health.

"Inactive license" means a license which is registered with the Commonwealth but does not entitle the licensee to practice, the holder of which is not required to submit documentation of CE necessary to hold an active license.

"Long-term care facility" means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.

"NABP" means the National Association of Boards of Pharmacy.

"Nuclear pharmacy" means a pharmacy providing radiopharmaceutical services.

"On duty" means that a pharmacist is on the premises at the address of the permitted pharmacy and is available as needed.

"Permitted physician" means a physician who is licensed pursuant to § 54.1-3304 of the Code of Virginia to dispense drugs to persons to whom or for whom pharmacy services are not reasonably available.

"Perpetual inventory" means an ongoing system for recording quantities of drugs received, dispensed or otherwise distributed by a pharmacy.

"Personal supervision" means the pharmacist must be physically present and render direct, personal control over the entire service being rendered or act being performed. Neither prior nor future instructions shall be sufficient nor, shall supervision rendered by telephone, written instructions, or by any mechanical or electronic methods be sufficient.

"Pharmacy closing" means that the permitted pharmacy ceases pharmacy services or fails to provide for continuity of pharmacy services or lawful access to patient prescription records or other required patient records for the purpose of continued pharmacy services to patients.

"Pharmacy technician trainee" means a person who is currently enrolled in an approved pharmacy technician training program and is performing duties restricted to pharmacy technicians for the purpose of obtaining practical experience in accordance with § 54.1-3321 D of the Code of Virginia.

"PIC" means the pharmacist-in-charge of a permitted pharmacy.

"Practice location" means any location in which a prescriber evaluates or treats a patient.

"Prescription department" means any contiguous or noncontiguous areas used for the compounding, dispensing and storage of all Schedule II through VI drugs and devices and any Schedule I investigational drugs.

"PTCB" means the Pharmacy Technician Certification Board, co-founded by the American Pharmaceutical Association and the American Society of Health System Pharmacists, as the national organization for voluntary examination and certification of pharmacy technicians.

"Quality assurance plan" means a plan approved by the board for ongoing monitoring, measuring, evaluating, and, if necessary, improving the performance of a pharmacy function or system.

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any nonradioactive 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.

"Repackaged drug" means any drug removed from the manufacturer's original package and placed in different packaging.

"Robotic pharmacy system" means a mechanical system controlled by a computer that performs operations or activities relative to the storage, packaging, labeling, dispensing, or distribution of medications, and collects, controls, and maintains all transaction information.

"Safety closure container" means a container which meets the requirements of the federal Poison Prevention Packaging Act of 1970 (15 USC §§ 1471-1476), i.e., in testing such containers, that 85% of a test group of 200 children of ages 41-52 months are unable to open the container in a five-minute period and that 80% fail in another five minutes after a demonstration of how to open it and that 90% of a test group of 100 adults must be able to open and close the container.

"Satellite pharmacy" means a pharmacy which is noncontiguous to the centrally permitted pharmacy of a hospital but at the location designated on the pharmacy permit.

"Special packaging" means packaging that is designed or constructed to be significantly difficult for children under five years of age to open to obtain a toxic or harmful amount of the drug contained therein within a reasonable time and not difficult for normal adults to use properly, but does not mean packaging which all such children cannot open or obtain a toxic or harmful amount within a reasonable time.

"Special use permit" means a permit issued to conduct a pharmacy of a special scope of service that varies in any way from the provisions of any board regulation.

"Storage temperature" means those specific directions stated in some monographs with respect to the temperatures at which pharmaceutical articles shall be stored, where it is

considered that storage at a lower or higher temperature may produce undesirable results. The conditions are defined by the following terms:

1. "Cold" means any temperature not exceeding 8°C (46°F). A refrigerator is a cold place in which temperature is maintained thermostatically between 2° and 8°C (36° and 46°F). A freezer is a cold place in which the temperature is maintained thermostatically between -20° and -10°C (-4° and 14°F).

2. "Room temperature" means the temperature prevailing in a working area.

3. "Controlled room temperature" means a temperature maintained thermostatically that encompasses the usual and customary working environment of 20° to 25°C (68° to 77°F); that results in a mean kinetic temperature calculated to be not more than 25°C; and that allows for excursions between 15° and 30°C (59° and 86°F) that are experienced in pharmacies, hospitals, and warehouses.

4. "Warm" means any temperature between 30° and 40°C (86° and 104°F).

5. "Excessive heat" means any temperature above 40°C (104°F).

6. "Protection from freezing" means where, in addition to the risk of breakage of the container, freezing subjects a product to loss of strength or potency, or to the destructive alteration of its characteristics, the container label bears an appropriate instruction to protect the product from freezing.

7. "Cool" means any temperature between 8° and 15°C (46° and 59°F).

"Terminally ill" means a patient with a terminal condition as defined in § 54.1-2982 of the Code of Virginia.

"Unit dose container" means a container that is a single-unit container, as defined in United States Pharmacopeia-National Formulary, for articles intended for administration by other than the parenteral route as a single dose, direct from the container.

"Unit dose package" means a container that contains a particular dose ordered for a patient.

"Unit dose system" means a system in which multiple drugs in unit dose packaging are dispensed in a single container, such as a medication drawer or bin, labeled only with patient name and location. Directions for administration are not provided by the pharmacy on the drug packaging or container but are obtained by the person administering directly from a prescriber's order or medication administration record.

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

"Well-closed container" means a container that protects the contents from extraneous solids and from loss of the drug under the ordinary or customary conditions of handling, shipment, storage, and distribution.

18VAC110-20-500. Licensed emergency medical services (EMS) agencies program.

A. The pharmacy may prepare a kit for a licensed ~~emergency medical services~~ EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit.

2. The kit is sealed, secured and stored in such a manner that it will deter theft or loss of drugs and devices and aid in detection ~~of such~~.

a. The hospital pharmacy shall have a method of sealing the kits such that once the seal is broken; it cannot be reasonably resealed without the breach being detected.

b. If a seal is used, it shall have a unique numeric or alphanumeric identifier to preclude replication and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a kit and maintain the record for a period of one year.

c. In lieu of a seal, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy may be used.

3. Drugs and devices may be administered by an ~~emergency medical technician~~ EMS provider upon an oral order or written order or standing protocol of an authorized medical practitioner in accordance with § 54.1-3408 of the Code of Virginia. Oral orders shall be reduced to writing by the ~~technician~~ EMS provider and shall be signed by a medical practitioner. Written standing protocols shall be signed by the operational medical director for the ~~emergency medical services~~ EMS agency. A current copy of the signed standing protocol shall be maintained by the pharmacy participating in the kit exchange. The ~~emergency medical technician~~ EMS provider shall make a record of all drugs and devices administered to a patient.

4. When the kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs and devices administered shall accompany the opened kit when exchanged. An accurate record shall be maintained by the pharmacy on the exchange of the kit for a period of one year. A pharmacist, pharmacy technician, or nurse shall reconcile the Schedule II, III, IV or V drugs in the kit at the time the opened kit is returned. A record of the reconciliation, to include any noted discrepancies, shall be maintained by the pharmacy for a period of two years from the time of exchange. The theft or any other unusual loss of any Schedule II, III, IV or V controlled substance shall be reported in accordance with § 54.1-3404 of the Code of Virginia.

5. ~~An accurate record~~ Accurate records of the following shall be maintained by the pharmacy on the exchange of the kit for a period of one year~~.~~:

a. The record of filling and verifying the kit to include the drug and device contents of kit, the initials of the pharmacist verifying the contents, date of verification, a record of an identifier if a seal is used, and the assigned expiration date for the kit which shall be no later than the expiration date associated with the first drug or device scheduled to expire.

b. The record of the exchange of the kit to include the date of exchange and the name of EMS agency and EMS provider receiving the kit.

6. Destruction of partially used Schedule II, III, IV and V drugs shall be accomplished by two persons, one of whom shall be the EMS provider and the other shall be a pharmacist, nurse, or prescriber. Documentation shall be maintained by the pharmacy for a period of two years from the date of destruction.

7. The record of the drugs and devices administered shall be maintained as a part of the pharmacy records pursuant to state and federal regulations for a period of not less than two years.

8. Intravenous and irrigation solutions provided by a hospital pharmacy to an emergency medical services agency may be stored separately outside the kit.

9. Any drug or device showing evidence of damage or tampering shall be immediately removed from the kit and replaced.

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse or prescriber.

B. In lieu of obtaining replacement intravenous and irrigation fluids via the exchanging of the kit, a licensed EMS agency may obtain a controlled substances registration pursuant to §54.1-3423 D for the purpose of performing a one-to-one exchange of such drugs.

1. The controlled substances registration may be issued to a single agency or to multiple agencies within a single jurisdiction.

2. The controlled substances registration issued solely for this intended purpose does not authorize the storage of drugs within the agency facility.

3. Pursuant to § 54.1-3434.02, the EMS provider may directly obtain intravenous and irrigation fluids from an automated drug dispensing device.

4. If such drugs are obtained from a nurse, pharmacist, or prescriber, it shall be in accordance with the procedures established by the PIC which shall include a requirement to record the date of exchange, name of licensed person providing drug, name of the EMS agency and provider receiving the drug, and assigned expiration date. Such record shall be maintained by the pharmacy for one year from the date of exchange.

Staff's suggested amendment:

18VAC110-20-590. Drugs in correctional facilities.

A. All prescription drugs at any correctional facility shall be ~~obtained only on an individual prescription basis from a pharmacy and~~ subject to the following conditions:

1. Notwithstanding the allowances in subsections B, C, and D, prescription drugs shall be obtained only on an individual prescription basis.

2. All prepared drugs shall be maintained in a suitable locked storage area with only the person responsible for administering the drugs having access.

~~2~~3. Complete and accurate records shall be maintained of all drugs received, administered and discontinued. The administration record shall show the:

a. Patient name;

b. Drug name and strength;

c. Number of dosage units received;

d. Prescriber's name; and

e. Date, time and signature of the person administering the individual dose of drug.

~~3~~4. All unused or discontinued drugs shall be sealed and the amount in the container at the time of the sealing shall be recorded on the drug administration record. Such drugs shall be returned to the provider pharmacy or to a secondary pharmacy along with the drug administration record, a copy of the drug administration record, or other form showing substantially the same information, within thirty days of discontinuance.

a. The provider or secondary pharmacy shall conduct random audits of returned drug administration records for accountability.

b. The drug administration records shall be filed in chronological order by the provider or secondary pharmacy and maintained for a period of one year or, at the option of the facility, the records may be returned by the pharmacy to the facility.

c. Drugs may be returned to pharmacy stock in compliance with the provisions of 18VAC110-20-400.

d. Other drugs shall be disposed of or destroyed by the provider pharmacy in accordance with local, state, and federal regulations.

45. Alternatively, drugs for destruction may be forwarded by a pharmacist directly from the correctional facility to a returns company after performing the audit required by subdivision ~~3~~ 4 a of this subsection and ensuring the proper maintenance of the administration records.

B. Emergency and stat-drug box. An emergency box and a stat-drug box may be prepared for a correctional facility served by the pharmacy pursuant to 18VAC110-20-540 and 18VAC110-20-550 provided that the facility employs one or more full-time physicians, registered nurses, licensed practical nurses, or physician assistants.

C. A correctional facility may maintain a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline to be accessed only by those persons licensed to administer drugs and administered only by such persons pursuant to a valid prescription or lawful order of a prescriber. Such stock shall be limited to a listing to be determined by the provider pharmacist in consultation with the medical and nursing staff of the institution.

~~C~~D. Except for drugs in an emergency box, stat-drug box, or a stock of intravenous fluids, irrigation fluids, sterile water, and sterile saline, ~~P~~prescription drugs, including but not limited to vaccines, may be floor-stocked only at a medical clinic or surgery center which is part of a correctional facility and which is staffed by one or more prescribers during the hours of operation provided the clinic first obtains a controlled substances registration and complies with the requirements of 18VAC110-20-690, 18VAC110-20-700, 18VAC110-20-710, and 18VAC110-20-720.

Agenda Item: Response to Petition for Rulemaking

Included in your agenda package are:

A copy of the petition received from Daniel Colpo

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

Copy of comments on the petition

Staff Note:

There was a comment period on the petition until February 12, 2014. Comments were received by hard copy sent to the Board, email or through the Virginia Regulatory Townhall.

Board action:

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

OR

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

OR

The Board may reject the petitioner's request but refer the matter to the Regulation Committee for further consideration and collection of data.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

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

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

Petitioner's full name (Last, First, Middle initial, Suffix,) COLPO DANIEL C		
Street Address 13901 SHADOW RIDGE LANE	**Area Code and Telephone Number** (804) 744-5948	
City MIDLOTHIAN	**State** VA	**Zip Code** 23112
Email Address (optional) DANCOLPO@AOL.COM	**Fax (optional)**	

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. 18VAC110-20-240 MAINTAINING RECORDS
18VAC110-20-270C
FILLING OF PRESCRIPTIONS - INCENTING PATIENTS TO ROUTINELY CHANGE PHARMACIES

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.
IN COMMUNITY PHARMACY WE INCENT PATIENTS TO PRACTICE POLY-PHARMACY THROUGH COUPONS TO TRANSFER PRESCRIPTIONS FROM ONE STORE TO ANOTHER. THIS PROMOTION LEADS TO OPENING PATIENTS UP TO POTENTIAL MEDICATION SAFETY CONCERNS THROUGH INCOMPLETE DUR/PROFILE DATA, TRANSCRIPTION ERRORS

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.
54.1-3307-1 MAINTENANCE OF QUALITY, INTEGRITY AND SAFETY OF DRUGS DISTRIBUTED, DISPENSED OR ADMINISTERED

Signature: Daniel C Colpo **Date:** 12/10/13

PETITIONS FOR RULEMAKING

VOL. 30 ISS. 10 - JANUARY 13, 2014

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TITLE 18. PROFESSIONAL AND OCCUPATIONAL LICENSING

BOARD OF PHARMACY

Initial Agency Notice

Title of Regulation: **18VAC110-20. Regulations Governing the Practice of Pharmacy.**

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

Name of Petitioner: Daniel Colpo.

Nature of Petitioner's Request: Prohibit acceptance of coupons for dispensing as it has potential for medication safety concerns through incomplete DUR/Profile data and transcription errors.

Agency Plan for Disposition of Request: The petition has been filed with the Virginia Register of Regulations and will be published on January 13, 2014. Comment on the petition may be sent by email, regular mail, or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until February 12, 2014. Following receipt of all comments on the petition to amend regulations, the board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the board's agenda for its meeting scheduled for March 26, 2014.

Public Comment Deadline: February 12, 2014.

Agency Contact: Elaine Yeatts, Agency Regulatory Coordinator, Department of Health Professions, 9960 Mayland Drive, Henrico, VA 23233, telephone (804) 367-4688, or email elaine.yeatts@dhp.virginia.gov.

VA.R. Doc. No. R14-04; Filed December 12, 2013, 3:22 p.m.

VIRGINIA PHARMACISTS ASSOCIATION

2530 Professional Road ~ Richmond, Virginia 23235
Phone: (804) 285-4145 Fax: (804) 285-4227
E-Mail: vpha@virginiapharmacists.org www.virginiapharmacists.org

February 11, 2014

Elaine Yeatts
Virginia Board of Pharmacy
Agency Regulatory Coordinator
9960 Mayland Drive
Henrico, VA 23233
elaine.yeatts@dhp.virginia.gov

Comments on Petition: "Coupons for dispensing prescriptions"

Dear Ms. Yates,

The Virginia Pharmacists Association (VPhA) is pleased to provide comments in support of the petition "Coupons for dispensing prescriptions". The Virginia Pharmacists Association has the following policy concerning the use of pharmacy coupons and transfer incentives:

12-B01 Use of Pharmacy Coupons and Transfer Incentives
The Virginia Pharmacists Association recognizes the use of pharmacy competitor prescription coupons and other transfer incentives may encourage poly pharmacy. The use of these incentives does not facilitate the goal of a concise medical home or complete medication record for review by the pharmacist(s). Whereas the use of prescription coupons in the form of manufacturer coupons can assist patients with compliance to their medication regimen, VPhA discourages the use of transfer coupons and transfer incentives among pharmacies. Transfer coupons and other transfer incentives fragment the medication record of patients which leads to inaccuracies in the medication records and is detrimental to patient care. VPhA advocates for the use of a single pharmacy for pharmaceutical services and promotes the prescriber-pharmacist-patient relationship.

We encourage the Board to consider implementing regulations in response to this petition.

Sincerely,

Timothy S. Musselman, Pharm.D.
Executive Director

AMCP Academy of Managed Care Pharmacy®

February 12, 2014

Elaine Yeats
Agency Regulatory Coordinator
Department of Health Professions
9960 Maryland Drive
Henrico, VA 23233

Re:In support of petition to prohibit acceptance of coupons for dispensing because of the potential for medication safety concerns through incomplete DUR/profile data and transcription errors; would amend 18 VAC 110-20. Regulations Governing the Practice of Pharmacy

Dear Ms. Yeats:

The Academy of Managed Care Pharmacy (AMCP) writes in support of the petition to prohibit acceptance of coupons for dispensing because of the potential for medication safety concerns and the potential to undermine formulary development and utilization management that health plans utilize to provide evidence-based, cost-effective access to medications. AMCP would support patient assistance programs offered through either philanthropic or manufacturer-sponsored organizations that offer assistance based on economic need or to ensure appropriate patient access to high-cost medications, particularly specialty products with no therapeutic alternative with high-cost sharing.

AMCP is a national professional association of pharmacists, physicians, nurses and other managed care practitioners with nearly 7,000 members who provide services on behalf of the more than 200 million Americans served by managed care organizations, including health plans and pharmacy benefit management companies. Our members are responsible for managing prescription drug benefits on behalf of clients of the managed care organizations that employ them. They are responsible for implementing a broad and diversified range of clinical, quality-oriented services and strategies whose objective is to assure that individual patients receive the appropriate drug at the right time in a convenient, cost-effective manner.

AMCP opposes the use of manufacturer coupons because the net result of these coupons is additional, unnecessary costs to plans, employers, state and federal governments and other payers. These programs often encourage patients to utilize high-cost medications when other formulary alternatives may be available at lower-cost sharing rates. Manufacturer coupons often steer patients to more-expensive products, but not necessarily clinically better products by eliminating the patient's cost differential among preferred agents. The manufacturer then reimburses the pharmacy for the cost of the coupon, but plans, employers, and federal and state governments are still be responsible for paying higher costs associated with that medication in reimbursement to the pharmacy. In many cases, medication classes offering prescription drug coupons (including statin medications to lower high cholesterol, medications for high

100 North Pitt Street | Suite 400
Alexandria, VA 22314
800 827 2627 | 703 683 8416
Fax 703 683 8417
www.amcp.org

blood pressure and other cardiovascular conditions) have multiple safe and effective alternatives available, including generics, at lower cost-sharing for patients. Medications included on a plan's formulary at more favorable cost sharing levels reduce patient, plan and payer costs by lowering overall medication spending.

Patients also often overlook that most coupon programs may only be used for a limited period of time and thus in the long run, may increase the cost of the medication for the patient. Many manufacturer programs limit the number of total prescription fills that qualify for the coupon, such as 12 total refills or 12 months total, and therefore, patients do not receive an indefinite benefit. Patients might then be forced to pay higher costs for the medication or change to a lower-cost, formulary alternative that would likely have been suitable at the beginning of therapy. In addition, additional costs incurred by plans and payers associated with providing the higher cost medications may also result in increased premium costs for patients.

AMCP also opposes the use of retail pharmacy coupons used to encourage patients to transfer prescriptions from a competing pharmacy. These coupons usually reward patients with store credit toward the purchase of non-pharmacy-related merchandise. When these coupons are used appropriately, patients may save money; however, patients who frequently transfer prescriptions among pharmacies to take advantage of such offers could see an increase in medication errors, duplicative therapy, and unnecessary medication-related problems. AMCP also opposes use of these coupons because of the safety concerns that result from pharmacies' and health plans' inability to access a full patient prescription record. This situation occurs because patients using the coupon may pay for the prescription in cash, rather than using their prescription drug benefit card, and thus the prescription would not be sent to the plan. While this might save the patient money, the plan has no record of the prescription and thus is unable to review the patient's record for duplicative claims, potential for adverse events, and for other medication-related problems. Therefore, if retail pharmacy coupons are used, at a minimum AMCP supports the requirement that cash claims be adjudicated to payers to ensure a medication record that allows for comprehensive drug utilization review and other safety checks used prior to dispensing.

AMCP thanks the Virginia Department of Health Professions for seeking comments on this important issue. AMCP reiterates support for programs that help patients afford prescription medications, but emphasizes that these programs should not be used when there is the potential to compromise patient safety and needlessly increase overall medication costs. If you have any questions, please contact me by email at erosato@amcp.org or by phone at 703-683-8416.

Sincerely,

Edith A. Rosato, R.Ph., IOM
Chief Executive Officer

Comments from Virginia Regulatory Townhall

Colpo Petition on Acceptance of coupons for prescriptions

Chapter

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

1/28/14 3:05 pm

Commenter: Travis Hale, Remington Drug Co *

Coupon Inflating Overall Costs

I am not a supporter of coupons as I feel they drastically add to the overall costs of the system as the patient, in many instances, does not see the true cost of the medication. Many times there is a generic alternative that would clinically provide the same benefit. I see this most often in dermatology as topical products come out under a new Brand Name with a slightly adjusted strength. Given the difference in cost of the medication, it is not necessarily cost effective to go with the Brand just because the doctors office has given the patient a coupon. Most patients will take the medication where the coupon has cut the price to $25 for example, when their normal copay would be $100. When that copay coupon is no longer active, they no longer want to get the product. They're willing to accept the generic at that point. This has resulted in a large dollar amount being applied to the overall system while they filled the Brand name with a coupon, when they would have been fine with a less expensive generic had they been responsible for their insurance copay. The pharmacy can also be stuck with a partial bottle of an expensive medication that they may or may not see another script for, resulting in drug expiration and a monetary loss.

2/12/14 12:27 pm

Commenter: Dave Jussen *

pharmacy coupons

I am not in support of pharmacy coupons. Tranferring prescriptions multiple times (for the benefit of cashing in on a coupon offer) increases the risk of potential mistakes and reduces the opportunity to perform a meaningful drug utilization review. (ie. compliance and interactions. Overall, we are contributing to the misconception that the service we perform is nothing more than putting a label on a smaller consumer-safe package.

2/12/14 5:50 pm

Commenter: big chain community pharmacist *

transfer coupons/incentive programs

Allowing transfer coupons and programs that encourage transfers only promotes poly-pharmacy. This breeds potiental for serious medication errors. The purpose of a pharmacist is to asses if a medication is safe for a patient to take or not. Patients have been taking advanage of these programs by transfering multiple scripts to multiple pharmacies that offer transfer gift cards. I personally had a patient ask me to transfer three of her prescriptions, one of which was a new presciption never filled, to three different chain pharmacies. Those pharmacists have no way of knowing if those prescriptions should or should not be filled without doctor intervention. I am concerned in this economy where every dollar counts patients will continue to fill their prescriptions at mulitple pharmacies leading a serious errors.

was made that the practice may increase drug compliance and reduce the probability of a patient losing the prescription(s). Members expressed an interest in learning the requirements in other states. Ms. Juran stated that Ohio's regulations require the "on-hold" prescription to be entered into the pharmacy's automated data processing system when received, assigned a serial number, and permanently filed chronologically. Additionally, she stated that staff had received an email in the past from DEA with an informal opinion that while not directly prohibited by federal regulation, the practice of a pharmacy "holding" a patient's prescription(s) for dispensing at a later time was not recommended due to concerns for diversion. There was discussion to delay the decision-making process until more research could be performed regarding other states' requirements.

Motion:

The Board voted unanimously to deny the petition for rulemaking to amend Regulation 18 VAC 110-20-240, but agreed to query other states to determine their policies and/or rules for the filing of "on-hold" prescriptions and to revisit the request in December after additional information is obtained. (motion by Kozera, second by Beckner)

UPDATE ON ACTION ITEMS:

- Pharmacy coupons

In response to the letter received by Jonathan Carter, a pharmacy student at VCU School of Pharmacy, requesting a prohibition on the use of pharmacy coupons and as requested by the Board at the June 2, 2010 board meeting, a survey of other states' restrictions on the use of pharmacy coupons was performed by NABP. Of the states that responded to the survey, Ms. Juran stated that she could only confirm that New York had current restrictions in place. New York restricts coupons to be used only for a discount or reduction of co-pay and not for other merchandise. Additionally, Mr. Yi stated that New Jersey's regulation regarding unprofessional conduct includes the distribution of premiums or rebates in connection with the sale of drugs, with some exception for trading stamps and discounts for seniors. Board counsel stated a prohibition of coupons may be a possible restraint of trade and that the Federal Trade Commission previously required the Board of Funeral Directors and Embalmers to reverse a prohibition of coupons/fee reductions. After further discussion, the Board decided to take no action at this time and to monitor future use of pharmacy coupons.

Motion:

The Board voted unanimously to take no action at this time regarding the request to prohibit the use of pharmacy coupons and to monitor the future use of these coupons. (motion by

Beckner, second by Kozera)

- Discussion regarding need for sending guidance document 110-27 to a new PIC now that attestation is included on the pharmacy permit application

Ms. Juran reported that staff had added the attestation to the pharmacy permit application, as requested at the June 2, 2010 board meeting, which requires the new pharmacist-in-charge to acknowledge having read and understood Guidance Document 110-27 and associated information regarding the inspection process. As a result, Ms. Juran asked if the Board wanted staff to continue mailing Guidance Document 110-27 along with the frequently asked questions (FAQs) regarding the pharmacy technician registration process after processing these submitted applications. The consensus was that staff should continue mailing the Guidance Document and the FAQs to ensure another opportunity for the PIC to read and understand the importance of the information contained within the document.

MISCELLANEOUS:

- Request from Allergan to discuss requirements for physician dispensing of topical drugs for aesthetic purposes

Ms. Juran stated that she; Scotti Russell, former Executive Director of the Board of Pharmacy; Scott Johnson and Tyler Cox of Hancock, Daniel, Johnson & Nagle, P.C.; and Pat Cannon, RN, Allergan, Inc., met on July 12, 2010. The meeting was to discuss current requirements for a physician to dispense drugs for aesthetic purposes. A formal request was then submitted to include this item on the September board meeting agenda to request an exemption from the security system and square footage requirements when dispensing topical Schedule VI drugs for aesthetic purposes. Ms. Juran explained that Regulation 18 VAC 110-30-20 already allows for the issuance of a limited-use license and that the Board has previously provided waivers of the 60 square feet requirement for the controlled substances selling and storage area when the scope, degree or type of services provided to the patient is of a limited nature and the inspector deems the square footage is sufficient for performing the limited purposes. There was discussion as to whether a security system should be required for protecting public safety when dispensing only topical Schedule VI cosmetic drugs and whether a limitation should be imposed on the number of drugs that could be dispensed by a physician when exempted from the security system requirement. After discussion, the Board determined it would delegate to the executive director, in consultation with the board chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses and a waiver of the square footage and security system may be provided when storing and selling multiple strengths and formulations of no more than 5 different topical Schedule VI drugs intended for cosmetic use.

Motion:

The Board voted unanimously to delegate to the executive

* 2009 request referenced in 9/8/10 minutes

COMMONWEALTH of VIRGINIA

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

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

www.dhp.virginia.gov
TEL (804) 367-4400
FAX (804) 527-4475

September 23, 2010

Jonathan Carter
9143 Green Road
Warrenton, VA 20187

Dear Mr. Carter:

I am writing in response to your letter received by the Board on November 13, 2009 expressing concerns for the "widespread use" of pharmacy coupons explaining that you believed it created a patient safety issue for persons to have multiple prescriptions at multiple pharmacies and impedes a pharmacist's ability to perform a satisfactory prospective and/or retrospective DUR process. Furthermore, you requested the Board to prohibit the use of pharmacy coupons in the Commonwealth of Virginia. Please be aware that your request was discussed at the March 2010 full board meeting, wherein the Board requested staff to research this topic through the National Association of Boards of Pharmacy (NABP) to determine how this issue is being addressed nationally. The results of the survey performed by NABP were then shared with the Board during the September 2010 full board meeting. Discussion points included the following information: two states have restrictions currently in place regarding the use of coupons; New York restricts coupons to be used only for a discount or reduction of co-pay and not for other merchandise; New Jersey's regulation regarding unprofessional conduct includes the distribution of premiums or rebates in connection with the sale of drugs, with some exception for trading stamps and discounts for seniors; and Board counsel opined that a prohibition of coupons may be a possible restraint of trade and that the Federal Trade Commission previously required the Board of Funeral Directors and Embalmers to reverse a prohibition of coupons/fee reductions. At the conclusion of the discussion, the Board decided to take no action at this time and to monitor future use of pharmacy coupons.

Thank you for sharing your concerns and request with the Board. Please contact me at (804) 367-4456 should you have any questions on this matter.

Sincerely,

Caroline D. Juran
Acting Executive Director

cc: Elaine Yeatts, Senior Policy Analyst, Department of Health Professions

NOV 13 2009

DHP

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

November 10, 2009

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

Dear Board Members,

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

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

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

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

87

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

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

Sincerely,

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

Containment Technologies Group, Inc.

DEC 1 1 2013
DHP

December 6, 2013

Caroline D. Juran
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico Virginia 23233-1463

Dear Ms. Juran,

It has come to the attention of Containment Technologies Group, Inc. that the Virginia Board of Pharmacy has included the following in its regulations:

1. ***What minimally should be taken into consideration when having primary and secondary engineering controls certified?***

   Certifying companies must comply with guidelines published by the Controlled Environment Testing Association (CETA). Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with CETA guidelines. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

We certainly agree that certification documentation should contain data not simply a pass / fail.

The board may not be aware that the CETA guides are the center of concern for several reasons. Based on the fact that the content of the CETA tests included in CAG-002-2006 are not consistent with ISO 14644-1 requirements for testing as outlined in ISO 14644- 2 Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 and ISO 14644-3 Part 3 Test Methods.

USP <797> requires compliance with the ISO 14644-1 standard for Class 5 conditions. CTG as the manufacturer of the MIC refuses to use the CETA CAG-002 as test methods because it does not follow the ISO 14644-1 guidance. The CETA CAG-002 contains the following conflicts with the 2012 USP <797> and ISO Standards.

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- The CETA document requires unrealistic testing conditions. See 2.06, 2.07, 2.09, 2.12 while ISO requires testing in any of three conditions; as built, static or in use. USP <797> required testing in "dynamic" conditions. The CETA tests enhance conditions by generating particle in excess of these requirements.

- The CETA CAG- 002 requires testing of things not specified in USP <797>. See 2.03, 2.04, 2.10, 2.11. 2.13. Pass / Fail cannot be based something that is not in the standard.

USP Chief legal counsel, Ms Susan deMars has provided documentation to the fact that the CETA guide is simply an example.

I respectfully request that your board review the attached documentation and remove the requirement of the CETA guide. Insert the correct reference which is ISO 14644-1 requirements for testing as outlined in ISO 14644- 2 Part 2: Specifications for testing and monitoring to prove continued compliance with ISO 14644-1 and ISO 14644-3 Part 3 Test Methods.

Sincerely,

Hank Rahe

Hank Rahe
Director Technology
CTG
hrahe@mic4.com
317 713-8203

ATTACHMENTS

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September 9, 2013

VIA CERTIFIED MAIL – RETURN RECEIPT REQUESTED

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Re: Containment Technologies Group, Inc.—MIC Dual Chamber Unit
Our File No. LR12685-0607739

Dear Executive Committee:

I represent Containment Technologies Group, Inc. ("CTG"). As you may know, CTG manufactures and sells CAI/CACI devices to health care facilities within the United States as well as a number of U.S. military facilities across the world.

It has come to the attention of CTG that its products, including its MIC device, were the subject matter of several discussions and presentations that took place at CETA's annual meeting in Orlando, Florida last April. Specifically, two different members of CETA (Medrep Technologies, Inc. of Port Charlotte, Florida and Quality Air Services, Inc. of Kalamazoo, Michigan) have made inaccurate and unsubstantiated statements that the "official" outcome of these discussions and presentations was that CTG's MIC unit did not satisfy USP <797>. These falsities are disrupting CTG's ongoing contractual relationships. Furthermore, and to the extent the inaccurate statements are intended to or have had the practical effect of artificially constraining competition, CETA is potentially engaging in anti-competitive behavior either directly or in concert with some of its members in violation of anti-trust laws, including but not limited to the Sherman Act.

First, CETA nor its members are qualified to conclude whether CTG's MIC unit is compliant with USP <797> without the correct protocols that address the MIC technology. According to CTG, the airflow in the MIC is unique and provides a greater sterility assurance level than conventional CAI/CACI's. Compounding sterile preparations in a manner that assures patient safety requires a combination of factors including a clean environment and decontamination techniques that reduce the potential of viable microorganisms. USP recognized this and has included in its standard a statement that allows for advancement of the sterile compounding practices beyond those described in the standard. The statement is "[t]he use of technologies, techniques, materials and procedures other than described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein". CTG, through validation of their technology and techniques used by the MIC, has demonstrated with statistical significance an equal to or greater sterility assurance level than conventional airflows.

Second, CETA's *Certification Guide for Sterile Compounding Facilities (CAG-00302006)* is not a standard mandated by USP <797>. The misuse of the reference to this document by CETA members amounts to an inappropriate restraint of trade. I attach two letters from Ms. Susan de Mars, General Counsel of USP, that respond to CTG's concern about the misuse and misrepresentations being made by certifiers as to USP <797>'s guidelines for

certification of CAI/CACI devices. I also attach Ms. de Mars letter of November 6, 2006 to Mr. Gene Klingbeil, President of CETA, admonishing CETA and its members to refrain from further misrepresentations that USP <797> mandates the use of CETA's *Certification Guide for Sterile Compounding Facilities* when certifying CAI/CACI devices.

CTG demands that CETA instruct all of its members, in writing, to cease making statements that CETA, itself or through any of its members, has concluded that CTG's MIC unit does not satisfy USP <797> and further refrain from making any statements that USP <797> mandates the use of CETA's *Certification Guide for Sterile Compounding Facilities* when certifying CAI/CACI devices. Please provide me a copy of the written instruction disseminated to CETA's members.

Sincerely,

FROST BROWN TODD LLC

Daniel P. King

DPK:tw
Enclosures

INDLibrary1 LR12685.0607739 1144453v1

bcc: Hank Rahe w/enc. (hrahe@mic4.com)

INDLibrary1 LR12685.0607739 1144453v1

U.S. Pharmacopeia
The Standard of Quality

August 29, 2006

Mr. Hank Rahe
Containment Technologies Group, Inc.
5460 Victory Drive
Indianapolis, IN 46203

Dear Mr. Rahe:

I am writing to respond to your letter of August 10, 2006, regarding the incorporation of the CETA Testing Guide in USP<797>, and to answer the questions you posed in your letter.

With regard to the current official version of <797>, the chapter contains no reference to the CETA testing guide. Thus, use of the CETA testing guide is not required under the existing USP standard.

The CETA Testing Guide is referenced in the proposed revisions to <797>. The relevant language referencing the guide states:

Engineering Control Performance Verification
Primary (e.g., LAFWs, BSCs, and CAIs) and secondary (e.g., buffer and ante rooms/areas) engineering controls are essential components of the overall contamination strategy for aseptic compounding. As such, it is imperative that they perform as designed and the resulting levels of contamination are within acceptable limits. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2005) should be 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.

As you can see, this language does not specifically require the use of CETA Testing Guide in order to meet the standard. Rather, it simply lists the guide as an example of a suitable certification procedure. Moreover, as you are also aware, the proposed revisions to <797>, including this language, are still under review by the Sterile Compounding Expert Committee. At this point, it would be premature to speculate whether and how the CETA Testing Guide might be referred to in the revised official version of <797>.

I would also like to clarify that neither the current official nor the revised version of <797> constitutes regulation", as your letter implies. USP produces public standards, but as a private, non-governmental body has no authority to establish law or regulations. It is up to the various State Boards of Pharmacy and other relevant regulatory authorities to determine whether and how the standards contained in <797> should be incorporated into laws or regulations and made legally enforceable.

I hope this sufficiently responds to your letter. Should you have further questions, please do not hesitate to contact me.

Sincerely,

Susan S. de Mars
Chief Legal Officer

U.S. Pharmacopeia
The Standard of Quality℠

November 6, 2006

Mr. Gene Klingbeil
President
Controlled Environment Testing Association
1500 Sunday Drive, Suite 102,
Raleigh, NC 27607

Dear Mr. Klingbeil:

As you may know, USP's Sterile Compounding Expert Committee has been working on revisions to <797> Pharmaceutical Compounding – Sterile Preparations. The proposed revisions, which recently were published for public comment, reference the CETA Certification Guide for Sterile Compounding Facilities (CETA Guide), as follows:

> Engineering Control Performance Verification
> Primary (e.g. LAFWs, BSCs, and CAIs) and secondary (e.g. buffer and ante rooms/areas) engineering controls are essential components of the overall contamination strategy for aseptic compounding. As such, it is imperative that they perform as designed and the resulting levels of contamination are within acceptable limits. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2005) should be 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.

This language does not specifically require the use of the CETA Guide; rather, it simply lists the Guide as an example of suitable certification procedures. USP will often reference other standards or guidance documents where appropriate, without necessarily making them an official part of the USP standard. Another example of this in the proposed revisions to <797> is the reference to ISO 4644-1 with regard to classification of air cleanliness.

Most importantly, while the CETA Guide, like ISO 4644-1, may provide a valuable tool, it is only referenced in the proposed changes to <797> at this time, and is not included in the current official version of the chapter. Like all other aspects of the proposed revisions, inclusion of this reference is still under review and consideration by the Expert Committee.

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I would appreciate your communicating this information to your members so that they understand that the reference to the CETA Guide is contained only in the proposed revisions to <797> and not in the official version of this chapter, and should not be characterized as part of the current USP standard or requirements.

Thank you for your assistance and cooperation, and should you have any questions, please do not hesitate to contact me.

Sincerely,

Susan de Mars
Chief Legal Officer

Virginia Board of Pharmacy

COMPLIANCE WITH USP STANDARDS FOR COMPOUNDING

§54.1-3410.2 requires pharmacies performing sterile or non-sterile compounding to comply with USP Standards. USP standards for sterile and non-sterile compounding may be found in the current editions of the USP-NF. In accordance with 18VAC110-20-170, the Board requires a pharmacy to maintain references consistent with the pharmacy's scope of practice and with public safety.

USP Chapter 795 lists the requirements for non-sterile compounding including information about the compounding environment, equipment, stability criteria and beyond-use dating and records. USP Chapter 797 lists requirements for policies and procedures, training and evaluation of personnel performing sterile compounding, determining risk levels and the physical standards for the sterile compounding area. The Board expects that the requirements of Chapters 795 and 797 will be found in compliance at time of inspection.

The terms "annually" and "semiannually" as used in USP Chapters 795 and 797 are defined to mean every 12 months and every 6 months, respectively. Records associated with annual and semiannual requirements shall be maintained in accordance with USP standards. Such records may be maintained as an electronic image that provides an exact image of the document that is clearly legible provided such electronic image is retrievable and made available at the time of inspection or audit by the Board or an authorized agent.

1. ***Where may information regarding USP-NF standards for compounding be located?***

   A subscription to the current version of "USP on Compounding: A Guide for the Compounding Practitioner" may be purchased at http://www.usp.org/store/products-services/usp-compounding This guide provides access to all compounding-related General Chapters from the USP-NF and is updated with the release of each new USP-NF edition and supplement. The latest edition, USP 36- NF 31, published on November 1, 2012 becomes official May 1, 2013.

2. ***Does the law require compliance only with Chapter <797>?***

   No, the law requires compliance with all applicable chapters within USP-NF. Regarding sterile compounding, pharmacists should pay particularly close attention to General Chapters: <1> Injections, <51> Antimicrobial Effectiveness Testing, <71> Sterility Testing, <85> Bacterial Endotoxin Testing, and <797> Pharmaceutical Compounding- Sterile Preparations.

3. ***In the absence of sterility testing, what beyond use dates (BUDs) must be used?***

   When sterility testing has not been performed, the assigned BUD must not exceed the following allowances:

	Controlled Room Temperature	Refrigerator	Freezer
Low-risk	48 hours	14 days	45 days
Medium-risk	30 hours	9 days	45 days
High-risk	24 hours	3 days	45 days

4. ***Is it appropriate to assign a BUD of 90 days in the absence of sterility testing if there is literature indicating the stability of the drug is assured for 90 days?***
   No, it is inappropriate and a violation of law to assign a BUD which exceeds the USP default BUDs in the absence of sterility testing. Drug stability should not be confused with drug sterility.

5. ***What is skip lot testing and may skip lot testing be used to perform sterility testing of compounded sterile products?***

   Skip lot testing is a process that only tests a fraction of the drugs compounded. It is NOT appropriate for sterility testing. It may only be used for ensuring consistency and drug strength (potency). Because skip lot testing is complex and requires a robust program, it may not be possible for a pharmacy to properly implement. Information regarding skip lot testing may be accessed at http://www.itl.nist.gov/div898/handbook/pmc/section2/pmc27.htm

6. ***How may a hospital pharmacy "batch-producing" limited quantity of CSPs for IN-HOUSE use extend the BUD past the default dating in Chapter <797>?***

   EACH BATCH must undergo sterility testing in accordance with USP Chapter <71> in order to extend the BUD past the default dating in Chapter <797> and the appropriate documentation to support an extended BUD must be kept on file for presentation upon inspection.

7. ***Do batches less than 25 require sterility testing to be performed?***

   No, however, the batches may not be assigned a BUD which exceeds the default BUDs in USP Chapter <797>. The chapter requires sterility testing according to USP <71> before CSPs are dispensed or administered when:
   - high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or
   - in multiple-dose vials (MDVs) for administration to multiple patients or
   - CSPs that are exposed longer than 12 hours at 2 to 8 C and longer than 6 hours at warmer than 8 C before they are sterilized.

8. ***How often must the primary engineering control, e.g., laminar airflow workbench and secondary engineering control, e.g., ante and buffer rooms be certified?***

   Certification of the primary and secondary engineering controls shall be performed no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. The certification must be performed no later than *the last day of the sixth month*, following the previous certification.

***Note-** this guidance reflects a change to Major Deficiencies 22 and 23 in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

9. ***Must compounding personnel who work in multiple pharmacies, to include pharmacy interns on rotations, pass a media-fill test at each pharmacy where they will prepare CSPs?***

Yes, all compounding personnel working in multiple pharmacies, to include pharmacy interns on rotations, must pass a media-fill test at each pharmacy prior to performing sterile compounding.

10. ***How often must media-fill testing be performed?***

Media-fill testing of all compounding personnel shall be performed initially prior to beginning sterile compounding and at least annually thereafter for low and medium-risk compounding, and semiannually for high-risk level compounding. ***Note -** the terms "annually" and "semi-annually" are defined within this guidance document to mean every 12 months and every 6 months, respectively.

11. ***If compounding personnel fail a media-fill test, may they continue preparing compounded sterile products?***

No, compounding personnel who failed a media-fill test may not be allowed to prepare compounded sterile products (low, medium, or high-risk) prior to retraining and receipt of a passing media-fill test. ***Note-** this guidance reflects a change to Major Deficiency 26a in Guidance Document 110-9 which was amended at the March 2013 full board meeting.

12. ***Because batches less than 25 do not require sterility testing to be performed, may the CSP which may have been autoclaved be assigned an extended BUD based on stability data?***

Yes, sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units. The board would expect to see that biological indicators are used with each autoclave batch and that the cycle time and temperature were recorded on a log or printer tape directly from the autoclave.

13. ***Does USP-NF address how long a CSP may hang for infusion?***

No, USP-NF does not address how long a CSP may hang for infusion. Refer to facility policy on this issue. USP-NF, however, does require the administration of CSPs to begin prior to the assigned BUD.

14. ***May a pharmacist repackage Avastin for office administration not pursuant to a patient-specific prescription?***

No. While pharmacists may repackage a drug product when dispensing a drug pursuant to patient-specific prescription, a pharmacist may not repackage a drug for another entity. The board has historically interpreted the repackaging of a drug for distribution purposes as an act restricted to a manufacturer, defined in Va Code §54.1-3401. This interpretation appears consistent with recent warning letters from the US Food and Drug Administration (FDA). The

allowance in Va Code §54.1-3401 for a pharmacist to provide compounded drugs to a physician for office administration does not apply. Repackaging Avastin does not constitute compounding as it does not involve the mixing of two of more substances.

15. May a pharmacist repackage Avastin pursuant to a patient-specific prescription?

Yes, a pharmacist may repackage a drug as part of the dispensing process pursuant to a patient-specific prescription.

16. What concepts, at a minimum, should be taken into consideration when performing sterility testing of CSPs?

- Maintain a written policy and procedure manual clearly identifying sterility testing procedures used by the pharmacy and processes for assigning BUDs.
- Prior to using an outside testing company to perform sterility testing, evaluate the company to determine if it performs testing in full compliance with USP Chapter <71>. This may be done by reviewing 483 reports issued by the FDA to the testing company and which may be available on the FDA website. Alternatively, request copies of the 483 reports directly from the testing company. The observed deficiencies noted on the 483 reports will assist the pharmacist in evaluating the testing company's level of compliance. Also, request written documentation from the testing company which explains the sterility testing processes used and how it complies with USP Chapter <71> in its totality. This documentation should contain, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of testing method (membrane filtration is the preferred method of testing), two growth media, and number of days of incubation. Have this documentation readily available for inspector review.
- When performing sterility testing in-house, document in the written policy and procedure manual, at a minimum, specific details regarding the method of testing, method suitability associated with each sterility testing process to ensure the drug being tested will not interfere with the test, identification of two growth media, and number of days of incubation.
- Vendors providing products for in-house testing must describe all conditions and limitations to their testing products. Ensure the appropriate filtration volume and sample size is being tested.
- When determining an appropriate sterility testing process, note that the preferred method per USP is membrane filtration. The Board strongly recommends that written documentation justifying the use of direct inoculation be available for inspection
- Ensure the sterility testing incorporates two media for growth.
- The sample size used for testing must comply with USP Chapter <71>, tables 2 and 3.
- Maintain robust recordkeeping, e.g., chart the dates, temperatures, growth associated with the two media incubations, and employee signatures. Do not simply indicate "no growth" without indicating which growth media was used and the number of days incubated.

17. Must sterility testing be performed on all batches of CSPs?

Sterility testing is not required of low and medium-risk level batched CSPs if the BUDs do not exceed the default BUDs found in USP Chapter <797>. If the low or medium-risk level batched CSP is to be assigned an extended BUD, then sterility testing must be performed. Sterility testing must always be performed of high-risk level CSPs in batches greater than 25. See Response to Q#7

18. What is the definition of a "batch"?

USP does not currently define the term "batch". In 21CFR210.3, FDA defines "batch" to mean a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture.

19. ***How should a dilution or stock bag for pediatrics be treated?***

USP does not currently address this issue, however, the Board advises that the dilution or stock bag should be treated as a single dose container/vial with the remains being discarded within 6 hours of compounding.

20. What concepts, at a minimum, should be taken into consideration when determining drug stability?

Pharmacists should use professional judgment to determine appropriate references of chemical stability information. When relying on information in studies, pharmacists should have at least two articles which justify the assigned stability. If stability is determined by extrapolating information from a reference source, then the pharmacist must ensure that the drug stability in the reference source is not concentration dependent. The process used by the pharmacist to determine drug stability should be well-documented and maintained for inspector review.

21. What are some important considerations regarding membrane filtration and filter integrity testing, aka bubble point testing?

Membrane filtration may be accomplished using a 0.22 micron filter. It is important to note that sterility testing cannot be accomplished by simply performing membrane filtration. Filter integrity testing, also known as a bubble point test, must be performed to verify that the filter was successful in its application. Smaller disc filters may have filter volume limitations which must be taken into consideration. Because it is known that filtration has not always been successful in preventing the passing through of microorganisms, pharmacists must always build quality processes into their sterile compounding to minimize the risk and the introduction of contamination.

22. What are some best practices for performing required media fill testing and gloved fingertip sampling?

Persons performing high-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and semi-annually (within 6 months of the last testing).

Persons performing low or medium-risk level CSPs must successfully pass media-fill testing prior to initially compounding sterile products and annually (within 12 months of the last testing). Persons who fail a media-fill test may not perform sterile compounding prior to retraining and receipt of a passing media-fill test.

Media fill testing should mimic the most challenging sterile compounding activity performed by those persons. Robust documentation regarding the media-fill testing process and individual testing must be maintained which documents, at a minimum, the media growth to include lot and expiration date, number of days in incubator, incubator temperature, name of person being tested, dates testing performed, results of growth. Blanks in the form used to document media fill testing should be evaluated and corrected to ensure an accurate testing process.

Glove finger tip testing verifies the person can properly don gloves without contaminating them and is routinely disinfecting them. To improve compliance with required testing, pharmacists should consider performing media-fill testing and glove finger tip testing around the same time that environments are being certified. Employees who use isolators must also perform gloved fingertip sampling by donning sterile gloves within the ISO Class 5 main chamber and testing those gloves.

23. How often must air and surface sampling be performed?

USP requires air and surface sampling to be performed "periodically". The Board advises that air and surface sampling should be performed at least annually. Air sampling shall be conducted using volumetric air sampling equipment and the appropriate media (bacterial sampling for all risk levels and fungi sampling for high-risk level compounding operations). It may be performed by pharmacy personnel or outsourced.

24. What minimally should be taken into consideration when having primary and secondary engineering controls certified?

~~Certifying companies must comply with guidelines published by the Controlled Environment Testing Association (CETA).~~ Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used. Pharmacists shall request written documentation from the certifying company explaining how the company's certifying processes fully comply with ~~CETA guidelines~~ these standards. This shall include written acknowledgement that certification testing will be performed under dynamic conditions. Certifications issued shall specifically indicate the ISO standard for each primary and secondary engineering control and not simply indicate "passed".

25. What minimally should be taken into consideration when compounding multidose vials?

Multidose vials of CSPs must comply with USP Chapter <51>. It must be determined that the preservative being used is bacteriostatic, fungistatic, effective at maintaining sterility for 28

days, and does not interact with the drug. Antimicrobial preservatives cannot be used as a substitute for good compounding practices.

26. What BUDs are recommended for non-sterile compounded products?

USP Chapter <795> makes the following recommendations for assigned BUDs of non-sterile compounded products:

Nonaqueous formulations - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.
Water-Containing Oral Formulations - The BUD is not later than 14 days when stored at controlled cold temperatures.
Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations – The BUD is not later than 30 days.

These maximum BUDs are recommended for nonsterile compounded drug preparations in the absence of stability information that is applicable to a specific drug or preparation. The BUD shall not be later than the expiration date on the container of any component.

27. May a non-sterile compounded product be assigned an extended BUD beyond the recommendations in USP Chapter <795>?

The Board advises that non-sterile compounded products should not be assigned an extended BUD unless the pharmacist maintains full documentation to justify the appropriateness of the extended BUD.

28. Under what conditions may a glove box be used to perform sterile compounding?

The glove box, referred to as an isolator (CAI/CACI) in Chapter <797>, must be placed in an ISO 7 buffer area UNLESS it meets all of the following conditions listed in USP Chapter 797:

- The isolator shall provide isolation from the room and maintain ISO Class 5 during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 levels during compounding operations.
- Not more than 3520 particles (0.5 μm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent upon the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 for 0.5-μm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the primary engineering control (PEC) is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

The weighing of chemicals must occur in at least ISO Class 8 conditions. An isolator used to compound hazardous drugs (with exception of "low volume") must be located in a separate negative pressure room and exhausted outside.

29. May hazardous sterile products be compounded in the same hood as non-hazardous sterile drugs?

No. Hazardous sterile products may not be compounded in the same hood as non-hazardous CSPs.

30. Under what conditions may hazardous drugs be compounded in a cleanroom with positive air pressure?

USP allows a "low volume" of hazardous CSPs to be compounded in a cleanroom with positive air pressure, however, USP does not currently define the term "low volume". The "low volume" hazardous CSPs must be compounded under two tiers of containment, the isolator or biologic safety cabinet and closed system transfer device.

31. Must a compounding pharmacy using Schedule II powders comply with the perpetual inventory requirements of Regulation 18VAC110-20-240?

Yes.

32. Must bladder irrigation fluids and irrigations for wounds be prepared in a sterile manner in compliance with USP-NF requirements?

Yes. USP Chapter <797> states that for the purposes of the chapter, a compounded sterile product includes any of the following: compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

33. May a pharmacist provide a compounded drug to another pharmacy or veterinarian who will then dispense the drug to his client?

No. Va Code §54.1-3410.2 indicates 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.

VA Code §54.1-3410.2 does authorize pharmacists to provide compounded drug 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. The compounded drug must be labeled 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.

34. May a prescriber or patient obtain a compounded sterile product from an out-of-state pharmacy that is not registered by the Virginia Board of Pharmacy as a nonresident pharmacy?

No, only nonresident pharmacies registered by the Virginia Board of Pharmacy may ship compounded sterile products into Virginia. Verification of registration may be determined at https://secure01.virginiainteractive.org/dhp/cgi-bin/search_publicdb.cgi by searching the business name and choosing the occupation of "non-resident pharmacy".

ACHC

FOR PROVIDERS.
BY PROVIDERS.

January 14, 2014

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

Reference: ACHC Accreditation/Certification Standards

Dear Ms. Juran,

Thank you for your consideration of the ACHC Accreditation and Certification Programs. For your review, I have enclosed copies of the following:

- ACHC Accreditation Standards for Infusion and Specialty Pharmacy
- ACHC Certification Standards for Non-Sterile Compounding
- ACHC Certification Standards for Sterile Compounding
- ACHC Policies and Procedures for DME and Pharmacy

When reviewing ACHC standards, please keep in mind the distinction between accreditation and certification:

- The accreditation process reviews all aspects of organization, including specific processes and overall operations. A pharmacy that chooses to become accredited is surveyed once every three years by an experienced Pharmacist.
- The certification focuses on the specific process of either sterile or non-sterile compounding. A pharmacy that chooses to become certified is surveyed once every three years by an experienced Pharmacist and is required to submit evidence annually of compliance for review.

After you have had a chance to review the enclosed materials, please let me know if there are any questions I can answer or additional information you may need.

Sincerely,

Mary Lou S. Fleming
Regulatory and Governmental Affairs Manager

Juran, Caroline (DHP)

From: Lou Diorio [lsdiorio@ldtrx.com]
Sent: Thursday, February 06, 2014 2:12 PM
To: Board of Pharmacy
Cc: David Thomas
Subject: LDT Verification BOP letter VABOP 020614.docx
Attachments: LDT Verfication BOP letter VABOP 020614.docx; GAP TOOL_Generic_Question_Setup.pdf; LDT complete GAP TOOL resource binder 051713.pdf; lsd cv 14 (1).pdf; DTRESUME2012_01_12.docx; References for LDT 2014_BOPs.docx

Dear Ms. Juran,
I hope our request will be given due consideration. Please feel free to contact me directly for any additional materials or questions.
Yours truly
lsd

Lou Diorio, R.Ph.
Principal
LDT Health Solutions, Inc.
201.738.9125
LSDiorio@LDTRx.com
www.LDTRx.com

108

LDT Health Solutions, Inc.
38 Cedar Place
Wayne, NJ 07470
862.221.9575
www.LDTRx.com

6 February 2014

Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463
804.367.4456
Ms. Caroline D. Juran, Executive Director
pharmbd@dhp.virginia.gov

Dear Ms. Juran,

LDT Health Solutions is a medication safety and quality management consultancy founded by pharmacists and we are now in our eight year providing guidance, technical expertise, and regulatory support to clients nationwide. We specialize in the area compounding of sterile drugs.

Our practice has had the unique opportunity to lend its talents to several Boards of Pharmacy in varying capacities as well as to lecture, precept students, and have been involved in the development of plans-of-correction for many pharmacies resulting from the FDA recent stepped up auditing of compounding pharmacies in the wake of the terrible tragedy surrounding the New England Compounding Center (NECC). It is tragic that your commonwealth has had to bear the burden of 54 diagnosed cases of meningitis and 5 deaths.

Since 2011 LDT has offered as part of it services auditing and compliance support for all models of compounding facility. These reports have been part of FDA actions, State Board of Pharmacy proceeding or third party payor audits to assure compliance to all prevailing statues rules and regulations surrounding the compounding of sterile preparations by Pharmacies.

We have been approached by several pharmacies both inside and outside of the Commonwealth to audit their compounding operations and provide standard reporting to be used either as proof of compliance to prevailing VA statute or to support their petition to the VA Board as part of their application as a Non-Resident Pharmacy. We have conducted these same activities in the states of NJ, NY, SC, and PA to date, and have had the State Boards in those jurisdictions accept our detailed Gap Analysis Tool as independent proof of compliance.

For the Board's information I have included a sample of the questions library and a sample report for you review. The materials attached represent our years of professional experience and expertise and are the intellectual property of LDT protected by copyright. We share them in confidence with the Board so that you may review them and possibly provide a determination whether the VA Board

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would be inclined to accept our independent assessment of a Pharmacy's sterile compounding compliance for either resident or non-resident pharmacies. Under VA 54.1-3434.1 A 3 of your drug control Act.

We are aware that currently VA only recognizes the NABP process, but it is our hope that we may convince the Board that our process is an independent and qualified as theirs since this is our primary practice area. With the nationwide effort to respond to the DQSA and to harmonize all State regulations with that Federal Act there has been a shortage of reliable resources in this area. It is not our intent to make this our primary business offering; however, where appropriate we feel that we can serve the public health by assisting pharmacies and Boards alike in the assurance of competent, qualified pharmacy providers so that critical access to this care is available for all.

To support our query I have included the CVs of both my partner and myself along with a reference list of fellow Board Executives who are familiar with our documents and methods.

I know this request is somewhat unusual but these are unfamiliar times within Pharmacy practice and out intent is only to offer what we feel are appropriate solutions.

Respectfully submitted,

Louis S. Diorio, R.Ph., FAPhA
Principal

Please contact us today for further information. Visit us on the web: *www.LDTRx.com.*

CC: File
Attachments

Virginia Board of Pharmacy

Requirement for Non-resident Pharmacies to Submit Current Inspection Report

The Board of Pharmacy may issue a permit to a non-resident pharmacy that meets requirements of law and regulation, including the submission of an inspection report satisfactory to the Board. The law (Code of Virginia) provides:

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

...

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

...

For the purpose of compliance with the requirement for such a report, the Board offers the following guidance:

An application for registration or renewal without an inspection report that indicates compliance with the requirements of this chapter, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, will be deemed incomplete and a registration will not be issued or renewed until such time as a report or other acceptable documentation is produced. Inspection reports from the National Association of Boards of Pharmacy (NABP) that satisfy the inspection report requirements of §54.1-3434.1 will be deemed acceptable alternatives to an inspection by the licensing or regulatory agency of jurisdiction or an inspection by the Board of Pharmacy's own agent.

Notwithstanding submission of an inspection report from a source acceptable to the Board, the Board may deny an application on the grounds that the applicant failed to comply with applicable laws or regulations. The applicant would have an opportunity for a hearing before a committee of the Board.

regulations.gov

Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II

This Proposed Rule document was issued by the **Drug Enforcement Administration** (DEA)

For related information, **Open Docket Folder**

Comment Now!

Due Apr 28 2014, at 11:59 PM

ID: DEA-2014-0005-0004

View original printed format:

Action

Notice of proposed rulemaking.

Summary

The Drug Enforcement Administration (DEA) proposes to reschedule hydrocodone combination products from schedule III to schedule II of the Controlled Substances Act. This proposed action is based on a rescheduling recommendation from the Assistant Secretary for Health of the Department of Health and Human Services and an evaluation of all other relevant data by the DEA. If finalized, this action would impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule II controlled substances on persons who handle (manufacture, distribute, dispense, import, export, engage in research, conduct instructional activities, or possess) or propose to handle hydrocodone combination products.

Dates

Interested persons may file written comments on this proposal pursuant to 21 CFR 1308.43(g). Electronic comments must be submitted, and written comments must be postmarked, on or before April 28, 2014. Commenters should be aware that the electronic Federal Docket Management System will not accept comments after midnight Eastern Time on the last day of the comment period.

Interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)," 21 CFR 1300.01, may file a request for hearing or waiver of an opportunity for a hearing or to participate in a hearing pursuant to 21 CFR 1308.44 and in accordance with 21 CFR 1316.45, 1316.47, 1316.48 or 1316.49, as applicable. Requests for hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing must be received on or before March 31, 2014.

Addresses

To ensure proper handling of comments, please reference "Docket No. DEA -389" on all electronic and written correspondence. The DEA encourages that all comments be submitted electronically through the Federal eRulemaking Portal which provides the ability to type short comments directly into the comment field on the Web page or attach a file for lengthier comments. Please go to *www.regulations.gov* and follow the on-line

Document Informati

Date Posted:
Feb 27, 2014

RIN:
Not Assigned

CFR:
21 CFR Part 1308

Federal Register Number:
2014-04333

Show More Details

Comments

41
Comments Receive

As a pharmacist I see this rescheduling as very dangerous to society. If it is a difficult to order Hydrocodone combination products as oxycodone, fentanyl...
View Comment

As a practicing community Pharmacist for 35 years, I cannot express strongly enough the negative impacts this proposal upon the deliver of pain controlling...
View Comment

instructions at that site for submitting comments. Paper comments that duplicate electronic submissions are not necessary. Should you, however, wish to submit written comments, in lieu of electronic comments, they should be sent via regular or express mail to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152. All requests for a hearing and waivers of participation must be sent to: Drug Enforcement Administration, Attention: Hearing Clerk/LJ, 8701 Morrissette Drive, Springfield, Virginia 22152.

For Further Information Contact

Ruth A. Carter, Office of Diversion Control, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152, Telephone: (202) 598-6812.

Supplementary Information

Posting of Public Comments

Please note that all comments received in response to this docket are considered part of the public record and will be made available for public inspection online at *www.regulations.gov.* Such information includes personal identifying information (such as your name, address, etc.) voluntarily submitted by the commenter.

The Freedom of Information Act (FOIA) applies to all comments received. If you want to submit personal identifying information (such as your name, address, etc.) as part of your comment, but do not want it to be made publicly available, you must include the phrase "PERSONAL IDENTIFYING INFORMATION" in the first paragraph of your comment. You must also place all of the personal identifying information you do not want made publicly available in the first paragraph of your comment and identify what information you want redacted.

If you want to submit confidential business information as part of your comment, but do not want it to be made publicly available, you must include the phrase "CONFIDENTIAL BUSINESS INFORMATION" in the first paragraph of your comment. You must also prominently identify the confidential business information to be redacted within the comment. If a comment has so much confidential business information that it cannot be effectively redacted, all or part of that comment may not be made publicly available. Comments containing personal identifying information or confidential business information identified as directed above will be made publicly available in redacted form.

An electronic copy of this document and supplemental information to this proposed rule are available at *www.regulations.gov* for easy reference. If you wish to personally inspect the comments and materials received or the supporting documentation the DEA used in preparing the proposed action, these materials will be available for public inspection by appointment. To arrange a viewing, please see the "For Further Information Contact" paragraph above.

Request for Hearing, Notice of Appearance at Hearing, or Waiver of an Opportunity for a Hearing or To Participate in a Hearing

Pursuant to the provisions of the Controlled Substances Act (CSA), 21 U.S.C. 811(a), this action is a formal rulemaking "on the record after opportunity for a hearing." Such proceedings are conducted pursuant to the provisions of the Administrative Procedure Act (APA), 5 U.S.C. 551-559. 21 CFR 1308.41-1308.45; 21 CFR Part 1316 subpart D. In accordance with 21

As a prescriber, I fully suppor changing hydro condone to Schedule II. This change will allow for tighter control of prescriptions and help limit access to...

View Comment

Docket Information

This document is contained in DEA-2014-0005

Related Dockets:
None

Related RINs:
None

Related Documents:
None

Related Comments:
View all

* This count refers to the total comments received on this *document*, as of 11:59 PM yesterday, from Regulations.go and alternate means. All comm including the bulk submissions received for this *document* may be posted at this time; therefore counts may differ between: tota comments received and posted well as the counts shown on the Docket Folder Summary page.

Document text and ima courtesy of the Federal Register

CFR 1308.44(a)-(c), requests for a hearing, notices of appearance, and waivers of an opportunity for a hearing or to participate in a hearing may be submitted only by interested persons, defined as those "adversely affected or aggrieved by any rule or proposed rule issuable pursuant to section 201 of the Act (21 U.S.C. 811)." 21 CFR 1300.01. Requests for hearing and notices of appearance must conform to the requirements of 21 CFR 1308.44(a) or (b), and 1316.47 or 1316.48 as applicable, and include a statement of the interest of the person in the proceeding and the objections or issues, if any, concerning which the person desires to be heard. Any waiver must conform to the requirements of 21 CFR 1308.44(c) and 1316.49, including a written statement regarding the interested person's position on the matters of fact and law involved in any hearing.

Please note that pursuant to 21 U.S.C. 811(a)(1), the purpose and subject matter of a hearing held in relation to this rulemaking is restricted to: "(A) find[ing] that such drug or other substance has a potential for abuse, and (B) mak[ing] with respect to such drug or other substance the findings prescribed by subsection (b) of section 812 of [title 21] for the schedule in which such drug is to be placed * * *." Requests for a hearing, notices of appearance at a hearing, and waivers of an opportunity for a hearing or to participate in a hearing must be submitted to the DEA using the address information provided above.

Legal Authority

The DEA implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. 21 U.S.C. 801-971. The DEA publishes the implementing regulations for these statutes in title 21 of the Code of Federal Regulations (CFR), parts 1300 to 1321. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while providing for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, controlled substances are classified into one of five schedules based upon their potential for abuse, their currently accepted medical use, and the degree of dependence the substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR Part 1308. 21 U.S.C. 812(a).

Pursuant to 21 U.S.C. 811(a)(1), the Attorney General may, by rule, "add to such a schedule or transfer between such schedules any drug or other substance if he (A) finds that such drug or other substance has a potential for abuse, and (B) makes with respect to such drug or other substance the findings prescribed by [21 U.S.C. 812(b)] for the schedule in which such drug is to be placed * * *." Pursuant to 28 CFR 0.100(b), the Attorney General has delegated this scheduling authority to the Administrator of the DEA.

The CSA provides that the scheduling of any drug or other substance may be initiated by the Attorney General (1) on his own motion; (2) at the request of the Secretary of the Department of Health and Human Services (HHS); or (3) on the petition of any interested party. 21 U.S.C. 811(a). This proposed action was initiated by a petition to reschedule hydrocodone combination products (HCPs) [1] from schedule III to schedule II of the CSA, and is supported by, *inter alia*, a recommendation from the Assistant Secretary for Health of the HHS. [2] If finalized, this action would impose the regulatory

controls and administrative, civil, and criminal sanctions of schedule II controlled substances on any person who handles, or proposes to handle, HCPs.

Background

Hydrocodone was listed in schedule II of the CSA upon the enactment of the CSA in 1971. Public Law 91-513, 84 Stat. 1236, sec. 202(c), schedule II, paragraph (a), clause (1) (codified at 21 U.S.C. 812(c)); initially codified at 21 CFR 308.12(b)(1)(x) (36 FR 7776, April 24, 1971) (currently codified at 21 CFR 1308.12(b)(1)(vi)). At that time, HCPs in specified doses (containing no greater than 15 milligrams (mg) hydrocodone per dosage unit or not more than 300 mg hydrocodone per 100 milliliters) were listed in schedule III of the CSA when formulated with specified amounts of an isoquinoline alkaloid of opium or one or more therapeutically active nonnarcotic ingredients. Public Law 91-513, 84 Stat. 1236, sec. 202(c), schedule III, paragraph (d), clauses (3) and (4) (codified at 21 U.S.C. 812(c)); initially codified at 21 CFR 308.13(e)(3) and (4) (36 FR 7776, April 24, 1971) (currently codified at 21 CFR 1308.13(e)(1)(iii) and (iv)). Any other products that contain single-entity hydrocodone or combinations of hydrocodone and other substances outside the range of specified doses are listed in schedule II of the CSA. [3]

Proposed Determination To Transfer HCPs to Schedule II

Pursuant to 21 U.S.C. 811(a), proceedings to add a drug or substance to those controlled under the CSA, or to transfer a drug between schedules, may be initiated on the petition of any interested party. In response to a petition the DEA had received requesting that HCPs be controlled in schedule II of the CSA, in 2004 the DEA submitted a request to the HHS to provide the DEA with a scientific and medical evaluation of available information and a scheduling recommendation for HCPs, pursuant to 21 U.S.C 811(b) and (c). In 2008 the HHS provided to the DEA its recommendation that HCPs remain controlled in schedule III of the CSA. In response, in 2009, the DEA requested that the HHS re-evaluate their data and provide another scientific and medical evaluation and scheduling recommendation based on additional data and analysis.

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144) (FDASIA). Section 1139 of the FDASIA [4] directed the Food and Drug Administration (FDA) to hold a public meeting to "solicit advice and recommendations" pertaining to the scientific and medical evaluation in connection with its scheduling recommendation to the DEA regarding drug products containing hydrocodone, combined with other analgesics or as an antitussive. Additionally the Secretary was required to solicit stakeholder input "regarding the health benefits and risks, including the potential for abuse" of hydrocodone combination products and the impact of up-scheduling of these products. Accordingly, on January 24-25, 2013, the FDA held a public Advisory Committee meeting at which the DEA made a presentation. The Advisory Committee included members with scientific and medical expertise in the subject of opioid abuse, and a patient representative. Members included representatives from National Institute on Drug Abuse (NIDA) and the Centers for Disease Control (CDC). There was also an opportunity for the public to provide comment. The Advisory Committee voted 19 to 10 in favor of recommending that hydrocodone combination products be placed into schedule II. According to the FDA, 768 comments were submitted by patients, patient groups, advocacy groups, and professional societies to the FDA.

Upon evaluating the scientific and medical evidence, along with the above considerations (e.g., recommendation of the Advisory Committee, the public comments, consideration of the health benefits and risks, and information about the impact of rescheduling) mandated by the FDASIA, the HHS on

December 16, 2013, submitted to the Administrator of the DEA its scientific and medical evaluation (henceforth called HHS review) entitled, "Basis for the Recommendation to Place Hydrocodone Combination Products in Schedule II of the Controlled Substances Act." Pursuant to 21 U.S.C. 811 (b), this document contained an eight-factor analysis of the abuse potential of HCPs, along with the HHS's recommendation to control HCPs under schedule II of the CSA.

The HHS stated that the comments received during the open public hearing, to the docket, and the discussion of the Advisory Committeemembers of the FDA Advisory Committee meeting provided support for its conclusion that individuals are taking HCPs in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; that there is significant diversion of HCPs; and that individuals are taking HCPs on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs. The HHS stated it has also given careful consideration to the fact that the members of the Advisory Committee voted 19 to 10 in favor of rescheduling HCPs from schedule III to schedule II under the CSA. The HHS considered the increasing trends, the public comments, the recommendation of the Advisory Committee, the health benefits and risks, and the information available about the impact of rescheduling, and concluded that HCPs have high potential for abuse.

Summary of Eight Factor Analyses

The DEA has reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, and all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811 (c). Included below is a brief summary of each factor as considered by the DEA in its proposed rescheduling action. Both the DEA and HHS analyses are available in their entirety in the public docket for this proposed rule (Docket No. DEA-389) at *www.regulations.gov* under "Supporting and Related Material." Full analysis of, and citations to, information referenced in this summary may also be found in the supporting material.

1. The Drug's Actual or Relative Potential for Abuse

The term "abuse" is not defined in the CSA. However, the legislative history of the CSA provides the following criteria to determine whether a particular drug or substance has a potential for abuse: [8]

(a) Individuals are taking the drug or other substance in amounts sufficient to create a hazard to their health or to the safety of other individuals or to the community; or

(b) There is a significant diversion of the drug or other substance from legitimate drug channels; or

(c) Individuals are taking the drug or other substance on their own initiative rather than on the basis of medical advice from a practitioner licensed by law to administer such drugs; or

(d) The drug is so related in its action to a drug or other substance already listed as having a potential for abuse to make it likely that it will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversions from legitimate channels, significant use contrary to or without medical advice, or that it has a substantial capability of creating hazards to the health of the user or to the safety of the community.

The DEA considered the HHS's evaluation and all other relevant data, including data related to the above mentioned criteria, and finds that:

(a) *Individuals are using HCPs in amounts sufficient to create a hazard to their health, to the safety of other individuals, or to the community.*

The HHS states that there are increasing trends in the adverse effects from abuse of HCPs, including emergency department (ED) visits, admissions to addiction treatment centers, and deaths in selected States. In 2011, HCPs were listed in 3,376 admissions for drug treatment as the primary drug of abuse and in 6,601 admissions listing HCPs in addition to other drugs in the Treatment Episode Data Set (TEDS). [6] HCPs are prescribed in an unprecedented manner and their total prescriptions exceed prescriptions for any other opioid analgesic; this characteristic drives their abuse potential and sets them apart from other opioid analgesics in terms of abuse risks.

Drug Abuse Warning Network (DAWN) [7] data indicate that abuse of HCPs, similar to oxycodone products [8] (schedule II), has been associated with large numbers of admissions to the ED. For example, in 2011 the total number of ED visits related to nonmedical use of HCPs and oxycodone products were 82,479 and 151,218, respectively. [9] The American Association of Poison Control Centers' National Poison Data System [10] (NPDS; formerly known as Toxic Exposure Surveillance System or TESS) reported that HCPs were involved in 30,792 and 29,391 annual toxic exposures in 2011 and 2012, respectively. The corresponding data for oxycodone products was 19,423 and 18,495. The majority of exposures for both drug products were for intentional reasons. [11]

The HHS mentions that nationwide estimates of overdose deaths due to HCPs cannot be quantified, but the available data for a limited number of States suggest that HCPs contribute to a substantial number of overdose deaths each year. According to the HHS, DAWN medical examiner (ME) data for five States from 2004 through 2010 reported an increase of 63% and 133% in deaths related to HCPs and oxycodone products, respectively. According to the Florida Department of Law Enforcement (FDLE), [12] HCPs havebeen associated with large numbers of deaths in Florida. For example, in 2012, HCPs were associated with 777 deaths, while oxycodone products were associated with 1,426.

As summarized below, a review of drug abuse indicators for HCPs over the past several years further indicates that these products, similar to oxycodone products, are among the most widely diverted and abused drugs in the country and have high potential for abuse.

(b) *There is a significant diversion of HCPs from legitimate drug channels.*

According to forensic laboratory data as reported by the National Forensic Laboratory System [13 14] (NFLIS) and the System to Retrieve Information from Drug Evidence [15] (STRIDE), HCPs, similar to oxycodone products, are among the top 10 most frequently encountered drugs. From 2002 through 2010, total cases (from both NFLIS and STRIDE) for both HCPs and oxycodone products gradually increased with some decline in 2011 and 2012. From 2002 through 2008, annual total cases involving HCPs (range: 9,106 in 2002 to 33,611 in 2008) consistently exceeded those for oxycodone products (range: 7,993 in 2002 to 28,343 in 2008). In 2009, total cases for HCPs (37,894) were similar to that for oxycodone products (37,680). From 2010 through 2012, total cases for oxycodone products (47,238 in 2010 and 41,915 in 2012) exceeded those for HCPs (39,261 in 2010 and 34,832 in 2012). The DEA has documented a large number of diversion and trafficking cases involving HCPs. DEA investigations conducted from 2005 through 2007 determined that HCPs were diverted from rogue Internet pharmacies.

(c) *Individuals are using HCPs on their own initiative rather than on the basis of medical advice.*

According to the data from the National Survey on Drug Use and Health [16] (NSDUH), the lifetime (i.e., ever used) users of HCPs for nonmedical purposes exceeded those for oxycodone products in the United States. For example, in 2004, over 17.7 million Americans age 12 years or older reported lifetime nonmedical use of HCPs as compared to over 11.9 million reported for oxycodone products. In 2012, the corresponding data for HCPs and oxycodone products were over 25.6 and 16 million, respectively. The NSDUH also reported large increases from 2004 through 2012 in the number of individuals using HCPs and oxycodone products for nonmedical purposes.

The past year initiates (i.e., the first use of a substance within the 12 months prior to the interview date) of HCPs exceeded those of oxycodone products from 2002 through 2005. Past year initiates for HCPs were over 1.3, 1.4, 1.3 and 1.3 million in 2002, 2003, 2004 and 2005, respectively. The corresponding data for oxycodone products were over 0.47, 0.5, 0.6 and 0.45 million. According to a report by the NSDUH, the combined data from 2002 through 2005 indicate that 57.7% of persons who first used pain relievers nonmedically in the past year used HCPs while 21.7% used oxycodone products. The NSDUH data from 2002 through 2006 also indicate that the lifetime users of HCPs have a higher propensity than that of lifetime users of oxycodone immediate release products (single-entity and combination products combined) to have used for nonmedical purposes any pain relievers in the past year.

According to the Monitoring the Future [17] (MTF) survey, from 2002 through 2011 the annual prevalence of nonmedical use of Vicodin®, an HCP, ranged from about 8% to 10.5% among high school seniors (12th graders) and exceeded that of OxyContin® (4% to 5.5%), an oxycodone extended release product. In 2012, the annual prevalence rate for nonmedical use of OxyContin® was 1.6%, 3.0%, and 4.3% among 8th, 10th and 12th graders, respectively. The corresponding rates for Vicodin® were 1.3%, 4.4% and 7.5%. According to the MTF, the annual prevalence of nonmedical use of Vicodin® in college students and young adults was 3.8% and 6.3% in 2012. The corresponding data for OxyContin® were 1.2% and 2.3%. The aforementioned data from drug abuse surveys (NSDUH and MTF) collectively indicate high prevalence of abuse of HCPs among Americans including students thereby indicating their high abuse potential.

(d) *HCPs are so related in their action to a drug or other substance already listed as having a potential for abuse to make it likely that they will have the same potential for abuse as such substance, thus making it reasonable to assume that there may be significant diversion from legitimate channels, significant use contrary to or without medical advice, or that they have a substantial capability of creating hazards to the health of the user or to the safety of the community.*

Hydrocodone possesses abuse liability effects substantially similar to morphine (schedule II) in both animals and humans. Hydrocodone, similar to morphine, is a μ opioid receptor agonist and shares pharmacological properties with morphine. Hydrocodone substitutes for morphine in animals trained to discriminate the presence and absence of morphine. Hydrocodone, similar to morphine, is self-administered by animals. Hydrocodone substitutes for morphine in opioid-dependent subjects. Clinical abuse liability studies have also demonstrated that HCPs (Hycodan® or hydrocodone in combination with acetaminophen) are similar to morphine with respect to physiological effects, subjective effects, and drug "liking" scores.

Hydrocodone/acetaminophen and oxycodone/acetaminophen combination products at equi-miotic doses, in general, produce similar profiles of psychopharmacological effects. These two opioid products produced prototypic opiate-like effects and psychomotor impairment of similar magnitudes.

Collectively these data demonstrate that HCPs have a high potential for abuse similar to other schedule II opioid analgesic drugs such as morphine and oxycodone products.

2.

The HHS states that hydrocodone's pharmacological effects are similar to other μ opioid receptor agonists. It is effective as an antitussive agent and as an analgesic drug. Opioid analgesics have an important role in the management of pain. HCPs contain other nonnarcotic active ingredients such as acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs) (aspirin and ibuprofen), chlorpheniramine or homatropine methylbromide. The mechanism of analgesic and antitussive effects of HCPs are different from those of nonnarcotic active ingredients present in HCPs. Acetaminophen and NSAIDs are less effective against severe pain, but have a recognized role in a variety of pain settings.

HCPs, similar to other opioid analgesics such as oxycodone products, are associated with a substantial number of overdose, suicide, abuse, and dependence reports. Overdose of HCPs, similar to other opioid analgesics, can lead to respiratory depression and death. Common adverse effects of NSAIDs include gastrointestinal, cardiovascular, renal and renovascular adverse events, and hepatic injury. Acetaminophen has low incidence of gastrointestinal side effects and is a common household analgesic available over the counter. Overdoses of acetaminophen can cause severe hepatic damage and death. Opioid/acetaminophen combination products are linked to numerous liver injuries.

3.

The HHS provided additional scientific information with focus on chemical and toxicological properties of hydrocodone and nonnarcotic components of HCPs. Hydrocodone is a semisynthetic opioid. The bitartrate salt form of hydrocodone is the main active component in all currently marketed HCPs. Nonnarcotic drugs present as co-ingredients are acetaminophen, aspirin, ibuprofen, chlorpheniramine or homatropine methylbromide. Hydrocodone and nonnarcotic drugs present in HCPs have potential to produce adverse effects.

4.

Soon after introduction for clinical use, there were reports of hydrocodone abuse and addiction. By the 1950s, it was established that hydrocodone has an abuse liability similar to that of morphine. Data regarding the pharmacological effects of hydrocodone and its high potential for abuse were available prior to the enactment of the CSA and the placement of hydrocodone in schedule II reflects that knowledge base. In the United States, popularity of hydrocodone as a drug of abuse increased in the 1990s coinciding with its increased use as an analgesic. Currently HCPs are widely diverted and abused throughout the United States as demonstrated in national and regional drug-abuse-related databases. HCPs and oxycodone products (schedule II) are the two most common opioid analgesic products encountered by law enforcement.

Data from DEA field offices indicate that HCPs are diverted and are among the most sought after licit drugs in every geographic region of the country. DEA case investigations document numerous methods of diversion of HCPs. These methods involve drug theft, doctor shopping, fraudulent oral

(call-in) prescriptions, fraudulent prescriptions, diversion by registrants, and various other drug trafficking schemes. HCPs are abused by individuals of diverse ages from adolescents to older populations. According to the NSDUH, in 2012, of the 37 million people in the United States who used pain relievers nonmedically in their lifetime, over 25.6 million (representing 9.9% of the United States population age 12 years or older) reported lifetime nonmedical use of HCPs. The MTF surveys indicate that from 2002 through 2012, 8.1% to 10.5% of high school seniors used Vicodin®, an HCP, for nonmedical purposes. In 2012, the annual prevalence of nonmedical use of Vicodin® in college students and young adults was 3.8% and 6.3%, respectively.

Several published epidemiological studies indicate that HCPs are widely abused. For example, a published epidemiological study reviewed prescription opioid abuse data collected by drug abuse experts (representatives of the nation's methadone programs, treatment centers, impaired health care professional programs, NIDA grantees and high-prescribing physicians) and found that HCPs are one of the most commonly abused prescription opioid drugs. Rates of abuse, expressed as cases per 100,000 population, were the highest for hydrocodone and extended release oxycodone products, while the rest of the opioid analgesics, including immediate release oxycodone products, had lower rates. Another published epidemiological study also indicates that the rate of intentional exposure (abuse, intentional misuse, suicide or intentional unknown) was highest for HCPs at 3.75 per 100,000 population followed by oxycodone products at 1.81 per 100,000. HCPs were involved in 55% of all of the intentional exposure cases, whereas oxycodone products were involved in 27%. In addition, published data on toxic exposure calls received by Texas poison centers from 1998 through 2009 showed that toxic exposure calls related to ingestion of the combination of HCPs, carisoprodol and alprazolam (commonly referred under street names such as "Holy Trinity," "Houston Cocktail," or "Trio") have increased from 2000 through 2007 with some decline in 2009.

5.

The HHS mentions that abuse of HCPs is considerable and is associated with considerable negative public health impact. The extent of nonmedical use of HCPs by adolescents is higher than for oxycodone products. These data are of significant concern as this may reflect particular risk for younger individuals. The HHS also states that because of the large number of prescriptions, large amounts of HCPs are potentially available for illicit use. Large numbers of adversely affected individuals and the severity of the adverse effects related to abuse of HCPs suggest that individuals are taking these products in amounts sufficient to create a hazard to their health and to the safety of other individuals and the community. Abuse of HCPs is associated with progressively increasing trends in serious adverse effects, including ED visits, admissions for abuse treatment, and in mortality data in selected States. The HHS cites the widespread prescriptions for HCPs as one of the reasons for these adverse outcomes. According to the HHS, data suggests that HCPs have high potential for abuse.

The DEA notes that initial reports of abuse of HCPs in the U.S. were published in the 1960s. Since the 1990s, the diversion and abuse of HCPs has escalated in the country. By the late 1990s, there were large increases in the diversion and abuse of HCPs. HCPs, similar to oxycodone products, are widely diverted and abused pharmaceutical opioid analgesics. HCPs are associated with significant illicit activity and abuse. Federal, State and local forensic laboratory data rank HCPs as one of the two most frequently encountered opioid pharmaceuticals in submissions to the laboratories. For example, in 2012, there were over 34,000 exhibits for HCPs (NFLIS). All DEA field divisions across the U.S. have reported that HCPs are among the most sought after pharmaceuticals.

In 2012, according to the poison control centers data (NPDS), there were over 29,390 toxic exposures involving HCPs. In 2002, there were over 25,000 DAWN ED visits associated with HCPs and it was ranked sixth among all controlled substances. According to DAWN, the nonmedical use related ED visits for HCPs were 86,258; 95,972; and 82,480 in 2009, 2010, and 2011, respectively. A number of data sources indicate that abuse of HCPs is associated with a large number of deaths. According to NSDUH, there were large numbers of lifetime and past year initiates of HCPs for nonmedical purposes and these numbers exceeded those of oxycodone. According to the MTF, about 8% to 10% of high school seniors reported nonmedical use of Vicodin®, an HCP, in recent years.

DEA case investigations document numerous methods of diversion of HCPs. These methods involve drug theft, doctor shopping, fraudulent oral (call-in) prescriptions, fraudulent prescriptions, diversion by registrants, and various other drug trafficking schemes.

6. What, if Any, Risk There Is to the Public Health

Despite the medical value of HCPs as antitussive and analgesic drugs, the misuse and abuse of these products present numerous risks to the public health. Many of the risk factors associated with these products are common risks shared with other μ opioid receptor agonists. These include the risks of developing tolerance, dependence and addiction, and the attendant problems associated with these risks including death. According to the CDC, from 1999 to 2010, the number of drug poisoning deaths [18] involving any opioid analgesic (e.g., oxycodone, methadone, or hydrocodone) markedly increased (over four-fold), from 4,030 to 16,651, and accounted for 43% of the 38,329 drug poisoning deaths and 39% of the 42,917 total poisoning deaths [19] in 2010. In 1999, opioid analgesics were involved in 24% of the 16,849 drug poisoning deaths and 20% of the 19,741 total poisoning deaths.

The HHS reviewed the HCPs related adverse events that were reported to the FDA Adverse Events Reporting System (FAERS) [20] from 1969 through 2012 and compared them to those associated with oxycodone products. The most common adverse events reported for HCPs included terms such as *complete suicide, intentional overdose, drug abuse, drug dependence, and drug abuser.* [21] The HHS found that both HCPs and oxycodone products are associated with substantial numbers of reports of overdose, suicide, abuse, and dependence reports. Both products have large numbers of adverse events reported that reflect abuse, misuse and injury due to inappropriate use. HCPs had fewer such reports than oxycodone products.

According to the DAWN, ED mentions associated with HCPs and oxycodone products are the highest among all opioid analgesics suggesting that both HCPs and oxycodone products have a great adverse risk to the public health. According to the HHS, DAWN ME data for five States from 2004 through 2010 reported an increase of 63% and 133% in deaths related to HCPs and oxycodone products, respectively. According to the FDLE, HCPs have been associated with large numbers of deaths in Florida in recent years. According to the NPDS annual reports, since 2002, annual figures for toxic exposures (within the category of opioid analgesic drugs) were the largest for HCPs, followed by oxycodone products (see summary of Factor 1 above). From 2006 through 2012, NPDS reported a total of 84,798 single substance exposures related to HCPs resulting in 195 deaths. The corresponding data for oxycodone products is 57,219 exposures and 173 deaths.

7. Its Psychic or Physiological Dependence Liability

According to the HHS, data from animal and human studies indicate the dependence potential of hydrocodone. The severe dependence potential is

reflected by the number of individuals admitted to addiction treatment centers citing HCPs as their substance of abuse. The HHS also states that the treatment admissions linked to abuse of HCPs are increasing. The HHS concluded that abuse of HCPs may lead to severe psychological or physical dependence.

The DEA notes that as evident from the NSDUH data from 2002 through 2006, the propensity of the lifetime users of HCPs to develop substance use disorders on any pain relievers is higher than that of lifetime users of any pain relievers, as well as lifetime users of oxycodone products other than OxyContin® (i.e., oxycodone immediate release single-entity products and immediate release combination products). The FAERS data (from 1969 through August 28, 2008) indicate that the abuse and dependence reports associated with HCPs expressed as a percentage of all its adverse events (13.3%) were similar (both in magnitude and temporal distribution) to that for oxycodone products other than OxyContin® (13.6%).

The DEA also notes that according to several published epidemiological surveys and retrospective review of medical records of addiction treatment populations, HCPs are among the most abused opioid pharmaceuticals in prescription opioid dependent individuals in the country and are frequently mentioned as the primary drug of abuse in these subjects.

The above data collectively indicate that HCPs, similar to oxycodone products, have high potential to cause severe psychological or physiological dependence.

8. Whether the Substance Is an Immediate Precursor of a Substance Already Controlled Under the CSA

HCPs are not immediate precursors of a substance already controlled under the CSA, as defined in 21 U.S.C. 811(e).

Conclusion

Based on consideration of the scientific and medical evaluation and accompanying recommendation of the HHS, and based on the DEA's consideration of its own eight-factor analysis, the DEA finds that these facts and all other relevant data constitute substantial evidence of high potential for abuse of HCPs. As such, the DEA hereby proposes to transfer HCPs fromschedule III to schedule II under the CSA.

Proposed Determination of Appropriate Schedule

The CSA outlines the findings required to transfer a drug or other substance between schedules (I, II, III, IV, or V) of the CSA. 21 U.S.C. 811(a); 21 U.S.C. 812(b). After consideration of the analysis and rescheduling recommendation of the Assistant Secretary for Health of the HHS and review of available data, the Administrator of the DEA, pursuant to 21 U.S.C. 811(a) and 21 U.S.C. 812(b)(2), finds that:

1. HCPs have a high potential for abuse similar to that of schedule II substances;

2. HCPs have a currently accepted medical use in treatment in the United States. According to the HHS, several pharmaceutical products containing hydrocodone in combination with acetaminophen, aspirin, NSAIDS, and homatropine are approved by FDA for use as analgesics for pain relief and for the symptomatic relief of cough and upper respiratory symptoms associated with allergies and colds; and

3. Abuse of HCPs may lead to severe psychological or physical dependence similar to that of schedule II substances.

Based on these findings, the Administrator of the DEA concludes that HCPs warrant control in schedule II of the CSA. 21 U.S.C. 812(b)(2).

Requirements for Handling HCPs

If this rule is finalized as proposed, persons who handle HCPs would be subject to the CSA's schedule II regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, dispensing, importing, exporting, research, and conduct of instructional activities, including the following:

Registration. Any person who handles (manufactures, distributes, dispenses, imports, exports, engages in research, or conducts instructional activities with) HCPs, or who desires to handle HCPs, would be required to be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312.

Security. HCPs would be subject to schedule II security requirements and would need to be handled and stored pursuant to 21 U.S.C. 821, 823, 871 (b) and in accordance with 21 CFR 1301.71-1301.93.

Labeling and Packaging. All labels and labeling for commercial containers of HCPs would need to comply with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302.

Quotas. A quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 would be required in order to manufacture HCPs.

Inventory. Any person who becomes registered with the DEA after the effective date of the final rule would be required to take an initial inventory of all stocks of controlled substances (including HCPs) on hand on the date the registrant first engages in the handling of controlled substances, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11(a) and (b).

After the initial inventory, every DEA registrant would be required to take a new inventory of all stocks of controlled substances on hand every two years, pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

Records. Every DEA registrant would be required to maintain records with respect to HCPs pursuant to 21 U.S.C. 827, 958, and in accordance with 21 CFR parts 1304, 1307, and 1312.

Reports. Every DEA registrant would be required to submit reports regarding HCPs to the Automation of Reports and Consolidated Order System (ARCOS) pursuant to 21 U.S.C. 827 and in accordance with 21 CFR 1304.33.

Orders for HCPs. Every DEA registrant who distributes HCPs would be required to comply with order form requirements, pursuant to 21 U.S.C. 828, and in accordance with 21 CFR part 1305.

Prescriptions. All prescriptions for HCPs would need to comply with 21 U.S.C. 829, and would be required to be issued in accordance with 21 CFR part 1306, and part 1311 subpart C.

Importation and Exportation. All importation and exportation of HCPs would need to be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312.

Liability. Any activity involving HCPs not authorized by, or in violation of, the CSA, would be unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Analyses

Executive Orders 12866 and 13563

In accordance with 21 U.S.C. 811(a), this proposed scheduling action is subject to formal rulemaking procedures performed "on the record after opportunity for a hearing," which are conducted pursuant to the provisions of 5 U.S.C. 556 and 557. The CSA sets forth the procedures and criteria for scheduling a drug or other substance. Such actions are exempt from review by the Office of Management and Budget (OMB) pursuant to Section 3(d)(1) of Executive Order 12866 and the principles reaffirmed in Executive Order 13563.

Executive Order 12988

This proposed regulation meets the applicable standards set forth in sections 3(a) and 3(b)(2) of Executive Order 12988 Civil Justice Reform to eliminate drafting errors and ambiguity, minimize litigation, provide a clear legal standard for affected conduct, and promote simplification and burden reduction.

Executive Order 13132

This proposed rulemaking does not have federalism implications warranting the application of Executive Order 13132. The proposed rule does not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government.

Executive Order 13175

This proposed rule does not have tribal implications warranting the application of Executive Order 13175. It does not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Regulatory Flexibility Act

The Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612) (RFA), has reviewed this proposed rule, and by approving it, certifies that it will not have a significant economic impact on a substantial number of small entities. The purpose of this proposed rule is to place HCPs into schedule II of the CSA. No less restrictive measures (i.e., non-control or control in a lower schedule) would enable the DEA to meet its statutory obligation under the CSA.

HCPs are widely prescribed drugs for the treatment of pain and cough suppression. Handlers of HCPs primarily include manufacturers, distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics. [22] It is possiblethat other registrants, such as importers, researchers, analytical labs, teaching institutions, etc., also handle HCPs. However, based on its understanding of its registrant population, the DEA assumes for purposes of this analysis that for all business activities other than manufacturers, distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics, that the volume of HCPs handled is nominal, and therefore *de minimis* to the economic impact determination of this proposed rescheduling action.

Because HCPs are so widely prescribed, for the purposes of this analysis, the DEA conservatively assumes all distributors, exporters, pharmacies, practitioners, mid-level practitioners, and hospitals/clinics currently registered with the DEA to handle schedule III controlled substances are also handlers of HCPs. The DEA estimated the number of manufacturers and exporters handling HCPs directly from DEA records. In total, the DEA

estimates that nearly 1.5 million controlled substance registrations, representing approximately 376,189 entities, would be affected by this rule.

The DEA does not collect data on company size of its registrants. The DEA used DEA records and multiple subscription-based and public data sources to relate the number of registrations to the number of entities and the number of entities that are small entities. The DEA estimates that of the 376,189 entities that would be affected by this rule, 366,351 are "small entities" in accordance with the RFA and Small Business Administration size standards. 5 U.S.C. 601(6); 15 U.S.C. 632. [23]

The DEA examined the registration, security (including storage), labeling and packaging, quota, inventory, recordkeeping and reporting, ordering, prescribing, importing, exporting, and disposal requirements for the 366,351 small entities estimated to be affected by the proposed rule. The DEA estimates that only the physical security requirements will have material economic impact and such impacts will be limited to manufacturers, exporters, and distributors. Many manufacturers and exporters are likely to have sufficient space in their existing vaults to accommodate HCPs. However, the DEA understands that some manufacturers, exporters, and distributors will need to build new vaults or expand existing vaults to store HCPs in compliance with schedule II controlled substance physical security requirements. Due to the uniqueness of each business, the DEA made assumptions based on research and institutional knowledge of its registrant community to quantify the costs associated with physical security requirements for manufacturers, exporters and distributors.

The DEA estimates there will be significant economic impact on 1 (2.0%) of the affected 50 small business manufacturers, and 54 (7.9%) of the affected 683 small business distributors. The DEA estimates no significant impact on the remaining affected 4 small business exporters, 50,774 small business pharmacies, or 314,840 small business practitioners/mid-level practitioners/hospitals/clinics. In summary, 55 of the 366,351 (0.015%) affected small entities are estimated to experience significant impact, (i.e., incur costs greater than 1% of annual revenue) if the proposed rule were finalized. The percentage of small entities with significant economic impact is below the 30% threshold for all registrant business activities. The DEA's assessment of economic impact by size category indicates that the proposed rule will not have a significant effect on a substantial number of these small entities.

The DEA's assessment of economic impact by size category indicates that the proposed rule to reschedule HCPs as schedule II controlled substances will not have a significant economic impact on a substantial number of small entities. The DEA will consider written comments regarding the DEA's economic analysis of the impact of such rescheduling, including this certification, and requests that commenters describe the specific nature of any impact on small entities and provide empirical data to illustrate the extent of such impact.

Unfunded Mandates Reform Act of 1995

On the basis of information contained in the "Regulatory Flexibility Act" section above, the DEA has determined and certifies pursuant to the Unfunded Mandates Reform Act (UMRA) of 1995 (2 U.S.C. 1501 *et seq.*), that this action would not result in any Federal mandate that may result "in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted for inflation) in any one year * * *." Therefore, neither a Small Government Agency Plan nor any other action is required under provisions of the UMRA of 1995.

Paperwork Reduction Act of 1995

This action does not impose a new collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3521). This action would not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1308 is proposed to be amended to read as follows:

Part 1308 Schedules Controlled Substances

1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority

21 U.S.C. 811, 812, 871(b) unless otherwise noted.

§ 1308.13
[Amended]

2. Amend § 1308.13 by removing paragraphs (e)(1)(iii) and (iv) and redesignating paragraphs (e)(1)(v) through (viii) as (e)(1)(iii) through (v), respectively.

Dated: February 21, 2014.
Michele M. Leonhart,
Administrator.

[FR Doc. 2014-04333 Filed 2-26-14; 8:45 am]
BILLING CODE 4410-09-P

Footnotes

(1) Hydrocodone combination products (HCPs) are pharmaceuticals containing specified doses of hydrocodone in combination with other drugs in specified amounts. These products are approved for marketing for the treatment of pain and for cough suppression.

(2) As set forth in a memorandum of understanding entered into by the HHS, the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of the NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations.

(3) In the United States there are currently no approved, marketed, products containing hydrocodone in combination with other active ingredients that fall outside schedule III of the CSA. Further, until recently, there were no approved hydrocodone single-entity schedule II products. In Oct. 2013, the FDA approved Zohydro (TM) ER, a single-entity, extended release schedule II product. The sponsor of this

product in a press release dated Oct. 25, 2013, stated that Zohydro [TM] ER will be launched in approximately four months. Accordingly, all of the historical data regarding hydrocodone from different national and regional databases that support this proposal should refer to HCPs only, regardless of whether the database utilizes the term "hydrocodone" or "hydrocodone combination products."

[4] FDASIA, SEC1139. SCHEDULING OF HYDROCODONE. (a) IN GENERAL.—Not later than 60 days after the date of enactment of this Act, if practicable, the Secretary of Health and Human Services (referred to in this section as the "Secretary") shall hold a public meeting to solicit advice and recommendations to assist in conducting a scientific and medical evaluation in connection with a scheduling recommendation to the Drug Enforcement Administration regarding drug products containing hydrocodone, combined with other analgesics or as an antitussive. (b) STAKEHOLDER INPUT.—In conducting the evaluation under subsection (a), the Secretary shall solicit input from a variety of stakeholders including patients, health care providers, harm prevention experts, the National Institute on Drug Abuse, the Centers for Disease Control and Prevention, and the Drug Enforcement Administration regarding the health benefits and risks, including the potential for abuse and the impact of up-scheduling of these products.

[5] Comprehensive Drug Abuse Prevention and Control Act of 1970, H.R. Rep. No 91-1444, 91st Cong., Sess.1 (1970) reprinted in U.S.C.C.A.N. 4566, 4601.

[6] TEDS is a program coordinated and managed by the SAMHSA. This database includes information on treatment admissions that are routinely collected by states to monitor their individual substance abuse treatment systems. Thus, TEDS includes data primarily from treatment facilities that receive public funds. TEDS includes information on demographic variables including age, gender, race and ethnicity. TEDS also reports on the top three drugs of abuse at the time of admission. TEDS does not include all drugs that may have been abused prior to admission. States and jurisdictions can choose whether or not to report the detailed listing.

[7] The Drug Abuse Warning Network (DAWN) is a nationally representative public health surveillance system that continuously monitors drug-related visits to hospital EDs. The DAWN data are used to monitor trends in drug misuse and abuse in the United States. DAWN captures both ED visits that are directly caused by drugs and those in which drugs are a contributing factor but not the direct cause of the ED visit.

[8] Unless otherwise specified, for purposes of this document "oxycodone products" refers to both its single-entity and its combination products. All oxycodone products are schedule II controlled substances.

[9] In DAWN, nonmedical use of pharmaceuticals includes taking more than the prescribed dose of a prescription pharmaceutical or more than the recommended dose of an over-the-counter pharmaceutical or supplement; taking a pharmaceutical prescribed for another individual; deliberate poisoning with a pharmaceutical by another person; and documented misuse or abuse of a prescription drug, an over-the-counter pharmaceutical, or a dietary supplement.

[10] The American Association of Poison Control Centers (AAPCC) maintains the national database of information logged by the United

States' 57 Poison Control Centers (PCCs). Case records in this database are from self-reported calls: they reflect only information provided when the public or healthcare professionals report an actual or potential exposure to a substance (e.g., an ingestion, inhalation, or topical exposure, etc.), or request information/educational materials. Exposures do not necessarily represent a poisoning or overdose. The AAPCC is not able to completely verify the accuracy of every report made to member centers. Additional exposures may go unreported to PCCs and data referenced from the AAPCC should not be construed to represent the complete incidence of national exposures to any substance(s).

[11] According to the AAPCC's NPDS database, "intentional reasons" include suspected suicide, misuse, abuse, and intentional unknown.

[12] The Florida Department of Law Enforcement Medical Examiners Commission publishes an Annual Medical Examiners Report, the Annual and Interim Drugs in Deceased Persons Report. In order for a death to be considered "drug-related" at least one drug identified must be in the decedent; each identified drug is a drug occurrence. The State's medical examiners were asked to distinguish between whether the drugs were the "cause" of death or merely "present" in the body at the time of death. A drug is only indicated as the cause of death when, after examining all evidence and the autopsy and toxicology results, the medical examiner determines the drug played a causal role in the death. It is not uncommon for a decedent to have multiple drugs listed as a cause of death.Although a medical examiner may determine a drug is present or detected in the decedent, the drug may not have played a causal role in the death. A decedent may have multiple drugs listed as present.

[13] The NFLIS is a program of the DEA, Office of Diversion Control. NFLIS systematically collects drug identification results and associated information from drug cases submitted to and analyzed by State and local forensic laboratories. NFLIS represents an important resource in monitoring illicit drug abuse and trafficking, including the diversion of legally manufactured pharmaceuticals into illegal markets. NFLIS is a comprehensive information system that includes data from forensic laboratories that handle approximately 90% of an estimated 1.0 million distinct annual State and local drug analysis cases. NFLIS includes drug chemistry results from completed analyses only.

[14] While NFLIS data is not direct evidence of abuse, it can lead to an inference that a drug has been diverted and abused. *See* 76 FR 77330, 77332, Dec. 12, 2011.

[15] STRIDE is a database of drug exhibits sent to DEA laboratories for analysis. Exhibits from the database are from the DEA, other federal agencies, and local law enforcement agencies.

[16] The National Survey on Drug Use and Health, formerly known as the National Household Survey on Drug Abuse (NHSDA), is conducted annually by the Department of Health and Human Service's Substance Abuse and Mental Health Services Administration (SAMHSA). It is the primary source of estimates of the prevalence and incidence of nonmedical use of pharmaceutical drugs, illicit drugs, alcohol, and tobacco use in the United States. The survey is based on a nationally representative sample of the civilian, non-institutionalized population 12 years of age and older. The NSDUH provides yearly national and state level estimates of drug abuse, and includes prevalence estimates by lifetime (i.e., ever used), past year, and past year abuse or dependence.

[17] Monitoring the Future (MTF) is a national survey conducted by the Institute for Social Research at the University of Michigan under a grant from the NIDA that tracks drug use trends among American adolescents among the 8th, 10th, and 12th grades.

[18] Drug poisoning deaths include unintentional and intentional poisoning deaths resulting from overdoses of a drug, being given the wrong drug, using the drug in error, or using a drug inadvertently.

[19] Total poisoning deaths include those resulting from drugs, and those associated with solid or liquid biologics, gases or vapors, or other substances. Poisoning deaths are from all manners, including unintentional, suicide, homicide, and undetermined intent.

[20] FAERS is a computerized information database designed to support FDA's surveillance program for the post-marketing safety of all drug and therapeutic biologic products. FDA receives adverse drug reaction reports from manufacturers as required by regulation. Health care professionals and consumers voluntarily submit reports through the MedWatch program. All reported adverse terms are coded according to standardized international terminology, MedDRA (the Medical Dictionary for Regulatory Activities). These numbers are crude reports and may include duplicates. These reports were not individually reported to determine the association between the drug and the adverse event reported and may contain concomitant use of other medications.

[21] The top 20 most frequently reported adverse event terms associated with all hydrocodone reports (a report may contain more than one adverse event) received from 1969 to 2012 in the FAERS, in decreasing frequency, were: Completed suicide, overdose, cardio-respiratory arrest, toxicity to various agents, cardiac arrest, respiratory arrest, drug ineffective, intentional overdose, nausea, intentional drug misuse, vomiting, death, drug abuse, accidental overdose, pain, dizziness, medication error, drug dependence, headache, and drug abuser.

[22] For purposes of performing regulatory analysis, the DEA uses the definition of a "practitioner" as a physician, veterinarian, or other individual licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he/she practices, to dispense a controlled substance in thecourse of professional practice, but does not include a pharmacist, pharmacy, or hospital (or other person other than an individual).

[23] The estimated break-down is as follows: 50 manufacturers, 4 exporters, 683 distributors, 50,774 pharmacies, and 314,840 practitioners/mid-level practitioners/hospitals/clinics.

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Virginia Board of Pharmacy
Practitioner of the Healing Arts Selling Controlled Substances
Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
1. Practitioner selling on an expired license.	18VAC110-30-30	Per individual	100
2. Selling by unauthorized individuals.	§ 54.1-3302 & 18VAC110-30-20	Per individual	500
3. Change of location, remodel, or addition of a selling location without application or Board approval.	18VAC110-30-80	must submit an application and fee	250
4. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency	100
5. Persons assisting in the performance of pharmacy technicians duties other than a registered pharmacy technician or licensed nurse or physician assistant who has received training in technician tasks.	18VAC110-30-40	Per individual	250
6. Refrigerator/freezer temperature out of range greater than +/- 4 degrees.	18VAC110-30-110	determined using inspector'calibrated thermometer	100 Drugs may be embargoed
7. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
8. Storage of drugs for sale not in the storage and selling area.	18VAC110-30-90		500
9. Alarm not operational or not being set. Enclosure not locked and alarmed when licensee not on duty.	18VAC110-30-120		1000
10. Unauthorized access to alarm or locking device to the drug storage and selling area.	18VAC110-30-120 & 18VAC110-30-130		1000
11. 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 & 18VAC110-30-180	Minor 23 if only expired drugs not included in inventory.	500
12. Theft/unusual loss of drugs not reported to the Board as required or report not maintained.	54.1-3404	per report/theft-loss	250
13. Hard copy prescription or record of sale not maintained or retrievable as required.	18VAC110-30-190		250
14. Automated data processing records of sale not maintained as required.	18VAC110-30-200		250
15. Practitioner not verifying or failing to document verification of prescriptions sold.	18VAC110-30-40	10% threshold for documentation	500
16. Practitioner not checking and documenting repackaging.	18VAC110-30-210	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant	250
17. Practitioner not documenting final verification of non-sterile compounding.	54.1-3410.2, 18VAC110-30-40		500
18. Practitioner not documenting final verification of sterile compounding.	54.1-3410.2 18VAC110-30-40		5000

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
19. Schedule II through VI drugs are being purchased from a wholesale distributor, warehouse, or other entity not licensed or registered by the Board or from a pharmacy not in compliance.	110-30-255		250
20. No clean room.	54.1-3410.2		10000
21. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling.	54.1-3410.2		2000
22. Performing sterile compounding outside of a clean room.	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	3000
23. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.	54.1-3410.2		2000
24. High-risk drugs intended for use are improperly stored.	54.1-3410.2		5000
25. Certification of the direct compounding area (DCA) for compounded sterile preparations 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

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
26. 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	
27. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		1000
28. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD).	54.1-3410.2		5000
29. No documentation of initial and annual (12 months) media-fill testing for persons performing low and medium-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelth month from the date the previous media-fill test was initiated.	500

Major Deficiency	Law/Reg Cite	Conditions	$ Penalty
30. No documentation of initial and semi-annual (6 months) media-fill testing for persons performing high-risk level compounded sterile preparations.	54.1-3410.2	Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated	5000
31. Documentation that a person who failed a media-fill test has performed low or medium risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		500
32. Documentation that a person who failed a media-fill test has performed high-risk level compounded sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill test.	54.1-3410.2		5000
33. Compounding using ingredients in violation of §54.1-3410.2.	54.1-3410.2		1000
34. Compounding copies of commercially available products.	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or $5000	50
35. Unlawful compounding for further distribution by other entities.	54.1-3410.2		500

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Minor Deficiencies

If five (5) 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 five.

Minor Deficiency	Law/Regulation Cite	Conditions
1. Selling drugs from a location prior to approval by the Board.	18VAC110-30-80	
2. Special/limited-use scope being exceeded without approval.	18VAC110-30-20	
3. More than one person present in the storage and selling area to assist in performance of pharmacy technician tasks.	18VAC110-30-40 & 18VAC110-30-130	per each person First Offense – Minor 3 deficiency Second Offense – Major 4 deficiency
4. No site-specific training program and manual.	18VAC110-30-40	
5. No documentation of successful completion of site-specific training program.	18VAC110-30-40	
6. Insufficient enclosures or locking devices.	18VAC110-30-120	Major 7 if there is evidence that non-compliance contributed to a drug loss. Minor 6 if no drug loss.
7. Emergency access alarm code/key not maintained in compliance.	18VAC110-30-120	
8. Selling and storage area, work counter space and equipment not maintained in a clean and orderly manner.	18VAC110-30-90	must have picture documentation
9. Controlled substances for ultimate sale not clearly separated from other drugs (i.e. samples, drugs for administration).	18VAC110-30-90	
10. Storage of prescriptions prepared for delivery not in compliance.	18VAC110-30-140	
11. Expired drugs in the working stock.	18VAC110-30-150	10% threshold

Minor Deficiency	Law/Regulation Cite	Conditions
12. No prescription balance sensitive to 15mg and weights or electronic scale if engaged in dispensing activities that require the weighing of components.	18VAC110-30-110	
13. Sink with hot and cold running water not available within the immediate vicinity of the selling and storage area.	18VAC110-30-90	
14. Failure to conspicuously display sign in a public area advising patients of their right to choose where to have their prescriptions filled.	18VAC110-30-170	
15. Documentation of patient's choice to have prescription filled by practitioner not in compliance..	18VAC110-30-170	
16. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit.	18VAC110-30-110	determined using inspector's calibrated thermometer
17. No current dispensing information reference source.	18VAC110-30-110	
18. Labels do not include all required information	18VAC110-30-220	10% Threshold Review 25 prescriptions
19. Special packaging not used, no documentation of request for non-special packaging, sign not posted near the compounding and selling area advising patients nonspecial packaging may be requested.	18VAC110-30-240	
20. Repackaging records and labeling not kept as required or in compliance.	18VAC110-30-210	10% threshold
21. Packaging not compliant with USP-NF standards.	18VAC110-30-230	

Minor Deficiency	Law/Regulation Cite	Conditions
22. Biennial inventory taken late but within 30 days.	54.1-3404 & 18VAC110-30-180	
23. Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404 & 18VAC110-30-180	
24. Records of receipt (e.g.invoices) of controlled substances not maintained as required.	§ 54.1-3404 & 18VAC110-30-180	
25. Offer to counsel not made as required.	18VAC110-30-40	
26. Prospective drug review not performed as required.	18VAC110-30-40	
27. Improper disposal of unwanted drugs.	18VAC110-30-160	
28. Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.	§54.1-3410.2	
29. Equipment for sterile compounding does not comply with USP-NF standards.	18VAC110-30-110 & § 54.1-3410.2	