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 Public Hearing and Full Board Meeting

December 9, 2014

9:00AM

TOPIC	PAGES

Call to Order of Public Hearing for Scheduling Certain Substances:
Ellen B. Shinaberry, Chairman

- Welcome & Introductions
- Reading of Emergency Evacuation Script

Call for Public Comment:

- Possible scheduling of the following substances:
  - N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide; (other name: AB-CHMINACA) 1-2
  - N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide; (other name: 5-fluoro-AMB)
  - 3,4-methylenedioxy-N,N-dimethylcathinone; (other names: Dimethylone, bk-MDDMA)

Consideration of Scheduling Action

Adjournment of Public Hearing

Call to Order of Full Board Meeting: Ellen B. Shinaberry, Chairman

- Approval of Agenda
- Approval of Previous Board Meeting Minutes:
  - September 9, 2014, Full Board Meeting 3-11
  - September 9, 2014, Panel Formal Hearing 12-14
  - September 16, 2014, Special Conference Committee 15-17
  - October 21, 2014, Special Conference Committee 18-20
  - October 28, 2014, Panel Formal Hearing

Call for Public Comment: The Board will receive <u>all</u> public comment at this time. The Board will not receive comment on any regulation process for which a public comment period has closed or any pending disciplinary matters.

DHP Director's Report: David Brown, DC

Regulatory Actions: Elaine Yeatts

- Regulatory Update
- Legislative Update

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New Business: Caroline D. Juran

- Request from Fresenius Medical Care to Perform Alternate Delivery of Certain Drugs to Dialysis Centers 22-28
- Request from Staff for Guidance regarding Acceptable Security Systems in Wholesale Distributors 29-39
- Request from Joint Commission to Accept their Screening Checklist for Satisfying Inspection Report Requirement in §54.1-3434.1 40-42
- Request to Consider Requiring PTCB for Pharmacy Technician Registration 43
- Consider Amending Guidance Document 110-34 regarding Licensure of Wholesale Distributors and Manufacturers 44-49
- Consider Amending Guidance Document 110-36 based on Recommendations from Compounding Workgroup 50-62
- Amend Guidance Document 110-12, Bylaws 63-66

Reports:

- Chairman's Report – Ellen B. Shinaberry
- Report on Board of Health Professions - Ellen B. Shinaberry
- Report on NABP/AACP Districts 1&2 Meeting – Cindy Warriner
- Report on NABP Taskforce –Jody H. Allen
- Report on NABP Meeting for PARE Exam – Empsy Munden
- 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, and possible summary suspensions

Adjourn

******The Board will have a working lunch at approximately 12pm and recognize former board members, Robert Rhodes, Pratt Stelly, and Crady Adams. ******

Notice of Public Hearing

Pursuant to subsection D of § 54.1-3443, the Board of Pharmacy is giving notice of a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act. The public hearing will be conducted at 9:00 a.m. on December 9, 2014 at the Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2, Richmond, VA 23233. Public comment may also be submitted prior to December 9, 2014 to Caroline Juran, Executive Director of the Board of Pharmacy to caroline.juran@dhp.virginia.gov.

As specified in § 54.1-3443, the Virginia Department of Forensic Science (DFS) has identified three (3) compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. We believe the Drug Enforcement Administration (DEA) is currently working to place these compounds into Schedule I Federally. Other drugs of this type have been placed in Schedule I in previous legislative sessions. A brief description and chemical name for each compound is as follows:

1. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other name: AB-CHMINACA)

AB-CHMINACA is classified as a cannabimimetic agent and has been identified in all four (4) DFS laboratories.

2. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(5-fluoropentyl)indazole-3-carboxamide (other name: 5-fluoro-AMB)

5-fluoro-AMB is classified as a cannabimimetic agent and has been identified in two (2) of the four (4) DFS laboratories.

3. 3,4-methylenedioxy-N,N-dimethylcathinone (other names: Dimethylone, bk-MDDMA)

Dimethylone is classified as a substituted cathinone, and has been identified in two (2) of the four (4) DFS laboratories.

If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall remain in effect for a period of 18 months from the date of Board action and shall then be de-scheduled unless the Drug Control Act is amended by enactment of legislation by the General Assembly.

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from *The Drug Control Act*, revision July 1, 2014

§ 54.1-3443. Board to administer article.

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

1. The actual or relative potential for abuse;

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

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

4. The history and current pattern of abuse;

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

6. The risk to the public health;

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

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

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

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

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

E. If any substance is designated, rescheduled, or descheduled as a controlled substance under federal law and notice of such action is given to the Board, the Board may similarly control the substance under this chapter after the expiration of 120 days from publication in the Federal Register of the final order designating a substance as a controlled substance or rescheduling or descheduling a substance without following the provisions specified in subsections A and B.

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

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

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

September 9, 2014
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT:
Jody H. Allen
Melvin L. Boone, Sr.
Michael Elliott
Sheila K. W. Elliott
Dinny Li
Ryan K. Logan
Empsy Munden
Rebecca Thornbury
Cynthia Warriner

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

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

APPROVAL OF AGENDA: Ms. Shinaberry noted two corrections in the tentative agenda: the minutes from August 14, 2014 were from a special conference committee meeting, not an informal conference committee meeting; and, a panel of the board will convene at 1:30pm or immediately following adjournment of the meeting, whichever is later, not at 2pm as listed on the tentative agenda. The tentative agenda was approved as amended.

APPROVAL OF MINUTES: The Board reviewed draft minutes for the June 3, 2014 (Informal Conference Committee-Innovative Pilot Program), June 4, 2014 (Public Hearing on Proposed Regulations for Administrative Fees for Duplicate Licenses and Verification), June 4, 2014 (Full Board Meeting), June 4, 2014 (Ad Hoc Inspection Committee), June 5, 2014 (Special Conference Committee), July 9, 2014 (Telephone Conference Call), July 22, 2014 (Panel Formal Hearing), July 29, 2014 (Special Conference Committee

and Informal Conference Committee), July 29, 2014 (Telephone Conference Call), August 14, 2014 (Special Conference Committee), and August 20, 2014 (Special Conference Committee).

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

PUBLIC COMMENTS:

Alexander Pytlarz, pharmacist practicing in northern Virginia, thanked the board for addressing compounding issues during the recent compounding working group meetings and asked the board to support the recommendations captured in the compounding working group report.

Tim Musselman, Executive Director of the Virginia Pharmacists Association (VPhA), provided comment on the agenda topic regarding interruptions when administering flu vaccinations. He asked the board to not restrict under what conditions vaccines may be administered, but to provide a balanced approach while acknowledging the raised concerns. He also offered assistance from VPhA to address the issue.

REGULATORY ACTIONS:

- Regulatory Update:

Ms. Yeatts reviewed the chart of regulatory actions found in the agenda packet.

- Adoption of Final Regulations for Administrative Fees:

Mr. Yeatts briefly reviewed the proposed regulations indicating no comment was received during the public comment period ending 7/18/14.

MOTION: **The board voted unanimously to adopt the proposed final regulations for administrative fees for duplicate licenses and license verifications. (motion by Warriner, second by Allen)**

- Discussion of Amended 2015 Legislative Proposals: Virginia Licensure for Outsourcing Facilities, Pharmacies that Compound Human Drugs, and Wholesale Distributor Notification of Suspicious Ordering:

Ms. Yeatts reported that the provision for compounding for office use in the legislative proposal primarily addressing outsourcing facilities and adopted by the board in June was recently amended based on a recommendation from the compounding working group. The proposal now includes language allowing pharmacies to provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry if there is a critical need to treat an emergency condition. Additionally, she noted that the paragraph regarding labeling requirements for compounded products for office use that was originally stricken in the proposal adopted by the board will need to remain to address the now proposed emergency provision. Ms. Yeatts explained that it may be early December before notification is received from the Governor as to whether the legislative proposal is approved for introduction in the upcoming General Assembly session.

MOTION:

The board voted unanimously to support amending the outsourcing facility legislative proposal by including language for pharmacies to provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry if there is a critical need to treat an emergency condition primarily addressing outsourcing facilities and by keeping the paragraph regarding labeling requirements for compounded products for office use that was originally stricken in the proposal adopted by the board in June. (motion by Warriner, second by Allen)

Ms. Yeatts reviewed the current language for the legislative proposal regarding wholesale distributor notification of suspicious ordering. The board offered no changes or comments.

OLD BUSINESS

- Update on Revising Physician Selling Drugs Inspection Process:

Ms. Juran provided a brief update on this matter and indicated that staff intends to begin piloting the process in October.

NEW BUSINESS

- Request to Use Numbered Stamps during Pharmacist Verification:

The Board discussed a request from a pharmacist to allow for the use of numbered rubber stamps which are cross referenced to pharmacist initials in lieu of handwritten pharmacist initials. The board took into consideration an allowance approved by the board in September 2007 to allow for the use of stamps to capture pharmacist initials. There was consensus to not approve the current request as the 2007 allowance appeared to provide a reasonable alternative to capturing handwritten pharmacist initials. Additionally, there was concern for the need to maintain an additional record, as outlined in the request, for cross referencing the pharmacist's initials as it appeared unnecessarily burdensome and could be misplaced. No action was taken by the board on this request.

- Concerns for Pharmacy Workflow Interruptions when Administering Influenza Vaccines:

The Board discussed concerns raised by a pharmacist regarding workflow interruptions in a community pharmacy when administering flu shots. Specific concerns included: expectations by some community pharmacies that a pharmacist must interrupt or rush through other activities to administer vaccines with little to no wait time for the patient regardless of staffing levels; and, the amount of time spent outside the prescription department administering vaccines, in lieu of supervising staff, answering prescriber telephone calls, and counseling patients.

MOTION:

The Board expressed concern for the issues raised by the pharmacist and directed staff to advise the pharmacist in writing of the following information:

- **§54.1-3434 and Regulation 18VAC110-20-110 B indicate that the pharmacist who signs the pharmacy permit application is in full and actual charge of the pharmacy, and that if the owner is not a pharmacist, he shall not abridge the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations;**
- **the PIC or the pharmacist on duty shall control all aspects of the practice of pharmacy and any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit;**
- **the Board included an article entitled *Concern for Contemporary Practice: Evidence Requested* in the February 2013 board e-newsletter which addressed similar concerns;**
- **a summary of responsibilities of the pharmacist-in-charge found in Guidance Document 110-27; and,**
- **instructions for filing a complaint when evidence exists regarding possible patient harm resulting from contemporary pharmacy practice or any violation of law, to include abridging the authority of the PIC to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations, or any decision overriding such control of the PIC or other pharmacist on duty.**

- Guidance for Security Systems Transitioning from 2G to 4G and if it Necessitates Submission of a Remodel Application:

The Board discussed the impact on facility security systems that currently utilize 2G cellular technology. The use of 2G technology is currently sunsetting. Industry is moving toward the use of 3G/4G. Any devices using 2G technology after December 31, 2016 will no longer work. Staff explained that some newer security systems using 2G technology will only require a minor upgrade to transition to 3G/4G while some older security systems will need a significant upgrade or replacement.

MOTION:

The Board offered the following direction to staff:

- **send letter to facilities alerting them to sunset of 2G technology;**
- **advise permit holder to contact alarm company to determine what actions, if any, will be necessary to upgrade security system;**
- **if upgrade requires only a change to the circuit board, then a remodel application does not need to be submitted to the board office;**
- **if upgrade requires a replacement of the alarm panel, then a remodel application and fee must be submitted to the board office;**
- **advise facilities whose security system uses cellular**

technology to maintain documentation on file indicating if 3G/4G technology is currently being used, or if and when an upgrade was performed, and what the upgrade entailed;
- **emphasize importance of ensuring security system operates at all times when activated and that action must be taken, when applicable, prior to December 31, 2016 when the 2G Sunset is complete;**
- **publish an article on this subject in an upcoming board e-newsletter.**

- Request from VDH for Guidance for Accessing Alternate Delivery Drugs

Ms. Juran reported that staff had received an inquiry from VDH as to who and under what conditions may someone access dispensed drugs maintained and delivered to a local health department under the alternate delivery provisions of 18VAC110-20-275. In researching the matter staff realized Guidance Document 110-3 should be amended to reflect current regulatory language and additional guidance could be provided to further clarify who may access alternate delivery drugs at a health department.

MOTION:

The Board voted unanimously to amend Guidance Document 110-3 as presented. (motion by Munden, second by Allen)

- Dates for 2015 Full Board Meetings and Tentative Regulation Committee Meetings

The following dates were selected for 2015 Full Board Meetings: 3/24/15; 6/16/15; 9/29/15; and, 12/1/15.

The following dates were selected for 2015 tentative Regulation Committee Meetings: 5/11/15 and 11/3/15.

REPORTS

- DHP Director's Report:

Due to a scheduling conflict, Dr. Brown was unable to provide a report to the board.

- Chairman's Report:

Ms. Shinaberry welcomed the three newly-appointed board members. She then announced her appointments to the standing committees as indicated on a handout.

MOTION:

Because the law now allows a special conference committee to address permit holders, there was consensus to rename the "Informal Conference" standing committee as listed on the handout the "Inspection Special Conference" standing committee.

- Report on Board of

A brief report was provided by Elizabeth Carter, Executive Director of

Health Professions:

the Board of Health Professions. It was stated that Ms. Shinaberry was recently appointed by the Governor to the board, along with 11 others. There are 18 member positions on the board. The next scheduled meeting of the board is September 25, 2014. The board will review the scope of practice for dental assistants and dental hygienists.

- Report on Compounding Workgroup:

Ms. Allen provided a brief report regarding the two meetings recently held by the compounding working group as required in the enactment clause of HB 1035 passed during the 2014 General Assembly session. The goal of the group was to explore and clarify issues related to the compounding of drugs for human and animal use and provide a report to the Chairmen of the House of Delegates' Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by November 1, 2014. She indicated the report has been sent to Secretary Hazel for his review prior to submission to the legislators.

MOTION:

There was consensus for staff to provide a copy of the compounding working group's report to the board members on November 1st, following submission to the Chairmen of the House of Delegates' Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health.

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

Ms. Warriner provided a brief update on the planning for the NABP/AACP Districts I & II meeting being held in Williamsburg, Virginia, October 5, 2014 through October 7, 2014. Ms. Warriner requested that board members provide possible roundtable discussion topics and possible resolutions to Ms. Juran by September 20, 2014.

- Report on Licensure Program:

Mr. Johnson reported the Board currently licenses over 35,000 individuals and facilities. The Board issued 1,408 licenses and registrations for the period of June 1, 2014 through August 31, 2014, including 480 pharmacists, 104 pharmacy interns, and 579 pharmacy technicians. Between June 1, 2014 and August 31, 2014, inspectors conducted 503 facility inspections including 198 routine inspections of pharmacies: 70 (35%) resulted in no deficiency, 71 (36%) with deficiencies and 57 (29%) with deficiencies and a consent order. This is the third consecutive quarter where deficiencies and a consent order have been below 40%. This may be attributed to educational efforts by the inspectors and amendments made to Guidance Document 110-9 at the December 12, 2013 board meeting that modified several major deficiencies and established new minor deficiencies. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies including "repeat" deficiencies. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012.

Mr. Johnson reported that the Item Review Committee met in August to develop new questions for the Virginia Federal and State Drug Law Exam.

Mr. Johnson reported that the Board is conducting its annual random audit of compliance with continuing education requirements by pharmacists and pharmacy technicians. In lieu of requesting, from those being audited, the submission of original certificates for all continuing education obtained in 2012 and 2013, the board will request NABP to provide information regarding any ACPE-approved CE maintained by the NABP CPE Monitor program for those being audited. If the information provided by NABP does not indicate full compliance with CE requirements, the licensee will be asked to submit original CE certificates to the board office to complete the auditing process.

- Report on Disciplinary Program:

Ms. Reiniers-Day provided the Board with the Open Disciplinary Case Report comparing the case stages between the four report dates of December 10, 2013; March 25, 2014; June 3, 2014; and September 9, 2014. For the final date, open cases are none at the entry stage; 61 at the investigation stage; 106 at the probable cause stage; three at the administrative proceedings division stage; 13 at the informal stage; three at the formal stage; and 131 at the pending closure stage.

- Executive Director's Report:

Ms. Juran provided an overview of the internal process to be used should the board, in consultation with the Department of Forensic Science, need to consider scheduling a chemical into Schedule I or II pursuant to §54.1-3443. She provided a similar report to the Forensic Science Board in August. Several announcements regarding DEA-related matters were highlighted: national take-back day Sept 27th, 10am-2pm; recent teleconference announcing publication of final federal rules for drug disposal. She reported a blast email will soon be sent to licensees regarding DEA's final rule, effective October 6, to reschedule hydrocodone combination products from CIII to CII. She provided an update on meetings recently attended or to be attended in the near future: July 17 and 18th, Mr. Johnson, Ms. O'Halloran, and Ms. Juran traveled to Rockville, MD to attend a 2-day USP training program hosted by USP; Mr. Johnson will participate in additional sterile compounding training Sept 16-17 with expenses paid by NABP; Ms. Allen was appointed to the NABP taskforce to address pharmacy robberies and internal/external theft and will attend a meeting October 22-23 with expenses paid by NABP; Ms. Juran has been appointed to the NABP Committee on Law Enforcement/Legislation and will attend a meeting in January with expenses paid by NABP; Ms. Juran has been invited to participate on an Advisory Committee on Compounding Best Practices put together by the Pew Charitable Trust and will attend a meeting on October 9th with

expenses paid by Pew; staff offered two presentations at the VPhA annual meeting August 3-5th; and, staff will offer two presentations at the VSHP meeting in October. She reported an e-newsletter was published in July to further educate licensees on compliance with laws and regulations.

SUMMARY SUSPENSIONS

DAVID O. COX
Pharmacy Technician
Registration Number:
0230-020185

Corie Tilman Wolf, 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:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by David O. Cox as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of David O. Cox to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Mr. Cox for the revocation of his pharmacy technician registration.

TIHESA N. ELLIOTT
Pharmacy Technician
Registration Number:
0230-014828

Corie Tilman Wolf, 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:

Upon a motion by Ms. Allen, and duly seconded by Ms. Warriner, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Tihesa N. Elliott as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Tihesa N. Elliott to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Elliott for the revocation of her pharmacy technician registration.

KILEY J. KESSLER
Pharmacy Technician
Registration Number:
0230-023259

Corie Tilman Wolf, 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:

Upon a motion by Ms. Allen, and duly seconded by Mr. Elliott, the Board voted 8-0 in favor of the motion that, according to the evidence presented, the continued practice by Kiley J. Kessler as a pharmacy technician poses a substantial danger to the public; and therefore, the registration of Kiley J. Kessler to practice as a pharmacy technician be summarily suspended. Further, a Consent Order shall be offered to Ms. Kessler for the revocation of her pharmacy technician registration.

ADJOURN: With all business concluded, the meeting concluded at approximately 1:10pm.

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

DATE:

DATE:

DRAFT

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF A PANEL OF THE BOARD

Tuesday, September 9, 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 panel of the Board of Pharmacy ("Board") was called to order at 1:30 p.m.

PRESIDING: Ellen Shinaberry, Chair

MEMBERS PRESENT:
Jody Allen
Melvin Boone
Michael Elliott
Sheila Elliott
Empsy Munden
Cindy Warriner

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Heather W. Hurley, Facility Licensing Specialist
Sharon Davenport, Administrative Assistant
James Rutkowski, Assistant Attorney General
Wayne T. Halbleib, Senior Assistant Attorney General
Mykl Egan, DHP Adjudication Specialist

QUORUM: With seven (7) members of the Board present, a panel was established.

MISTY DENISE SWORD WARD
License No. 0202-206495

A formal hearing was held in the matter of Misty Denise Sword Ward to discuss her petition for reinstatement of her pharmacist license following a mandatory suspension on April 2, 2014.

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

Robert Dwerkin, Rite Aid Asset Protection District Manager, and Kevin W. Almeida, DHP Senior Investigator, testified on behalf of the Commonwealth.

Ms. Ward testified on her own behalf and was represented by Richard Kennedy, Esquire.

Closed Meeting:	Upon a motion by Ms. Munden, and duly seconded by Ms. Warriner, the panel voted 7-0, 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 Misty Denise Sword Ward. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Heather W. Hurley and James Rutkowski attend the closed meeting.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Warriner, and duly seconded by Ms. Allen, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the Board and read by Mr. Rutkowski. Upon a motion by Ms. Warriner and duly seconded by Ms. Allen, the panel voted 7-0 to grant the application of Misty Denise Sword Ward for the reinstatement of her pharmacist license and that the license shall be placed on probation with terms and conditions.
CAROLYN A. FIELDS Registration No. 0230-010118	A formal hearing was held in the matter of Carolyn A. Fields, following the summary suspension of her pharmacy technician registration on August 5, 2014, to discuss allegations governing the practice of pharmacy technicians in Virginia. Ms. Fields was not present at the hearing. The Board proceeded with the hearing in Ms. Fields' absence as the Notice of Hearing dated August 5, 2014, was mailed to her legal address of record, both by regular and certified mail. Ms. Shinaberry ruled that adequate notice was provided to Ms. Fields. Wayne T. Halbleib, Senior Assistant Attorney General, prosecuted the case with the assistance of Mykl Egan, DHP Adjudication Specialist. Robert Dworkin, Rite Aid Asset Protection District Manager, and Denise Sexton, DHP Senior Investigator, testified on behalf of the Commonwealth.

Closed Meeting:	Upon a motion by Ms. Munden, and duly seconded by Mr. Elliott, the panel voted 7-0, 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 Carolyn A. Fields. Additionally, she moved that Cathy Reiniers-Day, Caroline Juran, Sharon Davenport, and James Rutkowski attend the closed meeting.
Reconvene:	Having certified that the matters discussed in the preceding closed meeting met the requirements of § 2.2-3712 of the Code, the panel re-convened in open meeting and announced the decision.
Decision:	Upon a motion by Ms. Warriner, and duly seconded by Ms. Elliott, the panel voted 7-0 to accept the Findings of Fact and Conclusions of Law as proposed by Mr. Halbleib, amended by the Board and read by Mr. Rutkowski. Upon a motion by Ms. Warriner and duly seconded by Ms. Elliott, the panel voted 8-0 to revoke Ms. Fields registration to practice as a pharmacy technician.
Adjourn:	With all business concluded, the meeting adjourned at 5:10 p.m.

Ellen Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, September 16, 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:	Jody H. Allen, Committee Chair
MEMBERS PRESENT:	Empsy Munden, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
CLINICAL MANAGEMENT CONCEPTS, INC., d/b/a ProCompoounding Pharmacy Permit Number 0214-001441	Perry Ripple, Pharmacist-in-Charge, appeared with Steve Lane, Director of Pharmacy; Whitney Larkin, Sales and Marketing Representative; and Hunter Jamerson, their attorney; to discuss allegations that ProCompounding Pharmacy may have violated certain laws and regulations governing the conduct of non-resident pharmacies July 31, 2014, Notice.
Closed Meeting:	Upon a motion by Ms. Munden, and duly seconded by Ms. Allen, 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 ProCompounding Pharmacy. 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. Munden, and duly seconded by Ms. Allen, the Committee closed this case as undetermined.

RUSSELL LEDERHOUSE, Pharmacist
License Number 0202-207604

Russell Lederhouse appeared to discuss his application for reinstatement of his pharmacist license as stated in the September 10, 2014, Notice.

Closed Meeting:

Upon a motion by Ms. Munden, and duly seconded by Ms. Allen, 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 Russell Lederhouse. 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. Munden, and duly seconded by Ms. Allen, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to issue an Order to Mr. Lederhouse to reinstate his license to practice pharmacy on probation with certain terms and conditions.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Mr. Lederhouse, unless a written request is made to the Board requesting a formal hearing on the allegations made against him is received from Mr. Lederhouse within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

ADJOURN: With all business concluded, the meeting adjourned at 4:25 p.m.

Jody H. Allen

Cathy M. Reiniers-Day
Deputy Executive Director

Date

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Tuesday, October 21, 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 12:30 p.m.
PRESIDING:	Ellen Shinaberry, Committee Chair
MEMBERS PRESENT:	Cindy Warriner, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
ROBERT H. AGEE, JR. License Number 0202-004442	Robert H. Agee, Jr., appeared to discuss allegations that he may have violated certain laws and regulations governing the practice of pharmacy as stated in the September 30, 2014, Notice.
Closed Meeting:	Upon a motion by Ms. Warriner, 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 Robert H. Agee, Jr. 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. Warriner, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that reprimands Mr. Agee.

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

DARLENE S. NEWMAN
Registration Number 0230-005557

Darlene S. Newman did not appear to discuss allegations that she may have violated certain laws and regulations governing the practice of pharmacy technicians as stated in the October 15, 2014, Corrected Notice. The Chair of the Committee chose to proceed with the informal conference as the Notice had been sent to Ms. Newman's legal address of record.

Closed Meeting:

Upon a motion by Ms. Warriner, 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 Darlene S. Newman. 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. Warriner, and duly seconded by Ms. Shinaberry, the Committee made certain Findings of Facts and Conclusions of Law and unanimously voted to enter an Order that reprimands Ms. Newman.

As provided by law, this decision shall become a final Order thirty (30) days after service of such Order on Ms. Newman, unless a written request is made to the Board requesting a formal hearing on the allegations made against her is received from Ms. Newman within such time. If service of the Order is made by mail, three (3) additional days shall be added to that period.

Upon such timely request for a formal hearing, the decision of this Special Conference Committee shall be vacated.

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

Ellen Shinaberry, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Board of Pharmacy

Chart of Regulatory Actions as of November 19, 2014

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Prohibition against incentives to transfer prescriptions [Action 4186] NOIRA - *At Secretary's Office for 152 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *At Secretary's Office for 559 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Maintaining floor stock of certain drugs onsite at correctional facilities [Action 4157] Fast-Track - *At Governor's Office for 99 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Nonresident pharmacy renewal date and access by suspended pharmacists to prescription department [Action 4215] Fast-Track - *At Governor's Office for 24 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Drugs and emergency medical services agencies [Action 4216] Fast-Track - *At Governor's Office for 32 days*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Continuous quality improvement programs [Action 3496] Final - *Register Date: 12/1/14* *Effective: 12/31/14*
[18 VAC 110 - 20]	Virginia Board of Pharmacy Regulations	Administrative fees for duplicate licenses and verification [Action 3444] Final - *At Secretary's Office for 58 days*

Request from Fresenius Medical Care to obtain a controlled substances registration pursuant to 18VAC110-20-275 C to deliver patient-specifically dispensed Schedule VI dialysis drugs to dialysis centers, instead of the patients' residences. The dialysis centers typically do not have a prescriber or pharmacist present at all times the site is open and therefore, 18VAC110-20-275 E must be taken into consideration.

Board actions on similar requests in the past:

- Excerpt from 3/29/07 minutes, request from Davita Rx
- Excerpt from 3/11/09 minutes, request from Home Choice Partners

Regulation authorizing alternate delivery of Schedule VI drugs

Possible board action:

- Grant request

  OR

- Deny request

$95. Further, Ms. Russell stated that for the exam to be approved as an alternative to The Pharmacy Technician Certification Board (PTCB) there would have to be a change in the statue. Ms. Abernathy continued to express concern as to whether ExCPT was a psychometrically sound exam. There was some concern about whether Dana P. Hammer's credentials qualified her as a psychometrician. Ms. Russell stated that she would contact Washington state to determine their requirements for being qualified as a psychometrician. After further discussions, Ms. Abernathy moved and the Board voted unanimously that it would consider approval of a second examination for pharmacy technicians, but would only reconsider the ExCPT exam upon receipt of supporting documentation and evidence that the test is psychometrically sound and that it meets APA standards.

REQUEST FROM MERCK NOT TO PROVIDE SOCIAL SECURITY NUMBERS FOR OWNERS:

Ms. Russell explained to the Board that Merck has applied for a registration as a non-resident wholesale distributor and submitted a recent letter expressing concerns with the requirement to provide social security numbers for the corporate officers and directors. The letter asked that the Board consider this request. Ms. Russell advised that staff members have communicated to Merck that social security numbers are required by statute, § 54.1-116 as well as Board regulation 18 VAC 100-50-70 and that application information is not subject to the provisions of FOIA. Mr. Casway advised the Board that it did not have the authority to waive the requirement. Mr. Stredler moved and the Board voted unanimously to inform Merck by letter that the Board has no authority to waive the requirements of statutes or of its regulations.

REQUEST FROM ROBERT M. WOLIN, ATTORNEY FOR DAVITA RX, NON-RESIDENT PHARMACIES TO DIPENSE TO DIALYSIS PATIENTS IN VIRGINIA:

Ms Russell provided a handout and gave some background concerning a request by Robert M. Wolin, attorney for Davita Rx, regarding a chain of dialysis centers being an alternate deliver site. There is a non-resident pharmacy associated with approximately 53 dialysis centers located in Virginia, and Davita Rx would like to offer the dialysis patients seen at these centers the option of having dialysis supplies and all prescription medications dispensed by Davita Rx and delivered to the dialysis center for pickup. Davita Rx would not want to limit this service to only those drugs used or administered in conjunction with the dialysis process. Davita Rx argues that this is a fragile population, that transportation to pharmacies is frequently an issue, and that it is more convenient for the patients to receive the medications at the dialysis centers because they already have transportation there three times a week. Further, this entity claims that because this particular population primarily consists of low income patients, the security and integrity of the drugs are compromised by mailing prescription medications directly to the patients' homes. Ms. Russell advised that, in the past, the Board had not approved

entities to be alternate delivery sites unless the second location was a pharmacy, had a physician on site during operating hours, or was either a government agency or was receiving prescription drugs from a government entity and there was a compelling patient safety reason for not delivering the drugs directly to the patient address. Mr. Kozera inquired how this request is different from the community services boards ("CSB"). Ms. Russell explained that the mental health patients are a fragile population due to the fact that many patients do not have a permanent address of record and they are not competent enough to self administer medications. The Board had allowed the "Aftercare Pharmacy" to deliver drugs to the patients at the community service boards for about 10 years before the law actually changed to allow this via a controlled substance registration certificate because of compelling patient safety reasons. Additionally, the majority of the prescription drugs for the CSB patient populations are dispensed by a government agency pharmacy and the CSBs are closely tied to local government with oversight by DMHMRSAS. The concern with delivery to any alternate location is that of diversion with a large quantity of drugs going to one location, as well as the risk of error in the wrong patient being handed the incorrect medication. After further discussion, Mr. Stredler moved and the Board voted unanimously to deny DaVita Rx's request to be allowed to deliver prescriptions for dialysis patients in Virginia to the dialysis centers as alternate delivery locations.

NEW PHARMACIES AND HOW FAR IN ADVANCE OF OPENING SHOULD THE BOARD INSPECT AND ISSUE THE PERMIT:

Ms. Russell provided a background summary regarding inspections and anticipated opening dates for new pharmacies. The Board office has received new applications requesting opening inspection dates ranging from six weeks to two months prior to the anticipated opening date. These requests are usually from pharmacies that are located in a grocery store and their reasons include delays in obtaining the Drug Enforcement Agency (DEA)'s registration and Schedule II order forms, delays in obtaining the NCPDP (a/k/a NABP) number for processing claims, or delays in entering into insurance contracts. Ms. Russell commented that staff is not sure if the reasons given by the pharmacies are valid for obtaining a permit so far in advance of the actual opening of the pharmacy. Ms. Russell explained that most pharmacies have already had the paperwork submitted to DEA and NCPDP and only need to provide documentation that the pharmacy permit has been issued. Staff members have had several conversations with DEA about this and they indicate that they can usually issue the registration within several days. There was some discussion of what would be a reasonable time frame to allow a Board inspection prior to the expected opening date. After further discussion, Mr. Yi moved and the Board voted unanimously to draft a guidance document with the following language, in

recommendations in consultation with PhRMA and the U.S. Department of Fish and Wildlife Services. Additionally, there will be a link to the recommendations for disposal by the White House Office of National Drug Control Policy. Both recommendations are similar.

Motion:

The Board voted unanimously to approve the addition of the link to SmartRx Disposal on its webpage. (Motion by Abernathy, second by Ross)

ORAL ORDERS TO MEDICAL EQUIPMENT SUPPLIERS

Ms. Russell stated that the Board has received calls asking whether it is lawful for personnel for a medical equipment supplier (MES) to take oral orders. Ms. Russell stated that this is not specifically addressed in statute, but that there were certain provisions that may relate to this issue. Mr. Casway advised that the Board could interpret its own statutes, but could not grant the authority for accepting an oral order if it does not exist. Ms. Russell stated that while the accepting of an oral prescription is an act restricted to pharmacists, so is the certification of accuracy of the completed prescription. The permit for a medical equipment supplier is a specific "carve-out" of the practice of pharmacy in which the General Assembly has determined that it is safe for medical devices, oxygen, and dialysis solutions to be dispensed to consumers by persons holding a permit from the Board of Pharmacy, but with no requirement for there to be a pharmacist to perform the dispensing, or certify the accuracy prior to dispensing. The statute says the dispensing may be done by a MES pursuant to a "lawful order" of a practitioner, but that term is not defined. The term "prescription" may be written or oral. Ms. Abernathy expressed concern that there could be a negative impact on patient health if a MES were not able to at least initially dispense pursuant to an oral order, such as in the case of patients being discharged from a hospital, when written orders may not be received timely enough.

Action Item:

Ms. Russell stated that if the Board concurs, she will do more research prior to the June meeting as to what is required by a MES in order to receive reimbursement, and that staff will draft a guidance document if necessary to address this. The Board agreed by consensus to continue this until the June meeting. There was no action taken by the Board at this time.

REQUEST FROM HOME CHOICE PARTNERS FOR DELIVERY OF IDPN SOLUTIONS TO DIALYSIS CENTERS

The Board reviewed a request from Home Choice Partners, an infusion pharmacy, to be allowed to deliver parenteral nutrition solutions to patients directly to the dialysis centers where they will be infused via dialysis by nurses. Home Choice stated that many of these patients are not mobile and rely on assisted transportation to get to dialysis, and that transporting of these large, heavy

solutions is very difficult. In addition, the solutions are very fragile and subject to contamination and degradation if not stored in an appropriate environment and under required temperature controls. The dialysis centers will be set up with the appropriate equipment to properly store the solutions.

Motion:

The Board voted unanimously to approve the request by Home Choice Partners to allow delivery of the solutions directly to the dialysis centers provided the centers obtain a controlled substances registration for alternate delivery, and the registration shall be limited to alternate delivery of these IDPN solutions. (Motion by Yi, second by Ross)

RESPONSE TO DEA ADVANCED NOTICE OF PROPOSED RULEMAKING FOR DISPOSAL OF CONTROLLED SUBSTANCES BY CONSUMERS AND LONG TERM CARE FACILITIES

Ms. Russell discussed with the Board the request for comment from DEA related to its notice of proposed rulemaking related to drug disposal programs for consumers. Ms. Russell provided a draft response in the agenda package for the Board to consider. The draft included factual responses to specific questions from DEA to regulatory authorities. Ms. Russell also suggested that the Board may want to comment that consumers should be allowed to return unwanted controlled substances to pharmacies or send them to returns distributors under controlled conditions as specified by DEA for reverse distributors, or Board regulation for pharmacies.

Ms. Russell also provided the Board in the agenda package with language in the 2009 budget bill that requires the Board of Pharmacy, in consultation with state police, to report in November 2009 to the money committees of the General Assembly with a recommendation for a statewide drug disposal program and any potential sources of revenue to fund such a program. Ms. Russell stated that recommendations for a program had already been provided in 2008, but that changes may need to be made if DEA initiates rulemaking to remove the requirement for law enforcement involvement which significantly increases costs of a program. Additionally, she provided a copy of a bill introduced in the U.S. House of Representatives to allow state "take-back" programs without the requirement for law enforcement involvement, which, if passed, would also necessitate the need for changes to the previous recommendation.

Motion:

The Board voted unanimously to send the response to DEA as included in the agenda package. (Motion by Beckner, second by Yi)

BOARD OF HEALTH PROFESSIONS

Ms. Edwards reported that the Board of Health Professions met once since the last Board meeting. She stated that the Board was studying emerging professions, specifically at this time, the need to

from *Regulations Governing the Practice of Pharmacy*, revision February 12, 2014

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

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

B. Delivery to another pharmacy.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b. Procedure for providing counseling;

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

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

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

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

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

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

Issue:

A wholesale distributor requests an allowance to use a combination of security devices which includes some dual motion detectors, door contacts, audible sensors, and security cameras which are monitored in parallel at two independent locations, in lieu of motion detectors fully covering prescription drug storage areas.

Background:

Regulation 18VAC110-50-40 requires the security system device to "fully protect all areas where prescription drugs are stored and shall be reasonably capable of detecting breaking by any means when activated". Additionally, it states the device "shall be a sound, microwave, photoelectric, ultrasonic, or any other generally accepted and suitable device". The Board has historically applied these requirements in a manner to require motion detectors fully covering all prescription drug storage areas and for an entity to monitor the system for a breach. While the Board has not prohibited a facility from installing door contacts, audible sensors, and security cameras, it has never deemed them to satisfy the minimal security requirements for a facility.

Possible Board Action:

- Approve request allowing a combination of security devices

  OR

- Deny request and require installation of motion detectors covering all prescription drug storage areas

from *Regulations Governing Wholesale Distributors, Manufacturers, and Warehousers*, revision August 2, 2013

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

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

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

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

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

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

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

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

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

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

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

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

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

from *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy*, revision August 2014

Section 6. Security.

(a) All facilities used for Wholesale Distribution of Medical Gases or Medical Gas Related Equipment shall be secure from unauthorized entry:
  (1) access from outside the premises shall be kept to a minimum and be well-controlled;
  (2) the outside perimeter of the premises shall be well-lighted; and
  (3) entry into areas where Medical Gas or Medical Gas Related Equipment are held shall be limited to authorized personnel; all facilities shall be equipped with a system to detect or deter entry after hours.

(b) All facilities shall be equipped with a system that will provide suitable protection against theft. When appropriate, the system shall provide protection against theft that is facilitated or hidden by tampering with computers or electronic records.

(c) All facilities shall be equipped with inventory management and control systems that protect against, detect, and document any instances of theft of nitrous oxide.

(d) Where Wholesale Distributors of Medical Gases or Medical Gas Related Equipment use electronic distribution records, they shall employ, train, and document the training of personnel in the proper use of such technology and equipment.

(e) All facilities shall be equipped with security systems to protect the integrity and confidentiality of data and documents and make such data and documents readily available to the Board and other state and federal law enforcement officials.

(f) Vehicles utilized for on-call delivery of Oxygen USP and oxygen related equipment for home care use by home care providers may be parked at a place of residence and shall be locked and equipped with an audible alarm while not attended.

(g) All Wholesale Distributors of Medical Gases or Medical Gas Related Equipment shall maintain records documenting from whom Medical Gases or Medical Gas Related Equipment are received and to whom Medical Gases and/or Medical Gas Related Equipment are distributed with information sufficient to perform a recall of Medical Gases or Medical Gas Related Equipment received and distributed in compliance with 21 CFR 150b, 21 CFR 211.196, and 21 CFR 820.160b.

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NOVEMBER 20, 2014
Fat - the $2 trillion burden on the world's economy

Drug theft goes big

FEATURES PHARMA

Drug theft goes big

by Katherin Eban @FortuneMagazine MARCH 31, 2011, 9:00 AM EST

Organized gangs are stealing prescription medicine in increasingly audacious heists. That's a problem for Big Pharma and for patients, who can unknowingly buy stolen — and sometimes dangerous — medications.

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MENU

PHOTO: ANDREW TINGLE

NOVEMBER 26, 2014

Fat - the $2 trillion burden on the world's economy

Drug theft goes big

FORTUNE — A few years ago a security expert visited Eli Lilly's vast warehouse in Enfield, Conn., one of the pharmaceutical giant's largest distribution facilities, where hundreds of millions of dollars' worth of prescription drugs are stored. The expert was surprised to see the facility lacked a perimeter fence. There wasn't even a $10-an-hour guard stationed outside. But Lilly officials assured the consultant there was nothing to be concerned about. Recalls the expert: "They were very proud to show me. 'We have four-foot-thick walls.'"

He then looked up at the ceiling. "I was like, 'What's up there?'" he says. "There" turned out to be a standard tar roof with no extra reinforcement or fortification. Sometime later, Lilly's security team suggested changes to protect the Enfield warehouse, including installing a fence. But those proposals went unheeded, according to two security experts in a position to know. Bob Reilley, Lilly's chief security officer, says the company had a response in the works. But to listen to him today, it didn't seem that urgent. "That warehouse had been there about 20 years in a nice industrial area," Reilley says, "and was part of the community as well."

Sure enough, Lilly's (▼)LLY-0.37% Enfield warehouse became the site of a headline-making heist — the largest pharmaceuticals theft in history. The burglars struck in the early-morning hours of Easter Sunday last year, as a heavy rain and windstorm knocked down trees and power lines, occupying local police.

Security was so lax that they pulled their tractor-trailer directly up to the loading dock and parked there for hours. Security cameras recorded the image of the truck, but no one was monitoring the cameras. The burglars drilled a hole in the tar roof and slid down ropes into the warehouse. Once inside, they disabled an alarm panel with a sledgehammer.

Another alarm went off at some point during the burglary, say those familiar with the break-in. Staff at ADT, which monitored the system, called the first name listed on Lilly's contact sheet and left a message. By the time a Lilly employee responded, the burglars were gone, along with $75 million worth of cancer, psychiatric, and blood-thinning drugs.

Pharma: The most lucrative target

As Eli Lilly executives reeled, the media played it as a bolt-out-of-the-blue crime committed by high-tech pharma thieves. In fact, it wasn't as unusual as it may have seemed. Only seven months before, a team of burglars — breaking through a warehouse roof in strikingly similar fashion — had made off with $6 million worth of prescription drugs from a GlaxoSmithKline (▲)GSK0.40% facility in Chesterfield, Va.

Indeed, theft of prescription drugs — once the realm of small-time criminals swiping a few bottles here and there — has graduated to the big time: Organized criminal gangs, many of them Cuban-American and operating out of South Florida, according to law enforcement, have dramatically increased both the size and the frequency of their heists.

Drugs account for about 15% of the estimated $8 billion to $12 billion in annual cargo theft, according to FreightWatch International, which advises Fortune 500 companies on supply-chain security. And the value of pilfered drugs has been steadily growing. Last year it rose 15%.

And pharmaceuticals top the list of the most lucrative targets. Of the 54 major pharma thefts that companies reported in 2010, the average value per incident was $3.7 million, according to FreightWatch. The next richest target: tobacco, at $1.4 million an incident.

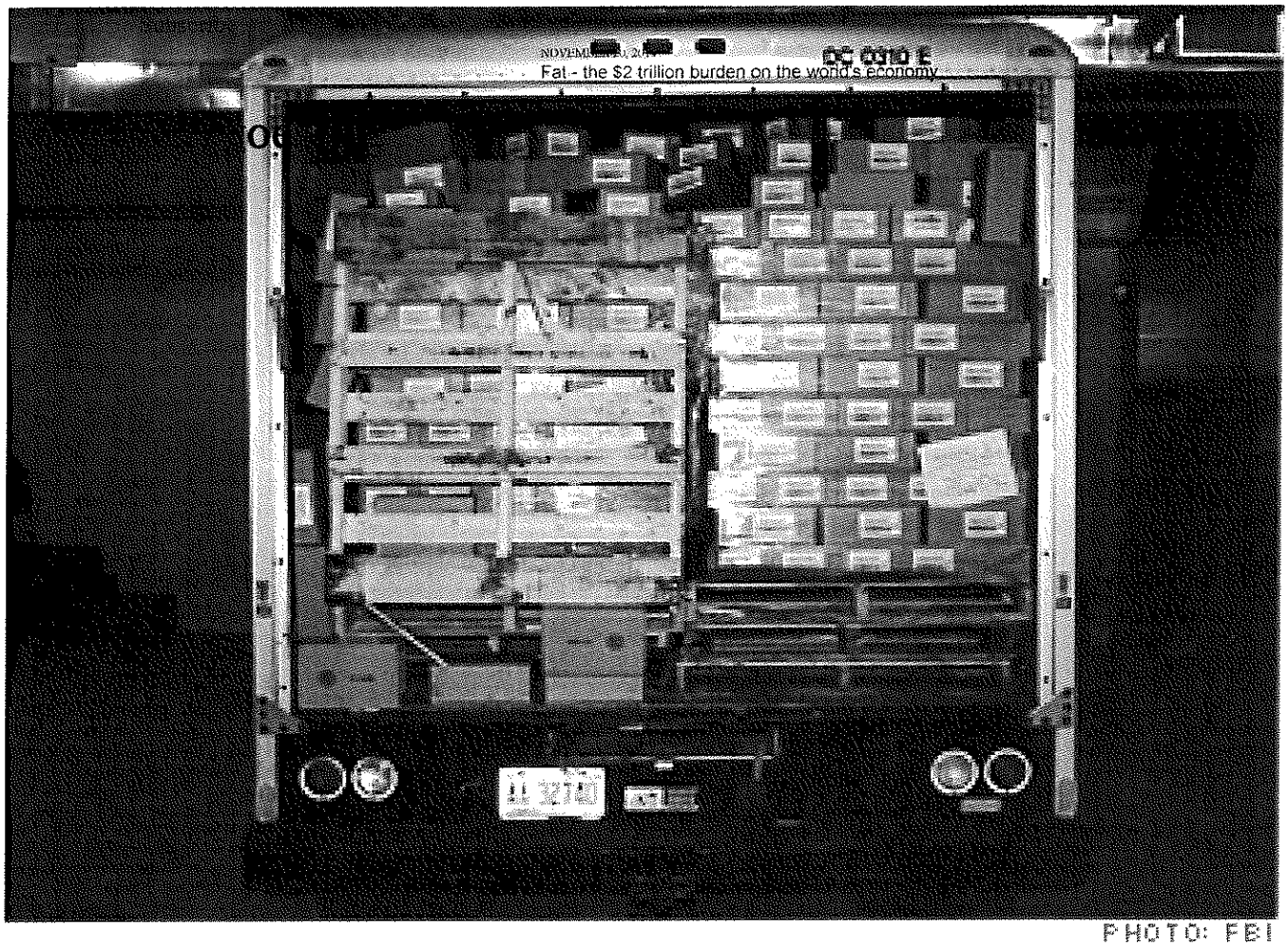

PHOTO: FBI

Unlike cigarettes or cellphones, which thieves often peddle to the black market or abroad, drugs are typically sold back into the supply chain, says the FBI's Tom Hauck, a special agent in an interstate theft task force out of the Newark division: "No one is selling Lipitor on the street." Instead, as we'll see, thieves sell the medicine to corrupt wholesalers and middlemen, and ultimately to pharmacies, where it is dispensed to unwitting consumers. Meanwhile the medicine can lose potency or turn toxic when not stored and shipped properly. Thieves, as you would imagine, ignore such safeguards, subjecting the meds to heat and other forces that can adulterate them.

Incidents in which patients are made sick because of stolen prescription medications bought from legitimate stores are almost never publicized. But Fortune has learned that in 2009, ineffective insulin hijacked from a truck months earlier was dispensed by pharmacies, including Kroger (▲)KR0.30%. One patient in Ohio who took the insulin went into convulsions; another, in Texas, saw his blood sugar spike.

Kroger bought the stolen goods and resold them even after the drug's manufacturer, Novo Nordisk, alerted the giant grocery and pharmacy chain about the theft. Kroger spokesman Brendon Cull declines to comment about the warning, but says,"We work with only safe and reputable organizations." Kroger's suppliers, he adds, must "follow all state and federal laws."

In the past, critics have charged drug companies with being lax. Big Pharma has viewed security as "an area of cost savings," says Patrick Sweeney II, founder of Odin Technologies, a company that specializes in protecting products through radio-frequency identification. "They don't need it to sell, and they have insurance to protect against it."

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But now the industry is showing signs of getting serious. In February five drugmakers — Abbott Laboratories (▲)ABT0.14%, Eli Lilly, GlaxoSmithKline, Johnson & Johnson (▼)JNJ-0.71%, and Novo Nordisk — announced the formation of the Coalition for Patient Safety and Medicine Integrity. They are seeking to amend the law governing cargo theft, which makes little distinction between stealing a load of cigarettes or chemotherapy drugs. The manufacturers want to change the criminal penalties to better reflect the risk to patient safety and give low-level participants more incentive to cooperate with investigators.

Drug theft goes big

Just weeks after the group was formed, on March 8, six U.S. senators proposed a bill that would grant police new investigative powers, including wiretaps, and toughen penalties for drug theft, allowing the use of the Racketeer Influenced and Corrupt Organizations Act (RICO) to prosecute such cases. That would be a start. But for now, it seems, the thieves are still ahead of the law and the drugmakers.

Increasingly sophisticated adversaries

After the high-profile thefts of recent years, some pharma executives acknowledge, if only obliquely, that the industry has not made security a top priority in the past. Says Kevin Donovan, vice president of global security for Johnson & Johnson: "A lot of the assessments made by companies are risk-based analyses. They're saying it's not in a high-risk area."

Lilly's security chief defends his company. There was "not less security than there should have been" at Enfield, Reilley says, adding that the warehouse "did have a sophisticated security system that was compromised in the commission of that burglary." Today Lilly's warehouse has a fence and is bristling with other security enhancements that Reilley says he can't discuss.

Would better security have changed the outcome? "Even with extraordinary measures in place, these things can happen," says Mark Geraci, chief security officer for Purdue Pharma. He adds, "With all the security measures, banks still get robbed — and they get robbed a lot."

Indeed, pharma faces sophisticated adversaries. The groups involved in bigtime theft are disciplined, prepare diligently, and clam up when caught. They are planners — with backgrounds in logistics, trucking, and construction — who patiently case warehouses, shadow truck stops, and detect security weaknesses.

In March 2009 burglars broke into a warehouse that stored Bayer products in Olive Branch, Miss. They severed alarm wires, sprayed the lenses of surveillance cameras black, and took the closed-circuit recording discs. They cut a hole in the exterior fence in case they needed an emergency exit. Then they helped themselves to $3 million worth of drugs.

At the GlaxoSmithKline warehouse in Chesterfield, burglars broke through the roof, climbed down a trapeze-style rigging, and hung from it as they disabled the primary and secondary alarm systems. The perpetrator, say two sources familiar with the investigation, exploited wiring shortcuts known to few within the company. Once inside, the burglars stayed for hours, loading two tractor-trailers with $6 million in drugs.

For all their precision, the thieves made two mistakes. Before they disabled the surveillance camera, it captured a grainy image of one of them. An informant identified the man as a 48-year-old Miami Cuban, a convicted burglar and electrician. The man was arrested but then released for lack of evidence. He has since been deported to Cuba, according to Immigration and Customs Enforcement records. The second mistake: One of the burglars left behind a coffee cup.

The FBI's top pharma-theft cop

With his bald head, black sunglasses, and chiseled features, Tom Hauck looks like a G-man — the fearsome sort you'd see in an action movie. Despite his forbidding appearance, he is low-key, amiable, and modest to a fault. A 39-year-old former Marine and ex-manufacturing manager at Frito-Lay, Hauck has become one of the FBI's top experts in pharma theft, learning to track the circuitous progress of pilfered drugs as they leave, and then return to, the supply chain.

Drug theft goes big

Here's how the system is supposed to work: Most medicines are sold by drugmakers to authorized distributors like AmerisourceBergen ( )ABC-0.53%, one of the country's largest, and then to pharmacies. A minority are sold through regional distributors that may specialize in certain types of drugs or supply particular treatment centers.

Then there's a subset of the business, which Hauck discovered when he first began investigating the problem of drug theft a decade ago: a coterie of secondary wholesalers and repackagers that also resell drugs, typically far below wholesale prices. These middlemen, he says, often employ a flimsy cover story backed by forged documents. The drugs they buy and sell often have an illegitimate origin.

Hauck decided that if he wanted to find thieves, the FBI would need to become a middleman. "When you're reacting [to the theft], you're already behind the power curve," says Hauck (who declines to discuss current investigations). "We wanted these guys coming to us, not us chasing them." He set the FBI up as a wholesaler called Pills Plus Inc. His allies at pharma companies became silent partners, testing the drugs he was buying for authenticity. Hauck found stolen, unapproved, illegally imported, expired, and counterfeit drugs in the marketplace. The two-year investigation, which ended in 2004, was called "Operation Pill Collector." It uncovered $100 million in illicit sales and resulted in 60 convictions.

It was a dramatic case. But, experts say, the problem has only gotten worse. It has left Hauck and his team trying to burrow inside the sleazy business to stop it from within.

From heist to pharmacists

So how do lifted drugs end up at your local pharmacy? Fortune has reconstructed one such episode through court records, adverse-event reports to the FDA, and extensive interviews. This one began on Feb. 5, 2009, when $10.9 million worth of Novo Nordisk pharmaceuticals were stolen from a tractor-trailer in Conover, N.C. The haul included almost 128,000 vials of Levemir, a long-acting insulin that requires constant refrigeration to preserve its potency.

Novo Nordisk immediately notified law enforcement and the FDA about the theft. Then, on Feb. 17, it FedExed a letter to all its authorized distributors and retail pharmacies, including Kroger, alerting them that three lots of Levemir had been taken, were unsafe, and should not be sold. It urged the companies to alert it should the drugs surface.

On Feb. 10, five days after the theft, at least 33,000 vials of the Levemir arrived at a licensed wholesaler called Ocean Pharmed in Irmo, S.C., according to an FDA investigator's affidavit. One employee told investigators that he was summoned to the warehouse there after midnight to help unload 46 pallets of Levemir.

Ocean Pharmed quickly resold the drugs to another wholesaler, Altec Medical, in Easley, S.C., for about half the typical wholesale price. Such a huge discount usually means that the drugs come from an illegal source, the FDA affidavit states. Lawyers for Altec, which has since had its license suspended (state authorities will not say why), and Ocean Pharmed, whose license has expired and whose second-in-command pleaded guilty to unlicensed distribution of prescription drugs in another case, declined to comment.

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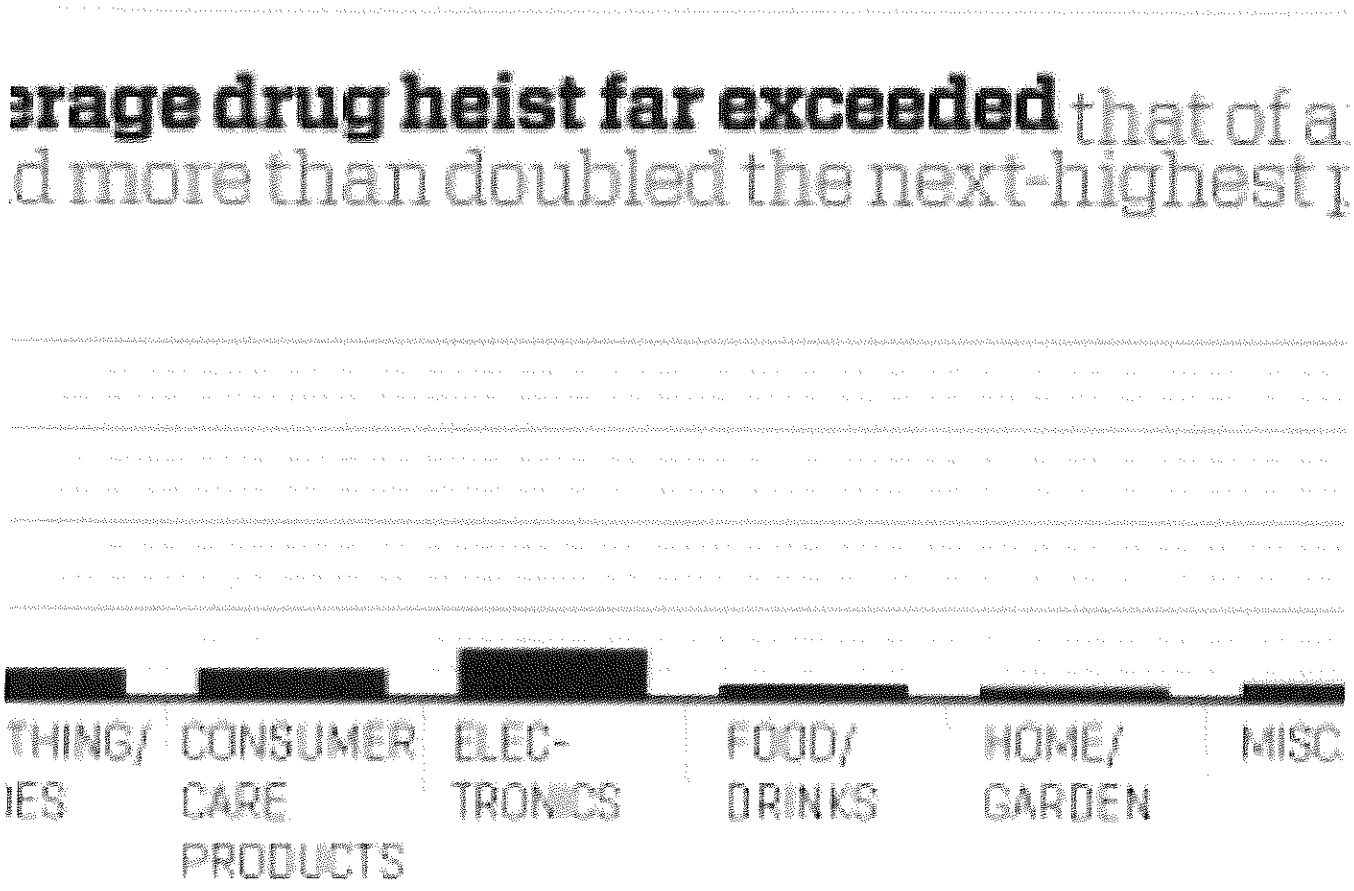
Altec then sold Kmart 9,500 vials of the Levemir to HealthSource Distributors, a licensed wholesaler in Baltimore that had previously paid Johnson & Johnson $600,000 to settle a suit claiming it and other distributors traded in counterfeit J&J glucose test strips. HealthSource maintained it made reasonable efforts to verify the origins of the test strips. "A pawnshop does more due diligence," counters attorney Geoffrey Potter, a partner at Patterson Belknap Webb & Tyler, which represented J&J in that case.

Drug theft goes big

When HealthSource bought the Levemir, it came with a "pedigree" documenting its origin, as required by federal rules. But the pedigree was phony, according to the FDA affidavit. It falsely claimed the drugs were originally sold by Amerisource. Any experienced person, experts say, would know that a price far below wholesale is a red flag not to rely on the pedigree –the company would need to do some homework of its own. But Amerisource says nobody checked with it.



Kroger then bought the Levemir from HealthSource -- despite the fact that Novo Nordisk had sent a warning. Almost immediately, people who purchased stolen Levemir from Kroger or other pharmacies had adverse reactions.

On May 13, 2009, at the M.D. Anderson Cancer Center in Houston, Dr. John Patlan saw a patient whose diabetes had been exacerbated by his cancer treatment. Patlan switched him to Levemir, which the patient purchased at an outside pharmacy. Levemir is supposed to lower blood sugar. But this patient's levels spiked uncontrollably. "It was striking," says Patlan. "It didn't seem to make any sense at all." Patlan contacted a hospital pharmacist, who reported the ineffective insulin to both the FDA and Novo Nordisk on June 4. (The patient recovered but later died from cancer-related causes.)

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A week later Kroger notified Novo Nordisk that some of the stolen Levemir was on its shelves in Texas, Georgia, and Kentucky. The next day the drugmaker and the FDA put out nationwide alerts, warning patients that the hijacked insulin had resurfaced. Kroger removed the affected lots from its stores. Two months after that, more reports of adverse health effects linked to stolen Levemir rolled in, and the FDA sent out new alerts. To date, only 2% of the insulin has been recovered, says a Novo Nordisk spokesman.

Fat - the $2 trillion burden on the world's economy

Drug theft goes big

To FDA officials, the Levemir case is highly significant. "That was the first incident in which we could directly link stolen products" to adverse events, says Dr. Ilisa Bernstein, deputy director of compliance in the FDA's center for drug evaluation and research. Fortune has learned that federal prosecutors in Florida are conducting a criminal investigation into the drug's theft and resale.

In March 2010, FDA investigators searched HealthSource's offices in a different case, taking files on Levemir, Kroger, and Altec, according to an inventory of items seized. Benjamin Martin, a lawyer for HealthSource, says HealthSource "fulfills its obligation" to protect the integrity of the drugs it sells and complies with all laws. He also asserts, "There is nothing that gives me any reason to believe that there is any open investigation targeting my client HealthSource Distributors."

In August the FDA found a second stolen drug on Kroger's shelves. The drug, an antiseizure medication, was also purchased from HealthSource (before the Levemir episode, according to Kroger spokesman Cull). After the Levemir incident, Kroger stopped buying from HealthSource for "many months," says Cull, until it was reassured that HealthSource had "the practices in place to make sure this didn't happen again." The buying relationship has since resumed.

A real solution

Despite the need to track drugs to prevent harm to patients, the best minds in pharma can't seem to agree on how to make it happen. United Parcel Service (▲)UPS0.92% knows where every package is at every second. Electronics manufacturers put a unique serial number on every cellphone and TV. But such a system for authenticating drugs appears to be years away.

This leaves companies to track drugs by lot number, a blunt and inadequate tool since lots (a nonstandard measurement that can encompass many thousands of pills) are rarely stolen in their entirety. Unless a drugmaker recalls the entire lot, it has no way to distinguish with certainty the drugs that are stolen and dangerous from the pristine ones already sold.

The result: Companies resist lot-wide recalls when only a portion has been lifted. "If you lose one trailer load [to theft], now you lose four trailer loads under that lot number," says Ed Petow, FreightWatch's law enforcement liaison. Eli Lilly, after the $75 million theft, stopped distributing any remaining drugs that had the same lot number as those taken in the burglary. But it did not issue recalls. If the stolen medicine had started to enter the supply chain, says Lilly's Reilley, "I think we would have gotten an indication."

Perhaps. Most experts agree that the best way to keep stolen, diverted, or counterfeit drugs out of the supply chain is to require an electronic pedigree, or audit trail, for each medication as it moves through the system. That way drugs of dubious origin will draw immediate suspicion. With no federal standard, California passed a law in 2008 that would have required it by 2009. The industry backlash, claiming high costs and difficult logistics, was so great that full implementation was deferred until 2017.

At the same time, the FDA's powers seem feeble. It can't compel drug companies to issue recalls after thefts, or even to report or publicize thefts in the first place. Still, the Levemir theft and the Lilly heist seem to have galvanized the industry and the FDA. Since last year, the FDA has standardized its response to cargo theft and set up a web page to alert consumers to purloined drugs. At the FDA's urging, companies are increasingly announcing thefts, hoping to brand the drugs as hot and make them harder to resell.

That's what Lilly did after the Enfield burglary, and so far that seems to have worked. The stolen drugs have yet to reappear. Industry experts with knowledge of the case suspect that the burglars can't, or won't, try to sell them for fear of being caught, and that the medicine is likely holed up in a Miami warehouse. If the thieves do have interested buyers, they must vet them to see if they are actually agents of undercover law enforcement like the FBI's Hauck fishing for product. Due diligence works both ways.

Drug theft goes big

Meanwhile, as the investigation into the burglary at Lilly's Enfield warehouse continues, the crime scene has yielded a clue: DNA found there matches that found on the coffee cup at the GSK warehouse, suggesting that at least one thief was involved in both burglaries. The genetic material points to a prolific convicted burglar — a fugitive Miami Cuban, according to sources familiar with the investigation.

But catching the man or his cohorts won't be enough to solve the problem. As long as there are middlemen and pharmacies hungry for unlikely bargains, theft — and the chances of taking a dangerous drug — will only increase.

Also from Fortune:

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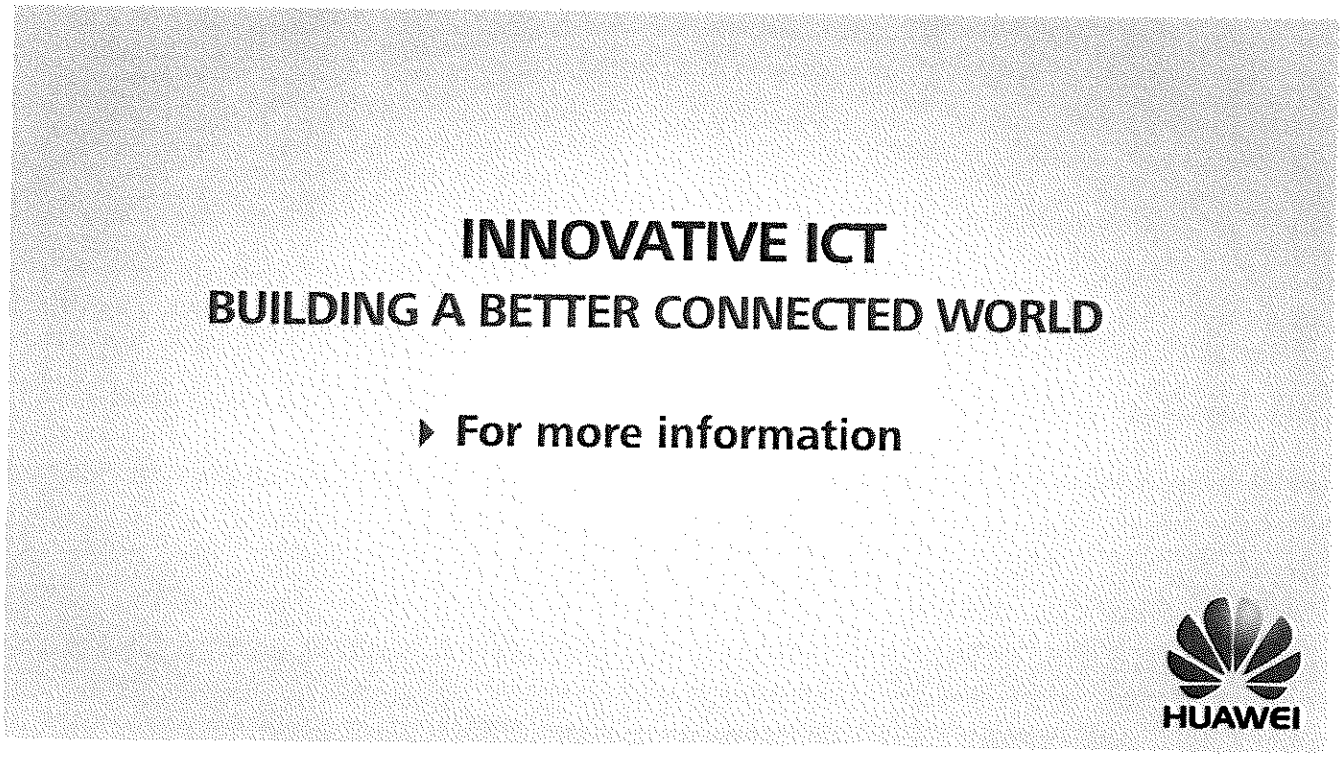

Virginia Board of Pharmacy

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.

An "opening" inspection report indicating compliance with the requirements of statute, including compliance with USP-NF standards for pharmacies performing sterile and non-sterile compounding, may satisfy the requirements for obtaining initial registration as a nonresident pharmacy. However, an "operational" inspection report shall be provided during the subsequent renewal of the registration.

Appendix __ Directed Risk Area Topic Screening Tool:
Sterile Compounding Pharmacies

Topic Area: Sterile Compounding Program: Home Care/Pharmacy
Part I: Directed Risk Area Topic Screening Checklist

Verify if pharmacy does sterile compounding. **If yes:** Integrate risk assessment activities into present survey process. Comments should be noted in the record review or tracer screen as appropriate and scored at the appropriate standard/EP as needed.

___Information to review during pharmacy tour:

- ___Discuss the medications/infusions that the pharmacy compounds (to validate low, medium, high risk compounding)
- ___Notify the organization that you will be observing the actual compounding process (and applicable policies as needed); the surveyor should enter the clean room to observe, unless there is an **unrestricted** view through an accessible window. This observation can occur as part of your patient tracer process or pharmacy tour.
- ___Request a list of compounding staff; notify the organization that you will review HR records for some of these staff members focusing on competency (see "Competency" section)
- ___Request the clean room monitoring records (either hard copy or electronic) for at least the last 12 months, in order to review the organization's monitoring of the compounding process. At a minimum, must see: (EQ.02.01.01, IC.02.02.01)
  1. Report from current clean room certification (hoods, room, etc.) and certification reports from last 36 months (EQ.02.01.01)
  2. Have a discussion with responsible pharmacist including what time of day certification was conducted and whether the certifier reviewed the results of the certification report with this individual. (EQ.02.01.01)
  3. Frequency of hood certification process (per policy and state regulations) (EQ.02.01.01)
  4. Organization's daily, weekly, monthly cleaning requirements and validation that these requirements were completed (per policy and state regulations) (IC.02.02.01)
- ___Verify that leaders analyze and respond to the data collected regarding the monitoring of the clean room (MM.08.01.01, PI.02.01.01)
- ___Review all pharmacy facility licenses as required by law (include all non-resident licenses) (LD.04.01.01)
- ___Review most recent Pharmacy Board report (if the Board was onsite in last 3 years) (APR.05.01.01 if refusal to share)
- ___Verify that the pharmacy staff has access to current reference materials (check for quality of information and current edition; maybe paper or electronic) (IM.03.01.01)

___**Patient tracer activity** utilizing a patient that is has orders for a compounded medication/infusion, with emphasis on the 5 identified compounding process focus areas on the Compounding Risk Assessment Checklist (Environment, Competency, Products, Performance Improvement, and Leadership); survey against organization's policies and state regulations.

- Interview staff about the scope and nature of pharmacy services they provide and how they were oriented to the organization's processes (HR.01.04.01)
- Observe the dispensing process from reception of physician order, through the entire compounding process, including the 5 identified topic areas below, and complete checklist:

➢ **Environment**

Facilities: ___Review clean room monitoring reports (IC.02.01.01, EP1 (surveillance), MM.05.01.07, EP2 (proper technique)
___Review hood certification reports (EQ.02.01.01)
___Review policy on refrigerator temperature ranges/checks (MM.03.01.01)
___Check documentation of temperature checks in refrigerators and storage areas (MM.03.01.01)

Hand washing, gowning and gloving: ___Review policy/process ___Observe staff (MM.05.01.07, IC.02.01.01)

Equipment:
-Auto-dispenser *(e. g., Baxa Pump)*: ___Pharmacist oversight of calibration process/documentation (EQ.02.01.01, EP4)
-Compounder *(TPN)*: ___Pharmacist oversight of calibration process/documentation (EQ.02.01.01, EP4)
-Other equipment: _____ (EQ.02.01.01)

PI/Quality control/Monitoring of clean room, cleansing and sanitizing:
___Review of plan/process ___Review documentation of data collected (hard copy or electronic)
(Plan-PI.01.01.01; Process-PI.02.01.01)

➢ **Products**

Product selection: ___Inquire about ordering process and staff responsibilities (MM.02.01.01)
Storage: ___Review drug storage areas, specific to temperature ranges, security, etc. (MM.03.01.01)
Sterility: ___Observe compounding process (maintaining aseptic technique throughout process) (MM.05.01.07, EP2)

- **Products (cont'd.)**

  Labeling: ___Observe labeling process, information on labels (MM.05.01.09)

  Product testing: ___If organization does this due to state law, discuss their policy/process (LD.04.01.01, EP2)

  Packing and shipping methods: ___Review policy (if available)/process for packing medications, related to maintaining medications in acceptable temperature ranges (MM.03.01.01, MM.05.01.11)

  Extended dating: ___If organization does this, discuss their policy and process (MM.05.01.09, EP5)

  Beyond use dating: ___If organization does this, ask why and for what products, and what resources are used to support extending dates (e.g., documented research findings, either from their own organization or in the literature) (MM.05.01.09, EP5)

  Documentation: ___Review all pharmacy records, including the compounding record(s) (MM.05.01.11)
  ___Verify documentation is complete and compliant with organization policy, law, and regulation (MM.05.01.11)

  Drug recalls: ___Review organization's policy (in accordance with state law) (MM.05.01.17)
  ___Interview staff to determine knowledge (HR.01.04.01, HR.01.06.01)

  Drug expiration and disposal
  (e.g., quarantine process): ___Review organization's policy (MM.03.01.01, EP8)
  ___Interview staff to determine knowledge (HR.01.04.01, HR.01.06.01)

  Controlled substances: At a minimum, review the following items:
  ___Generated DEA form #222 (LD.04.01.01, EP2) ___POA (MM.05.01.11) ___Storage (MM.03.01.01, EP3)
  ___Perpetual inventory (MM.05.01.11, EP2) ___Destruction/disposal process (MM.03.01.01, EP8)
  ___Observation of non-sterile to sterile compounding of narcotic infusion (if available)

  High risk/hazardous medications: ___Review/observe compounding process as available (MM.05.01.07)
  ___Review list and process (MM.01.01.03)

- **Competency**

  ___Review responsibilities of compounding staff (e.g., job descriptions) (HR.01.02.01)
  ___Review personnel training and competency policy/plan (HR.01.04.01, HR.01.05.03, HR.01.06.01)
  ___Review competency requirements for compounding staff (e.g., continuing education, exams, etc.) (HR.01.06.01, HR.01.05.03)
  ___Validate process for evaluation of compounding staff's aseptic skills (e.g., media fills, finger-tip testing, hand hygiene, garbing) (HR.01.06.01)
  ___Review documentation that validates direct observation of staff competency of aseptic skills (may be in HR files or in clean room binder/records) (HR.01.06.01)

- **Leadership** (during leadership session or during individual tracer or data session) (LD.04.01.05, EP1 for all)

  ___Interview organizational leaders about their oversight process for pharmacy compounding
  ___Ask leaders how they decide which items/issues they will monitor (establish priorities)
  ___Verify that leaders monitor compounding process
  ___Verify leaders take steps to improve the compounding process if it does not meet expectations

- **PI**

  ___Review pharmacy PI Plan as it applies to compounding pharmacy (if the organization is monitoring criteria specific to sterile compounding, do a focused review) (PI.01.01.01)
  ___Data is monitored and timely actions are taken in response to trends – data monitored at least annually (PI.02.01.01)

If initial review indicates compliance – STOP. There is no need to pursue additional review.

WST(*Future State*) – Check off Directed Risk Area Evaluated – YES

PART II: If the severity and or frequency of issues identified through the Directed Risk Area Topic Screening Checklist drives the need for further exploration, continue with the Second Generation tracer activities which may include:

- Additional patient tracer activity
- Additional HR file review
- Verify education, orientation and competency process for pharmacy compounding staff

WST – Check off Second Generation if Directed Risk Assessment drives the need for further exploration. Observations should be noted in the record review or tracer screen as appropriate and scored at the appropriate standard/EP as needed.

NOTES: (optional)

from *The Pharmacy Act*, revision July 1, 2014

§ 54.1-3321. Registration of pharmacy technicians.

A. No person shall perform the duties of a pharmacy technician without first being registered as a pharmacy technician with the Board. Upon being registered with the Board as a pharmacy technician, the following tasks may be performed:

1. The entry of prescription information and drug history into a data system or other record keeping system;

2. The preparation of prescription labels or patient information;

3. The removal of the drug to be dispensed from inventory;

4. The counting, measuring, or compounding of the drug to be dispensed;

5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;

7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and

8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

B. To be registered as a pharmacy technician, a person shall submit satisfactory evidence that he is of good moral character and has satisfactorily completed a training program and examination that meet the criteria approved by the Board in regulation or that he holds current certification from the Pharmacy Technician Certification Board.

C. A pharmacy intern may perform the duties set forth for pharmacy technicians in subsection A when registered with the Board for the purpose of gaining the practical experience required to apply for licensure as a pharmacist.

D. In addition, a person enrolled in an approved training program for pharmacy technicians may engage in the acts set forth in subsection A for the purpose of obtaining practical experience required for registration as a pharmacy technician, so long as such activities are directly monitored by a supervising pharmacist.

E. The Board shall promulgate regulations establishing requirements for evidence of continued competency as a condition of renewal of a registration as a pharmacy technician.

F. The Board shall waive the initial registration fee and the first examination fee for the Board-approved examination for a pharmacy technician applicant who works as a pharmacy technician exclusively in a free clinic pharmacy. If such applicant fails the examination, he shall be responsible for any subsequent fees to retake the examination. A person registered pursuant to this subsection shall be issued a limited-use registration. A pharmacy technician with a limited-use registration shall not perform pharmacy technician tasks in any setting other than a free clinic pharmacy. The Board shall also waive renewal fees for such limited-use registrations. A pharmacy technician with a limited-use registration may convert to an unlimited registration by paying the current renewal fee.

Issue:

Consider amending Guidance Document 110-34 to require wholesale distributors and manufacturers which hold New Drug Applications or Abbreviated New Drug Applications to obtain licensure as a wholesale distributor, manufacturer, or nonresident wholesale distributor regardless of whether they physically possess the drug. As holder of NDA or ANDA, it is argued they control the direction of the distribution.

Background:

- Relevant current laws
- Excerpt from 3/29/07 minutes regarding draft guidance document related to nonresident entities involved in manufacturing and distribution
- Draft amendments to guidance document prepared by staff
- Staff has received inquiries from New York and Delaware Boards of Pharmacy encouraging Virginia board to license these entities
- Increased momentum to license these entities in recent years
- Passing of Title II of the Drug Quality and Security Act may mitigate the 2007 concerns with Florida's pedigree requirements

Board Action:

- Adopt guidance document as presented, OR
- Adopt guidance document as amended, OR
- Take no action

from *The Drug Control Act*, revision July 1, 2014

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

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

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

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

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

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

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

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

§ 54.1-3437. Permit to manufacture drugs.

It shall be lawful to manufacture, make, produce, pack, package, repackage, relabel or prepare any drug not controlled by Schedule I after first obtaining the appropriate permit from the Board. Such permits shall be subject to the Board's regulations on sanitation, equipment, and safeguards against diversion. This provision shall not apply to manufacturers or packers of medicated feeds who manufacture or package no other drugs.

§54.1-3401

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

"Manufacturer" means every person who manufactures.

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

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

prescriber of an authorized agent as defined in § 54.1-3408.01 C of the Code of Virginia for transmission of oral prescriptions directly to the dispensing pharmacy. For electronic transmission of Schedule II-V prescriptions, transmissions shall comply with any security or other requirements of federal law. All electronic transmissions shall also comply with all security requirements of state law related to privacy of protected health information."

AMENDMENT OF GUIDANCE DOCUMENT 110-35 TO ADD CHART ORDER USE IN OUTPATIENT PHARMACIES:

In follow-up from the January 31, 2007 meeting, Ms. Russell reviewed draft Guidance Document 110-35, as included in the agenda, with amendments to provide direction related to chart orders being filled by community pharmacies for outpatient or discharge medications. Ms. Yeatts was concerned about placement of the new language and suggested to make a separate section concerning chart orders instead of keeping them in a bullet mark under written prescriptions, which could have the potential to cause confusion. It was agreed that this information should be in a second bullet. Additionally, there was discussion that the use of the term "enough" that was used to modify "information" and "direction" in the second and third bullets of the new language was subjective, therefore, it would be changed to "all information necessary to constitute a valid prescription" in the second bullet and just "direction" in the second bullet. Ms. Abernathy moved and the Board voted unanimously to adopt amendments to Guidance Document 110-35 as presented in the agenda and amended as described above.

DRAFT GUIDANCE DOCUMENT RELATED TO NON-RESIDENT ENTITIES INVOLED IN THE MANUFACTURING AND DISTRIBUTION OF A PRESCRIPTIO DRUG, BUT THAT DO NOT PHYSICALLY POSSESS OR DISTRIBUTE INTO VIRGINIA:

Ms. Russell reviewed a draft guidance document included in the agenda concerning non-resident wholesale distributor inquiries regarding registration with the Board as a non-resident wholesale distributor. Ms. Russell stated that Board staff has received numerous requests to write individual letters to various out-of-state entities advising that if they do not physically possess or distribute any prescription drugs into Virginia, they do not have to be registered with the Board. Ms. Russell advised the Board that these questions may have to do with the Florida pedigree requirements, but the Board staff does not have the time to respond to these individual requests. Further, staff is uncomfortable writing such a response because these entities are not registered with the Board, and staff is relying on a few statements presented by representatives from that particular entity to write a letter telling them they do not have to be licensed. In many cases, staff will receive two separate requests, one from the manufacturer or wholesaler and the second from their legal representative. Ms. Russell advised the Board that the draft guidance document could be scanned on the agency letterhead and posted to the Board of Pharmacy website. Staff would then refer the entities to the website upon receiving requests. Ms. Russell advised that the

draft guidance document may need to be amended in the future pending different scenarios. Mr. Brown moved and the Board voted unanimously to adopt the new guidance document.

REQUEST BY JOE LEMING, M.D., FOR GUIDANCE DOCUMENT THAT ADDRESSES SUBSTITUTION OF ALBUTEROL CFC INAHLERS WITH HFA INHALERS:

Ms. Russell reviewed the draft guidance document included in the agenda regarding HFA inhalers being substituted for albuterol CFC inhalers. The guidance document was a result of a request from Joe Leming, M.D., for the Board to allow pharmacists to substitute the HFA formulation on prescriptions where the CFC formulation had been previously dispensed but was no longer available. The Board agreed that if the prescription was not specifically written for albuterol and not albuterol "CFC", then substitution would not be prohibited. Mr. Stredler moved and the Board voted unanimously to adopt the new guidance document on this subject. There was a question about the accuracy of a deadline date contained within the guidance document. Staff agreed to check the date and amend it if needed before posting the document.

EXCPT EXAM; REQUEST TO BE A BOARD APPROVED EXAMINATION FOR PHARMACY TECHNICIAN REGISTRATION

Ms. Russell discussed the background and history of Ken Shafermeyer's request to have the ExCPT examination be another Board approved examination for pharmacy technicians. At their January 31, 2007, meeting, the examination committee reviewed documents presented by Ken Schafermeyer. The minutes of that meeting reflect that there was still some concern by the committee as to whether the examination met the American Psychological Association (APA) standards for testing, which is required in the Board regulations. Ms. Russell presented an audit letter from Dana P. Hammer, Director of Bracken Pharmaceutical Care Learning Center and Teaching Certificate Program in Pharmacy Education, that was intended to be an analysis of the ExCPT examination, but was actually an analysis of the Virginia exam. Ms. Hammer stated that the ExCPT exam uses the National Commission for Certifying Agencies (NCCA) standards as a guide. Ms. Russell explained that NCCA standards incorporate APA standards and would meet the requirements in the regulations; however, the ExCPT has not been accredited by NCCA. Mr. Schafermeyer stated that they are taking steps in that direction, but that a certification program cannot receive accreditation until it has been in existence for at least two years. Several Board members expressed concern about having a second Board-approved examination in that it may cause confusion since the ExCPT exam was developed by and is offered by the same person who has the contract for the Virginia Exam. There was also a concern that pharmacy technicians may get confused and take the ExCPT exam and pay more money than they need to pay to be registered. The Virginia Exam is a one hour exam costing $65 versus the ExCPT exam, which is a two hour exam costing

Guidance Document: 110-34 **Revised: ~~3/9/11~~ 12/9/14**

Virginia Board of Pharmacy

Wholesale Distributor Licensure Guidance

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

The holder of a New Drug Application or Abbreviated New Drug Application, regardless of whether it physically receives, stores or ships prescription drug must obtain a non-restricted manufacturer permit or nonresident wholesale distributor registration, whichever is applicable, prior to engaging in business in Virginia.

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

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

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

Report of the Workgroup on Compounding Drugs

I. Introduction.

This report summarizes the actions taken by a workgroup convened by the Board of Pharmacy pursuant to the enactment clause of Chapter 147 (HB1035) of the 2014 Acts of the Assembly. The charge to the workgroup was to explore and clarify issues related to the compounding of drugs for human and animal use. The 12-member workgroup included representation from the Boards of Pharmacy, Medicine, and Veterinary Medicine, the Virginia Pharmacists Association, the Virginia Society of Health System Pharmacists, the Virginia Veterinary Medicine Association, the Virginia Society of Eye Physicians and Surgeons, a practicing hospital pharmacist who participated at the request of the Board chairman, and a member of the 2010-2015 United States Pharmacopeia (USP) Compounding Expert Committee. Jody H. Allen, PharmD, Board of Pharmacy member presided over the workgroup. The workgroup met for approximately nine hours over two meetings held on July 31, 2014 and August 26, 2014.

Board staff solicited feedback for agenda topics from the workgroup members prior to the first meeting and received several suggestions. During the first meeting, the workgroup had in-depth discussions on the agenda topics which were divided into the following subtopics: compounding performed in pharmacies; compounding performed in physician offices; compounding performed in outsourcing facilities; and miscellaneous topics. During the discussions, state and federal law, board regulations, board guidance, and current and proposed USP chapters were taken into consideration.

II. Discussion on Compounding Performed in Pharmacies.

Through consensus the workgroup recommended that the Board of Pharmacy consider amending Guidance Document 110-36 on *Compounding for Compliance with USP Standards* by:

- Revising the response to question #23 to advise that surface sampling should be performed at least quarterly;

- Including additional guidance regarding personnel competency by referencing the training and educational requirements in USP Chapter <797> and the requirement for a site-specific training program in Regulation 18VAC110-20-111;
- Adding guidance indicating the repackaging of undiluted multi-dose vials (e.g., insulin) into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times (Note: this guidance addresses repackaging, not administration);
- Including the following guidance for the beyond use date (BUD) for a single dose vial:
    - a single dose vial punctured outside of an ISO class 5 environment shall not exceed 1 hour, unless specified otherwise by the manufacturer;
    - a single dose vial punctured and stored in an ISO class 5 environment shall not exceed 6 hours;
    - a punctured single dose vial that is removed from the ISO class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO class 5 environment or the originally assigned BUD of 6 hours within the ISO class 5 environment, whichever is shorter (reference the Center for Disease Control (CDC) and USP Appendix);
    - a closed system transfer device (CSTD) cannot be used to extend the BUD of a single-dose vial to exceed the 1 hour BUD when punctured outside of an ISO Class 5 environment or 6 hour BUD when punctured within and not removed from an ISO Class 5 environment.
- Providing guidance that sterile and non-sterile drug stability is formulation-specific and that stability information may only be used when the drug has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source;
- Providing guidance that stability could be estimated for an aqueous or non-aqueous compound under the following conditions:
    - stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in-between could be estimated;
    - stability is not concentration-dependent; and,

- the drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.

- Providing guidance for the assignment of BUDs that stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgment of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>;
- Clarifying that nasal sprays and nasal irrigations may be prepared as a non-sterile compound while nasal inhalations for the lungs shall be prepared as a sterile compound; and,
- Removing reference to USP Chapter <51> from question #2, repeal question #25, and provide a reason for the repeal using the following explanation from USP: currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for testing, labeling, and container closures for compounded multiple-dose containers; and, that Chapter <797> references Chapter <51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer.

Additionally, the workgroup briefly discussed the differences in federal oversight for compounding for animals versus humans and the recent allowance in state law for pharmacists to provide a veterinarian a supply of compounded drug to dispense to his clients under limited circumstances. If there is a need for clarity in interpretation of the statute, the Board of Pharmacy, in conjunction with the Board of Veterinary Medicine, should consider adopting guidance on the subject.

III. Discussion on Compounding Performed in Physician Offices.

There was discussion regarding the existence of differences in requirements for mixing, diluting and reconstituting under Board of Medicine regulations and USP standards as required in law for compounding. The work group was advised that the Board of Medicine Legislative Committee

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. ***Are there specific educational and training requirements regarding personnel?***

   Yes. In USP chapter <797>, compounding personnel are required to be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties: perform aseptic hand cleansing and disinfection of nonsterile

compounding surfaces; select and apropriately don protective garb; maintain or achieve sterility of compounded sterile products in ISO class 5 environments; identify, weigh, and measure ingredients; manipulate sterile products aseptically; sterilize high-risk level compounded sterile products and label; and, inspect the quality of compounded sterile products. Personnel must also sucessfully complete a site-specific training program as required in Regulation 18VAC110-20-111.

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. ***What BUD must be assigned to a single dose vial used in preparing a compounded sterile product?***

- If the single dose vial is punctured outside of an ISO Class 5 environment, the assigned BUD shall not exceed 1 hour, unless specified otherwise by the manufacturer;
- If the single dose vial is puntured within and stored within an ISO Class 5 environment, the assigned BUD shall not exceed 6 hours;
- A puntured single dose vial that is removed from the ISO Class 5 environment such as for final verification purposes shall not exceed 1 hour from being removed from the ISO Class 5 environment or the originally assigned BUD of 6 hours within the ISO Class 5 environment, whichever is shorter (reference the Center For Disease Control (CDC) and USP Appendix);
- A closed system transfer device (CSTD) cannot be used to extend the BUD of a single dose vial to exceed the 1 hour assigned BUD when punctured outside of an ISO Class 5 environment or the 6 hour assigned BUD when puntured within and not removed from an ISO Class 5 environment.

5. ***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.

6. ***How may stability information be taken into consideration when assigning a BUD?***

Stability information for multiple drugs may be considered when combining the drugs in a compound, assuming the shortest BUD is used to assign stability to the compound. Peer-review or reference source literature shall be consulted and the professional judgement of the pharmacist exercised when assigning the BUD of a compound containing multiple drugs. Any extended BUD must also comply with the applicable USP Chapter <795> or <797>.

7. ***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 and note that sterile and non-sterile drug stability is formulation specific. Existing stability information may only be used when the compound has been prepared using the same formulation (USP-NF equivalent ingredients) as used in either at least one peer-reviewed article or other reliable reference source. ~~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.

Additionally, stability may be estimated for an aqueous or non-aqueous compound under the following conditions:

- Stability information exists in peer-reviewed articles or reference sources indicating stability at a low concentration and high concentration and therefore, stability for concentrations in-between could be estimated;
- Stability of the drug is not concentration-dependent; and,
- The drug is compounded using the same formulation (USP-NF equivalent ingredients) as used in the peer-reviewed articles or reference sources.

8. ***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

9. ***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.

10. ***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.

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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

21. 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.

22. 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.

23. 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.

24. 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.

25. 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 quarterly ~~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.

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

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 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".

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

28. ~~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.~~ Currently USP Chapter <797> does not contain specific requirements for compounding multiple-dose containers, such as the need for a preservative, nor requirements for

testing, labeling, and container closures for compounded multiple-dose containers. Chapter <797> references Chapter <51> for informational purposes as the source of the 28-day BUD after initially entering or opening a multiple-dose container, unless otherwise specified by the manufacturer. ***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.

29. 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.

30. 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.

31. 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.

32. 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.

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

Yes.

34. 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.~~

35. <u>In addition to bladder irrigation and irrigations for wounds, what other types of drugs must be prepared in a sterile manner in compliance with USP-NF requirements?</u>

<u>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 for the</u>

lungs, 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. Note: Nasal sprays and irrigations for the nasal passages may be prepared as non-sterile compounds.

36. 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.

37. 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".

38. What risk-level is associated with repackaging an undiluted multi-dose vial?

The repackaging of a undiluted multi-dose vial, e.g., insulin, into multiple syringes is a medium-risk level manipulation when puncturing the vial more than 3 times. Note: this guidance addresses repackaging, not administration.

Revised: ~~September 10, 2013~~
December 9, 2014

(DRAFT)
BYLAWS OF THE VIRGINIA BOARD OF PHARMACY

ARTICLE I: GENERAL

The organizational year for the Board shall be from July 1st through June 30th. At the last meeting before July 1, the Board shall elect from its members, a chairman and a vice chairman. The term of office shall be one year and shall begin on July 1. A person shall not serve as chairman or vice chairman for more than two consecutive terms.

For purposes of these Bylaws, the Board schedules full board meetings four times a year, with the right to change the dates, schedule additional meetings as needed, or cancel any board meeting, with the exception that one meeting shall take place annually. Board members shall attend all board meetings in person, unless prevented by illness or similar unavoidable cause. A majority of the members of the Board shall constitute a quorum for the transaction of business. The current edition of *Robert's Rules of Order*, revised, shall apply unless overruled by law, regulation, or these bylaws, or when otherwise agreed.

ARTICLE II: OFFICERS OF THE BOARD

A. The officers of the Board shall be the chairman and the vice chairman.

B. The chairman presides at all meetings and formal administrative hearings in accordance with parliamentary rules and the Administrative Process Act, and requires adherence of same on the part of the board members. The chairman shall appoint all committees unless otherwise ordered by the Board.

C. The vice chairman shall act as chairman in the absence of the chairman.

D. In the absence, or inability to serve, of both the chairman and vice chairman, the chairman shall appoint another board member to preside at the meeting and/or formal administrative hearing.

E. The executive director shall be the custodian of all Board records and all papers of value. She/he shall preserve a correct list of all applicants and licensees. She/he shall manage the correspondence of the Board and shall perform all such other duties as naturally pertain to this position.

ARTICLE III: ORDER OF BUSINESS MEETINGS

The order of business shall be as follows:

1. Call to order with statement made for the record of how many board members are present and that it constitutes a quorum.
2. Approval of Agenda
3. Public comment received
4. Approval of Minutes
5. The remainder of the agenda shall be established by the executive director in consultation with the chairman.

ARTICLE IV: COMMITTEES

A. There shall be the following standing committees:

Special Conference Committee
Inspection Special Conference Committee
Examination Committee
Item Review Committee
Regulation Committee
Pilot Committees

1. Special Conference Committees. These committees shall consist of two board members who shall review information regarding alleged violations of the pharmacy laws and regulations and determine if probable cause exists to proceed with possible disciplinary action. The special conference committees shall meet as necessary to adjudicate cases in a timely manner in accordance with agency standards for case resolution. The chairman may designate board members as alternates on these committees in the event one of the standing committee members is unable to attend for all or part of a scheduled conference date. The chairman shall appoint committees as needed to expedite the adjudication of cases. ~~These committees may also function as informal conference committees if a case involves a permit.~~

2. Examination Administrator Selection Committee. This committee shall consist of three board members, the deputy executive director supervising the examination contracts, and the executive director. The Committee shall meet as required to review proposals and select the administrators of the Drug Law Examination and the Pharmacy Technician Examination.

3. Item Review Committee. This committee shall consist of at least six pharmacists, to include one board member and the executive director, holding current and unrestricted licenses to practice pharmacy in the Commonwealth of Virginia. The Item Review Committee shall meet as required for the purpose of writing new items for the Drug Law Examination item bank to maintain the integrity and defensibility of the examination. Additionally, the Board delegates to this Committee the approval of the Drug Law Examination for the purpose of licensure.

4. Regulation Committee. This committee shall consist of five Board members. The Board delegates to the Regulation Committee the authority to consider and respond to petitions for rulemaking. This committee is responsible for the development of proposals for new regulations or amendments to existing regulations with all required accompanying documentation; the development of proposals for legislative initiatives of the Board; the drafting of Board responses to public comment as required in conjunction with rulemaking; conducting the required review of all existing regulations as required by the Board's Public Participation Guidelines and any Executive Order of the Governor, and any other required tasks related to regulations. In accordance with the Administrative Process Act, any proposed draft regulation and response to public comment shall be reviewed and approved by the full Board prior to publication.

5. Pilot Committees. These committees shall consist of two board members who review applications for approval of innovative programs and any matters related to such programs.

B. Ad Hoc Committees.
The chairman shall also name such other committees as may be deemed necessary.

C. A majority of a committee shall constitute a quorum and the act of a majority of the members present at a meeting at which a quorum is present shall constitute the act of the committee.

ARTICLE V: GENERAL DELEGATION OF AUTHORITY

The Board delegates the following functions:

1. The Board delegates to Board staff the authority to issue and renew licenses, permits, registrations and certificates where minimum qualifications have been met.

2. The Board delegates to the executive director the authority to reinstate licenses, permits, registrations and certificates when the reinstatement is due to the lapse of the license, permit, registration or certificate and not due to Board disciplinary action.

3. The Board delegates to Board staff the authority to develop and approve any and all forms used in the daily operations of Board business, to include, but not be limited to, licensure applications, renewal forms and documents used in the disciplinary process.

4. The Board delegates to the Department of Health Professions' inspectors the authority to issue summaries of inspection deficiencies upon completion of an inspection, and the Board delegates to the executive director the authority to issue letters regarding reported deficiencies to the facilities or licensee.

5. The Board delegates to the executive director the authority to sign as entered any Order or Consent Order resulting from the disciplinary process or other administrative proceeding.

6. The Board delegates to the executive director, who may consult with a special conference committee member, the authority to provide guidance to the agency's Enforcement Division in situations wherein a complaint is of questionable jurisdiction and an investigation may not be necessary.

7. The Board delegates to the executive director, in consultation with the chairman, the review and approval of applications for special or limited use pharmacy permits. If the executive director and chairman do not reach consensus regarding the issuance of a permit, or if the requested waivers are unusual or different from those routinely approved, the review and approval may be referred to an informal conference committee.

8. The Board delegates to the executive director, in consultation with the chairman, the review and approval, in accordance with regulations, for exceptions to the notice requirements for pharmacies going out of business and for exceptions to notice requirements for pharmacies changing hours of business for more than one week. Should the executive director and the chairman not reach consensus, or if the request for exception is unusual or questionable, the review and approval may be referred to a special conference committee.

9. The Board delegates to the executive director the authority to grant extensions for continuing education on a one-time basis upon written request of the licensee prior to the renewal date in accordance with regulations. Approval of any request for an extension where the licensee must show good cause or approval of any request for an exemption is delegated to the executive director in consultation with the chairman. Should the executive director and chairman not reach agreement, the matter shall be referred to a special conference committee.

10. The Board delegates to the chairman, the authority to represent the Board in instances where Board "consultation" or "review" may be requested, but where a vote of the Board is not required and a meeting is not feasible.

11. The Board delegates the approval of continuing education programs to the executive director in consultation with one member of the Board.

12. The Board delegates the convening of a quorum of the Board by telephone conference call, for the purpose of considering the summary suspension of a license in accordance with § 54.1-2408.1, to the executive director or deputy executive director. The Board delegates the convening of a meeting by telephone conference call, for the purpose of considering settlement proposals in accordance with § 54.1-2400 (13), to the executive director or deputy executive director. The Board delegates the determination of probable cause for disciplinary action to a special conference committee of the Board, wherein the committee may offer a confidential consent agreement, offer a pre-hearing consent order, cause the scheduling of an informal conference, request additional information, or close the case. The Board further delegates the determination of probable cause, for the purpose of offering a confidential consent agreement or a pre-hearing consent order or for scheduling an informal conference in accordance with established Board guidelines, to the executive director or deputy executive director.

13. The Board delegates to the chairman, or the vice chairman in his absence, the approval of waivers in declared disasters or states of emergency in accordance with § 54.1-3307.3.

14. The Board delegates to the executive director, in accordance with § 54.1-3434.1(A)(2), the authority to accept an inspection report or other documentation for a non-resident pharmacy from an entity that may not be listed on the Board's guidance document, or to request an inspection by an agent of the Board.

15. The Board delegates to the executive director the authority to grant an accommodation of additional testing time, up to a maximum of double time, to candidates for Board required examinations pursuant to the Americans with Disabilities Act provided the candidate provides documentation that supports such an accommodation as required by Board regulation or guidance document. Any other requests for accommodation beyond additional testing time shall be reviewed by the Board at the next available Board meeting.

16. The Board delegates to the executive director, in consultation with the chairman, the authority to review and approve applications for limited-use practitioner of the healing arts to sell controlled substances licenses. A waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

ARTICLE VI: AMENDMENTS

Amendments to these Bylaws may be proposed by a board member or staff personnel by presenting the amendment in writing to all Board members prior to any scheduled meeting of the Board. Upon favorable vote of at least two-thirds of the Board members present at said meeting, such proposed amendment shall be adopted. If notice is given to the Board members at the previously held board meeting, a favorable vote of a majority of the Board members present at the current board meeting is required to adopt the amendment.

Effective Date:	July 1, 1997
Revised:	October 9, 1997, August 17, 1999, June 13, 2001, September 15, 2004, June 7, 2005, September 13, 2005, June 5, 2006, June 10, 2009, September 8, 2010, September 10, 2013 December 9, 2014