COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Public Hearing and Full Board Meeting
June 14, 2016
9:00AM

TOPIC	PAGES
Call to Order of Public Hearing for Scheduling Certain Substances: Cynthia Warriner, Chairman	
• Welcome & Introductions	
• Reading of Emergency Evacuation Script	
Call for Public Comment:	
• Possible scheduling of the Certain Chemicals in Schedule I of the Drug Control Act	1-2
Adjournment of Public Hearing	
Call to Order of Full Board Meeting: Cynthia Warriner, Chairman	
• Approval of Agenda	
• Approval of Previous Board Meeting Minutes:	
o March 24, 2016, Regulation Committee Meeting	3-11
o March 25, 2016, Full Board Meeting	12-24
o March 25, 2016, Public Hearing for Scheduling Certain Chemicals	25-26
o April 13, 2016, Special Conference Committee	27-28
o May 26, 2016, Regulation Committee Meeting	handout
o June 8, 2016, Special Conference Committee	handout
Call for Public Comment: The Board will receive 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	
Update on VCU Compounding Center: Dean Joseph DiPiro	
Regulatory Actions:	
• Regulatory Update - Elaine Yeatts	29
• Adoption of Regulation to Schedule Certain Chemicals in Schedule I – Elaine Yeatts	30-33
• Report from Regulation Committee – Ellen Shinaberry/Elaine Yeatts	
o Decision to Convene a Regulatory Advisory Panel for Developing Emergency Regulations for Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil	34-38
o Recommend Adoption of Fast-track Regulations for Amending Regulations for "Public Participation Guidelines (PPG)"	39-42
o Recommend Adoption of Re-Proposed Regulations on Setting Certain Conditions on Work Hours for Pharmacists	43-45
o Recommend that PMP Advance Legislative Proposal to Amend "Covered Substance" to	46-48

Include Schedule V

- Recommend Gathering of Additional Information from NABP Discussions regarding White Bagging and Brown Bagging 49-52A
- Recommend Meeting of PBM Task Force Subgroup to Address Concerns with Designation of Specialty Drugs 53-57
- Recommend Adoption of 2017 Legislative Proposals
  - Proposal to Clarify Collaborative Practice Authority 58-60
  - Requiring PTCB Certification for Initial Pharmacy Technician Registration 61-72
- Other 2017 Legislative Proposals Considered, No action Recommended
  - Addressing Compounding Best Practices 73-81
  - Removing One Prescription per Blank Prohibition 82-83
  - Requiring Temperature Monitoring Devices 84-92

Old Business: Caroline Juran/Jim Rutkowski

- Amend Guidance Document 110-29 *Physicians Dispensing Drugs,* Counsel to Research 21-22, 93-99

New Business: Caroline D. Juran

- Consideration for Accepting Inspections or Documentation, in lieu of FDA Inspection of Outsourcing Facility from:
  - Bestech GMP Contracting, Inc. - Matthew Bestercy, Owner and Principal Consultant 100-120
  - Florida Department of Health (provide presentation in agenda and handouts of CVs)
- Results from 2015 Healthcare Workforce Surveys – Elizabeth Carter, Ph.D., Director, HWDC
  - Pharmacist Survey - Attachment #1 1-25
  - Pharmacy Technician Survey – Attachment #2 1-25

Election of Officers - Chairman and Vice-Chairman

Reports:

- Chairman's Report – Cynthia Warriner
- Report on Board of Health Professions – Ryan Logan
- Report on Licensure Program – J. Samuel Johnson, Jr.
- Report on Disciplinary Program – Cathy M. Reiniers-Day Handout
- Executive Director's Report –Caroline D. Juran Handout
  Handout

Consideration of consent orders & possible summary restrictions/suspensions, if any

Adjourn

******The Board will have a working lunch at approximately 12pm and recognize former board member Dinny Li. ******

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 June 14, 2016** at the Perimeter Center, 9960 Mayland Drive, Suite 201, Richmond, VA 23233. Public comment may also be submitted electronically or in writing prior to June 10, 2016 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 17 compounds for recommended inclusion by the Board of Pharmacy into Schedule I in the Code of Virginia. A brief description and chemical name for each compound is as follows:

The following compounds are classified as research chemicals. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

1. Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB)
2. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone)
3. 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP)
4. 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP)
5. 4-Chloroethcathinone (other name: 4-CEC)
6. 3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone)

The following compounds are classified as cannabimimetic agents. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

7. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate (other names: AMB-FUBINACA, FUB-AMB)
8. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)
9. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48)
10. Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005)
11. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide (other name: AB-CHMICA)

The following compounds are powerful synthetic opioids. DFS recommends placing these compounds into Schedule I (§ 54.1-3446(6)).

12. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700)

13. 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921)

14. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl)

15. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl)

16. N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl)

The following compound is classified as a benzodiazepine, which is a central nervous system depressant. Clonazolam has no accepted medical use in the United States. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(4)).

17. Clonazolam

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.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY REVIEW

March 24, 2016
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER:	The meeting was called to order at 1:15pm
PRESIDING:	Ellen B. Shinaberry, Chairman
MEMBERS PRESENT:	Ryan K. Logan Cynthia Warriner Melvin L. Boone Sr. Rebecca Thornbury
NON-COMMITTEE MEMBERS PRESENT:	Freeda Cathcart Rafael Saenz
STAFF PRESENT:	Caroline D. Juran, Executive Director J. Samuel Johnson, Deputy Executive Director Cathy Reiniers-Day, Deputy Executive Director Elaine J. Yeatts, Senior Policy Analyst Beth O'Halloran, Individual Licensing Manager
APPROVAL OF AGENDA:	Amended agenda presented for review which included consideration for amendments to Guidance Documents 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide* and 110-15 *Delegation of Authority for Disciplinary Matters*
MOTION:	**The Committee voted unanimously to approve the amended agenda as presented. (motion by Boone, second by Logan)**
PUBLIC COMMENT:	John Lubkowski, Pharmacy Operations Manager of RMH Sentara Hospital, provided a handout with two suggestions for amending sections 18VAC110-20-250 and 18VAC110-20-275 of the Regulations. In section 18VAC110-20-250(4) the suggestion was to allow a system to capture a secure identification of the pharmacist responsible for each phase of the prescription processing record to include a daily generated barcode or other acceptable measure. In section 18VAC110-20-275(B)(1) the suggestion was to allow delivery of specialty pharmacy prescriptions to a clinic or hospital based outpatient center to comply with all requirements in this regulation. Stated reasons for the request

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included: tighter regulation of insurers and the requirement that patients obtain certain specialty medications from select specialty pharmacies that has created a gap in care for these patients, delays in patient care, patient inconvenience, inability to assure drug security and storage, patient safety issues, and pedigree tracking concerns.

AGENDA ITEMS:

- Review summary of Committee's recommendations for periodic review of *Regulations Governing the Practice of Pharmacy,* chapter 20, and *Regulations Governing Wholesale Distributors, Manufacturers and Warehousers,* chapter 50

Ms. Yeatts reviewed the procedure with the Committee of this periodic review process.

Ms. Shinaberry led the Committee through a review of each suggested area for amendment in chapters 20 and 50 that had previously been identified by the Committee at the November 2015 and January 2016 meetings, and encouraged members to identify any additional areas that may need consideration. A summary of the regulations agreed upon by the Committee for possible amendment are included in Attachment 1.

MOTION:

The Committee voted unanimously to recommend to the full Board that it adopt a Notice of Intended Regulatory Action (NOIRA) for the periodic review of chapters 20 and 50, and include the identified regulatory subjects listed in Attachment 1 of these minutes in the NOIRA packet. (motion by Warriner, second by Boone)

- Amendment to Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide*

Ms. Juran and Mr. Johnson reviewed the suggested amendments to Guidance Document 110-9 which included: striking references to the terms "major" and "minor" throughout the document; removing the subheadings in the document that reference categories of deficiencies since any recently added deficiencies were placed at the end of the document and not within the appropriate subcategory; amending Deficiencies #25c and #26a to include gloved fingertip testing; and considerations for increasing the monetary penalty for Deficiencies #1 and #2 based on a noticeable increase in non-compliance with pharmacy owners not assigning new pharmacists-in-charge within the required timeframe. Ms. Juran also provided information that NABP is asking states to pilot the newly developed uniform inspection form and provide feedback to NABP. Virginia has agreed to pilot the form in the near future.

- Amendment to Guidance Document 110-15

Ms. Juran and Mr. Johnson reviewed the suggested amendments to Guidance Document 110-15 to delegate the authority for the Executive

Delegation of Authority for Disciplinary Matters

Director to have the ability to issue a pre-hearing consent order to impose the recommended monetary penalty as listed in Guidance Document 110-9 for either not having a pharmacist-in-charge fully engaged in the practice of pharmacy or not having a pharmacist-in-charge in place and application filed within the required time frame. Presently, when these violations are identified, staff requests the inspector to cite the deficiency during the next routine inspection, but that inspection may not occur for approximately 18-24 months. Staff is requesting the ability to issue the pre-hearing consent order when the violation occurs and to not have to wait until the next routine inspection.

MOTION:

The Committee voted unanimously to recommend to the full board the following amendments, as presented and amended, to Guidance Document 110-9:

- **Increase the monetary penalty for Deficiency #1 to $2,000 and Deficiency #2 to $1,000;**
- **Remove reference to the terms "major" and "minor" throughout the document;**
- **Remove the subheadings of deficiency categories;**
- **Renumber the previously termed "minor" deficiencies to begin with number 101; and,**
- **Add reference to "gloved finger tip test" to Deficiencies #25c and #26a.**

It further recommended to the full board that it amend Guidance Document 110-15 as presented by including the following language in #4:

- **"Application for a change in pharmacist-in-charge (PIC) is submitted beyond the required timeframe for designating a new PIC-PHCO would impose recommended monetary penalty as indicated in Guidance Document 110-9 for either not having a PIC fully engaged in the practice at the pharmacy location or having a PIC in place, inventory taken, but application not filed with Board within the required timeframe." (motion by Boone, second by Logan)**

ADJOURN:

With all business concluded, the meeting adjourned at approximately 5:15 pm.

Ellen B. Shinaberry, Chairman

Caroline D. Juran, Executive Director

Date

Date

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Attachment 1

DRAFT Substance for Notice of Intended Regulatory Action

Substance

Please briefly identify and explain the new substantive provisions that are being considered, the substantive changes to existing sections that are being considered, or both.

As part of the periodic review, the Board has determined that provisions in Chapter 20 relating to the licensure of pharmacists and registration of pharmacy technicians should be re-promulgated into a separate chapter, Chapter 25, to reduce the size and complexity of this chapter. Some of Part I, General Provisions, will be included in a new chapter, and all of Parts II and III will be repealed and restated. Additionally, section 15, *Criteria for delegation of informal fact-finding proceedings to an agency subordinate,* will be moved into a separate chapter, Chapter 16, because it applies to all types of licensees, registrants, and permit holders regulated by the board.

Amendments to the following sections of Chapter 20 (or the new chapter 25) will be considered in the promulgation of proposed regulations:

PART I. General Provisions.

18VAC110-20-10. Definitions

- Modifying definition for "robotic pharmacy system", "pharmacy technician program" and "storage temperature."

18VAC110-20-20 Fees

- Changing the renewal for pharmacist licenses and pharmacy technician registrations to a date different from December 31st, but retain the facility renewal dates for facilities. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-21 Public address

- Adding requirement for notification to the board if there is a name change and specify documentation that must be submitted. Consider a specific timeframe for notification.

18VAC110-20-25 Unprofessional conduct

- Adding failure to submit corrective action related to inspection deficiency within a specified time frame.
- Adding dispensing any controlled substance with the intent or knowledge that it will be used otherwise than medicinally, for accepted therapeutic purposes, or with the intent to evade any law with respect to the sale or use of such drug.

PART II. Licensure Requirements for Pharmacists.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Specifying a timeframe for validity of law exam score to 3 years, consistent with requirements for record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee rather than the current active renewal fee.
- Revising terms "reactivate" and "reinstate" for correct and consistent usage.

18VAC110-20-90 Requirements for continuing education (CE)

- Accepting additional inter-professional continuing education.
- Changing wording in (B) (2) from "Category I Continuing Medical Education" to "Accreditation Council for Medical Education" which appears to be the current title for this type of continuing education.
- Requiring a portion of the 15 required hours to be live or real-time interactive continuing education.
- Deleting #3 which references programs approved by the Board.

18VAC110-20-100 Approval of continuing education programs

- Deleting ability for board to approve CE programs.

PART III. Requirements For Pharmacy Technician Registration.

18VAC110-20-101 Application for registration as a pharmacy technician

- Clarify that the 9 month time frame for allowance of a person to perform the duties of a pharmacy technician can begin after completion of didactic training rather than at the time of initial enrollment in the program.

18VAC110-20-102 Criteria for approval of training programs

- Including requirement for training program approval number to be printed on certificate awarded by training program.
- Requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.
- Setting some minimum standard for the length as well as the content of a training program.
- Include in the student record the date on which the student began performing duties of a pharmacy technician as a part of the program.

18VAC110-20-106 Requirements for continued competency

- Changing "original certificates" to "documentation" in both sentences of subsection D.

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PART IV. Pharmacies.

18VAC110-20-110 Pharmacy permits generally

- Specifying minimum number of hours pharmacist-in-charge (PIC) must practice at the location listed on the pharmacy permit application
- Requiring minimum number of years of experience for pharmacist-in-charge eligibility.

18VAC110-20-111 Pharmacy technicians

- Including in the documentation of a technician's training the date on which the technician began training that constitutes performance of pharmacy technician tasks.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarifying requirements for acquisitions with regard to inspection and inventory
- Requiring an inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarifying requirements for acquisitions with regard to inspection and inventory
- Allowing Board to rescind pharmacy permit if not opened within 60 days of issuing permit.

18VAC110-20-150 Physical standards for all pharmacies

- Specifying acceptable refrigeration facilities based on Center for Disease Control guidance for vaccine storage, require calibrated thermometer, temperature logs or documentation; exemption of sink requirement if pharmacy does not stock prescription drugs.

18VAC110-20-180 Security system

- Requiring security system to have at least one hard-wired communication method for transmitting breach as is required for wholesale distributors.
- Clarifying that monitoring entity shall notify PIC or pharmacist practicing at the pharmacy; simply notifying non-pharmacist manager is insufficient.

18VAC110-20-190

- Amending physical requirements for a prescription department's enclosure.
- Amending requirement for locking of enclosure if front door to pharmacy is locked and the entire pharmacy is covered by the security system.

18VAC110-20-200 Storage of drugs, devices, and controlled paraphernalia; expired drugs

- Adding language from Guidance Document 110-40 regarding dispersion of Schedule II drugs.

PART VI. Drug Inventory and Records.

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

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- Adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Clarifying in subsection C that chart orders used in long term care facilities must include a quantity or duration of treatment.

PART VII. Prescription Order and Dispensing Standards.

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

- Separating subsections A and B from the rest of the regulation.
- Addressing concern in subsection B by the Virginia Pharmacist Association with pharmacists not being provided adequate pharmacy technician support.
- Reviewing appropriateness of requiring pharmacists to not return a forged prescription.
- Adding language from Guidance Document 110-32 regarding use of drop boxes into a new subsection G, but the last sentence regarding a prohibition for patients to leave containers which contain drug or drugs should be reworded to regulate pharmacists, not the consumer.

18VAC110-20-275 Delivery of dispensed prescriptions

- Addressing concerns with white bagging and brown bagging.

18VAC110-20-277 Prescription Requirements

- Adding new regulation in section 277 to clarify that prescriptions, unless electronically transmitted, must include manual signature and that all prescriptions must include a quantity or duration of treatment.

18VAC110-20-280 Transmission of a prescription order by facsimile machine

- Clarifying that a requirement for a signature to be manual for written prescriptions unless electronically transmitted is unnecessary if proposed 18VAC110-20-277 is adopted.
- Considering whether there is value in the allowance in 18VAC110-20-280 A, 4, C for residents of long term care facilities and provider pharmacies or if it should be removed.

18VAC110-20-290 Dispensing of Schedule II drugs

Adding language from Guidance Document 110-41 regarding allowable changes to a Schedule II.

PART VIII. Labeling and Packaging Standards for Prescriptions.

18VAC110-20-355 Pharmacy repackaging of drug; records required; labeling requirements

Amending requirement for how to identity pharmacist verifying accuracy of the process.

PART X. Unit Dose Dispensing Systems.

18VAC110-20-425 Robotic Pharmacy Systems

- Streamlining robotic pharmacy system regulations by striking #5 and simplifying #4.
- Strengthening requirements for pharmacist accountability in assigning bar codes.

Part XI Pharmacy Services to Hospitals

18VAC110-20-470 Emergency room

In #2, consider changing "practitioner" to "prescriber"

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

- Streamlining requirements for automated dispensing devices in hospitals.

Part XII Pharmacy Services to Long-Term Care Facilities

18VAC110-20-550 Stat-drug box

- Clarifying in 5, b whether one unit of liquid is allowable in each drug schedule.
- Clarifying that a facility may possess multiple stat drug boxes and that contents do not have to be uniform between boxes.

18VAC110-20-555 Use of automated dispensing devices

- Clarifying that drug for emergency use may include drugs for first doses.
- Clarifying drugs stored in automated dispensing device for emergency purposes not restricted to quantities for emergency boxes.
- Considering whether requirements in 18VAC110-20-490 and 18VAC110-20-555 should be similar.

PART XIII Other Institutions and Facilities

18VAC110-20-580 Humane societies and animal shelters

- Amending regulation based on recent amendments to §54.1-3423; changing term for humane societies to public or private animal shelters.

PART XV Medical Equipment Suppliers (MES)

18VAC110-20-630 Issuance of a permit as a medical equipment supplier

- Adding requirement that applications must include name of responsible party.
- Requiring MES to notify the Board within 14 days of a change in the responsible party.

18VAC110-20-680 Medical equipment suppliers

- Adding language from Guidance Document 110-19 for MES to transfer prescriptions.
- Adding requirement to provide Board with hours of operation and notification to board and public when hours change.

PART XVI Controlled Substance Registration for Other Persons or Entities

18VAC110-20-710 Requirements for storage and security for controlled substance registrants

- Amending schedules to include Schedule I for researchers who are allowed to store and use Schedule I drugs.

The Board considered whether there is a better method for identifying the responsible pharmacist as initials are required 23 times throughout regulations of the Board. It is likely the Board will review all regulations that require a pharmacist's initials to determine if there is a better method or use of technology, such as the use of unique identifiers, for accurately identifying the responsible pharmacist.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

In section 30, 40 and 50 –Including prescription devices in addition to prescription drugs.

18VAC110-50-40 Safeguards against diversion of drugs

- Amending B, 2 that communication line must be hardwired, but sensors may be wireless.
- Amending B, 3 to require the security system to be capable of sending an alarm signal to the monitoring entity when breached if the communication line is not operable.

Part II Wholesale Distributors

18VAC110-50-60 Special or limited-use licenses

- Expanding ability to issue limited use for other entities such as third party logistic providers consistent with the law that passed during 2016 General Assembly session to create this licensing category.

18VAC110-50-70 Minimum required information

- Placing information from Guidance Document 110-34 regarding submission of social security number or control number into regulation.

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

- Requiring federal criminal history record check, not simply the Virginia Central Criminal Records Exchange since Virginia database would likely not have information on responsible parties for nonresident wholesale distributors.

18VAC110-50-70 through 18VAC110-20-140

- For consistency, considering similar requirements in section 70 through 140 for manufacturers.

DRAFT/UNAPPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF BOARD MEETING

March 25, 2016
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

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

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart (departed at 2:00pm)
Ryan K. Logan
Raphael Saenz
Rebecca Thornbury
Ellen B. Shinaberry
Jody H. Allen

MEMBERS ABSENT:
Sheila K. W. Elliott
Michael I. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
David Brown, Director, DHP
Lisa Hahn, Chief Deputy Director, DHP
James Rutkowski, Assistant Attorney General (absent 10:00am-11:08am)
Elaine J. Yeatts, Senior Policy Analyst, DHP

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

APPROVAL OF AGENDA: A handout for an amended agenda was provided. The amended agenda moved the discussion for amending Guidance Document 110-9 *Pharmacy Inspection Deficiency Monetary Penalty Guide* to the Report from Regulation Committee section along with discussion for amending Guidance Document 110-15 *Delegation of Authority for Disciplinary Matters.* Additionally, the minutes from the March 21, 2016 Special Conference Committee was added to the list of minutes for approval.

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

APPROVAL OF MINUTES: In addition to the minutes included in the agenda packet, a handout of the March 21, 2016 Special Conference Committee minutes was provided to the Board. The following minutes were considered for approval:

- November 23, 2015 Special Conference Committee

- December 1, 2015 Full Board Meeting
- December 1, 2015 Public Hearing for Hours of Continuous Work by Pharmacists
- December 15, 2015 Special Conference Committee
- December 29, 2015 Pilot Informal Conference Committee
- January 5, 2016 Regulation Committee
- March 21, 2016 Special Conference Committee

MOTION:

The Board voted unanimously to approve the minutes as presented for the meetings held between November 23, 2015 and March 21, 2016. (motion by Allen, second by Saenz)

PUBLIC COMMENTS:

Tim Musselman, Executive Director for the Virginia Pharmacists Association, provided a request by membership input for the Board to consider adding promethazine with codeine as a drug of concern so that it may be reported to the Prescription Monitoring Program.

Michael Rush, Executive Director of Global Health Policy at Temptime Corporation requested the Board consider legislative or regulatory changes to require temperature sensitive medications that are shipped via mail to be accompanied with a device to monitor temperature during shipping. He indicated Georgia recently passed such a law. Mr. Rush provided background on how this type of temperature monitoring has vastly reduced waste in third world countries, specifically in terms of vaccines. Mr. Rush provided examples of factors contributing to drug waste in today's society which included delays in patients receiving mailed packages containing temperature-sensitive drugs. Mr. Rush stated the temperature devices that his corporation provides fall within USP guidelines.

DHP DIRECTOR'S REPORT:

Dr. David Brown introduced the recently appointed Chief Deputy Director, Lisa Hahn. He then provided a summary of the report generated by the Pharmacy Benefits Manager Workgroup, stating that he believes Virginia is in a good position having now completed this work should legislators need information on the subject of the oversight of pharmacy benefit managers. The report summarizes the discussion on several issues identified by the workgroup and provides potential policy options. He stated there was consensus among the workgroup members that:

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

He, also, indicated those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

Dr. Brown also commented generally that it was a busy legislative session and that there were a number of pharmacy-related bills. Ms. Warriner thanked Dr. Brown for his leadership.

REGULATORY ACTIONS:

- LEGISLATIVE UPDATE

Ms. Yeatts provided an overview of the summary of bills, contained in the agenda packet, recently considered by the General Assembly. She stated most bills will become law on July 1, 2016 and some may require the Board to promulgate emergency regulations.

- REGULATORY UPDATE

Ms. Yeatts provided an update of the recent regulatory actions affecting the Board of Pharmacy. Repackaging at PACE sites will become effective on April 21, 2016. The comment period has ended for the prohibition against incentives to transfer prescriptions and addressing hours of continuous work by pharmacists. The regulations for collection sites for disposal of unused drugs became effective March 24, 2016. Ms. Juran reported that staff will be including information regarding the collection site regulations in an upcoming blast email or e-newsletter.

REPORT FROM REGULATION COMMITTEE

- ADOPTION OF NOIRA FOR PERIODIC REVIEW OF CHAPTERS 20 AND 50

Ms. Shinaberry provided a report on the regulation committee meeting held on March 24, 2016. Ms. Juran reviewed the written comments received during the open comment period, November 30, 2015 through

December 30, 2015 and reported the Regulation Committee's recommendations which were as follows:

- Comment regarding tech-check-tech, received 12/24/15 = the Regulation Committee recommends not including this issue in the periodic regulatory review since licensees may potentially utilize pharmacy technicians to check other pharmacy technicians through approval of an innovative (pilot) program;
- Comment regarding regionalization of hospital packaging, received 12/11/15 = the Regulation Committee recommends not including this issue in the periodic regulatory review since the federal law does not appear to support 503A facilities providing non-patient specific compounded sterile products to other pharmacies for further dispensing, regardless of ownership;
- Comment regarding prescription department enclosures and access to the prescription department, along with lack of adequate technician help, received 12/30/15 = the Regulation Committee recommends including these issues in the periodic regulatory review;
- Comment regarding inconsistencies with regulations governing wholesale distributors, manufacturers, and warehousers with the provisions of the Drug Quality and Security Act = the Regulation Committee recommends not including this issue in the periodic regulatory review as it will be addressed in a separate regulatory package resulting from the amendments in law effective July 1, 2016.

A handout of the draft substance for a notice of intended regulatory action for the periodic review of chapters 20 and 50 which captured the Regulation Committee's recommendations from the March 24, 2016 meeting was provided. Ms. Shinaberry reviewed these recommendations with the Board. Ms. Juran added that a clarification may be needed to reflect the Regulation Committee's recommendation that Regulations 18 VAC 110-50-40 through 18 VAC 110-50-140 be reviewed to determine if similar requirements should also apply to manufacturers.

MOTION:

The Board voted unanimously to accept the recommendation of the Regulation Committee to adopt a Notice of Intended Regulatory Action for the periodic review of chapters 20 and 50 along with the identified regulatory sections in the draft substance as presented and amended with clarification that Regulations 18 VAC 110-50-40 through 18 VAC 110-50-140 be reviewed to determine if similar requirements should also apply to manufacturers. (motion by Allen, second by Saenz)

- AMENDMENTS TO GUIDANCE DOCUMENT 110-9 *PHARMACY INSPECTION DEFICIENCY*

Ms. Shinaberry then reviewed the Committee's recommendation to the full board regarding the amendments of Guidance Documents 110-9 and 110-15.

MONETARY PENALTY GUIDE AND 110-15 *DELEGATION OF AUTHORITY FOR DISCIPLINARY MATTERS*

MOTION:

The Board voted unanimously to accept the recommendations of the Regulation Committee to amend Guidance Document 110-9 as presented by:

- **Increasing the monetary penalty for Deficiency #1 to $2,000 and Deficiency #2 to $1,000;**
- **Removing reference to the terms "major" and "minor" throughout the document;**
- **Removing the subheadings of deficiency categories;**
- **Renumbering the previously termed "minor" deficiencies to begin with number 101; and**
- **Adding reference to "gloved fingertip test" to Deficiencies #25c and #26a;**

and to amend Guidance Document 110-15 as presented by including the following language in #4:

- **"Application for a change in pharmacist-in-charge (PIC) is submitted beyond the required timeframe for designating a new PIC-PHCO would impose recommended monetary penalty as indicated in Guidance Document 110-9 for either not having a PIC fully engaged in the practice at the pharmacy location or having a PIC in place, inventory taken, but application not filed with Board within the required timeframe."**

Mr. Johnson stated that Mr. Musselman had identified after the Regulation Committee meeting that "gloved fingertip testing" should probably also be added to the "conditions" for Deficiencies 25a and 26.

MOTION:

The Board voted unanimously to further amend Guidance Document 110-9 by adding reference to "gloved fingertip test" to the "conditions" of Deficiencies #25a and #26. (motion by Allen, second by Cathcart)

Mr. Saenz commented that he would like to see the board discuss concerns with repeat deficiencies at a later time.

- CONSIDERATION OF ANY SCHEDULING ACTION FROM PUBLIC HEARING

Ms. Yeatts summarized the information from the public hearing held just prior to the Board meeting pursuant to subsection D of 54.1-3443 of the Code regarding the possible placement of six substances identified by the Department of Forensic Science into Schedule I of the Drug Control Act. If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30

days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

MOTION:

The Board voted unanimously to adopt a notice of intended regulatory action, pursuant to subsection D of 54-1-3443 of the Drug Control Act, for placing the following chemicals into Schedule I:

- **N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl)**
- **Flubromazolam**
- **5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT)**
- **N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA)**
- **Methyl 2-[1-[(4-flurophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA)**
- **Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB and 5-Fluoro-MDMB-PINACA). (motion by Saenz, second by Boone)**

- PETITONS FOR RULEMAKING

  - Allow long term care facility to provide prescription information for Schedule VI drugs to a backup pharmacy located near the facility

Ms. Yeatts summarized a petition for rulemaking from Bill Irvin with Omnicare to allow a pharmacy servicing long term care facilities to provide prescription information for "first fill" doses of Schedule VI drugs to a local backup pharmacy located near the long term care facility without the provision of information constituting a transfer of the prescription. The Board reviewed the three comments provided, all of which supported the request for rulemaking.

MOTION:

The Board voted unanimously to include the relevant sections of regulation in the NOIRA for the periodic review of chapters 20 and 50 in order to consider the petitioner's request for allowing a pharmacy servicing long term care facilities to provide prescription information for "first fill" doses of Schedule VI drugs to a local backup pharmacy located near the long term care facility without the provision of information constituting a transfer of the prescription.. (motion by Shinaberry, second by Allen)

  - Allow pharmacists in hospitals or free-standing emergency departments to adjust or order medications

Ms. Yeatts reviewed the petition for rulemaking from Angela Gilley to amend Part XI of the Regulations, Pharmacy Services to Hospitals, to allow pharmacists to make changes to orders according to clinical guidelines in hospitals and free-standing emergency departments. No comment was received during the open comment period. The Board discussed if this request was already covered under the collaborative

according to clinically accepted guidelines

practice allowance and if any necessary changes could be addressed in regulation or if a statutory amendment would be necessary. It was mentioned that the subject of collaborative practice agreements may be discussed at the May meeting of the Regulation Committee.

MOTION:

The Board voted unanimously to deny the petition for rulemaking to allow pharmacists to make changes to medication orders according to clinical guidelines in hospitals and free-standing emergency departments, but to research the issue further with counsel to determine if such allowance is already addressed under the collaborative practice agreement provisions. (motion by Saenz, second by Thornbury)

- Allow bar code and RFID scanning to extend the pharmacists check, once bar code or RFID scan has been verified.

Ms. Yeatts reviewed the petition for rulemaking from David Merryfield. No comments were received during the open public comment period. The Board discussed this proposal and Mr. Johnson remarked that there are several hospitals who have applied for and been granted a pilot program for this technology. The Board discussed that the pilot program allows for a facility to apply for this type of allowance while still under certain limitations as well as providing reports to the Board of the progress of the pilot program. It was stated that the use of and quality of technology, along with the impact of the technology can vary from pharmacy to pharmacy. The was consensus that the innovative pilot programs allow the board to pilot new technologies and monitor the processes closely to ensure the safety of the process prior to allowing widespread use of the technology via regulation.

MOTION:

The Board voted unanimously to:

- **deny the petition for rulemaking regarding the allowance of using RFID and bar code scanning to extend a pharmacist's check;**
- **direct staff to inform the petitioner that RFID and bar code scanning technology may presently be used to assist pharmacy staff in the dispensing process, but cannot be used to replace pharmacist verification; and,**
- **direct staff to recommend to the petitioner that he may wish to submit an application for an innovative (pilot) program for expanded use of this technology. (motion by Thornbury, second by Boone)**

- ADOPTION OF PROPOSED REGULATIONS TO REPLACE EMERGENCY REGULATIONS FOR PERMITTED FACILITIES USED BY PRACTITIONERS OF THE HEALING ARTS TO SELL

Ms. Yeatts provided background on proposed regulations for permitted facilities used by practitioners of the healing arts to sell controlled substances. The proposed regulations are identical to the emergency regulations that are currently in effect until June 6, 2017.

CONTROLLED SUBSTANCES

MOTION:

The Board voted unanimously to adopt the proposed regulations for permitted facilities used by practitioners of the healing arts to sell controlled substances (motion by Cathcart, second by Allen)

- ADOPTION OF PROPOSED REGULATIONS TO REPLACE EMERGENCY REGULATIONS FOR OUTSOURCING FACILITIES

Ms. Yeatts provided background on proposed regulations for outsourcing facilities which are identical to the emergency regulations that are in effect until June 6, 2017.

MOTION:

The Board voted unanimously to adopt the proposed regulations for outsourcing facilities (motion by Shinaberry, second by Boone)

- ADOPTION OF PROPOSED REGULATIONS FOR A PROHIBITION ON INCENTIVES TO TRANSFER PRESCRIPTIONS

Ms. Yeatts provided background on the NOIRA for prohibiting incentives to transfer prescriptions and the public comments received. The Board reviewed the written comments received from individual pharmacists and VPhA during the open comment period, all of which were in support of the NOIRA. It was reported that the Regulation Committee adopted a recommendation at its January 5, 2016 meeting to recommend to the full board that it adopt the proposed regulations, as presented, for a prohibition on incentives to transfer prescriptions.

MOTION:

The Board voted unanimously to adopt the proposed regulations, as presented and recommended by the Regulation Committee, for a prohibition on incentives to transfer prescriptions.

- ADOPTION OF FINAL REGULATIONS ON SETTING CERTAIN CONDITIONS ON WORK HOURS FOR PHARMACISTS

Ms. Yeatts reviewed with the Board the proposed final regulations and a summary of the 15 comments received which mostly supported the proposed rulemaking.

MOTION:

The Board voted unanimously to adopt as presented final regulation to amend 18VAC110-20-110 by drafting a new subsection B to read, "Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day without being allowed at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break." (motion by Shinaberry, second by Logan)

- ADOPTION OF FAST TRACK AMENDMENT FOR 18 VAC 110-20-540,

Ms. Yeatts stated that a request had been received from Omnicare to amend Regulation 18VAC110-20-540 to allow a pharmacy providing services to a long term care facility to place diazepam rectal gel in the

EMERGENCY DRUG KIT

emergency drug kit. Omnicare provides services to a skilled nursing facility that provides sub-acute care for children that suffer from complex physical and neurological diseases with frequent seizures. It was stated that limiting access to this drug may threaten successful patient outcome up to and including the survival of the patient.

MOTION:

The Board voted unanimously to amend Regulation 18 VAC 110-20-540 by a fast-track action by inserting into subsection 2 the phrase "and diazepam rectal gel" following the word "Nitroglycerin SL". (motion by Allen, second by Boone)

- POSSIBLE TOPICS FOR 2017 LEGISLATIVE PROPOSALS

Ms. Juran reviewed with the Board possible topics for their consideration of 2017 legislative proposals. They included a constituent's request for removing the statutory prohibition of one prescription per blank, possible clarifications to the collaborative practice allowance, possible amendments to compounding requirements based on Pew Charitable Trust's recent publication of best practices for overseeing compounding, and the possibility of a new requirement for temperature devices to be included in shipments of temperature-sensitive drugs. The Board agreed to consider all of these topics at its May Regulation Committee meeting for possible adoption by the full board in June, along with consideration for requiring PTCB certification for pharmacy technician registration.

OLD BUSINESS:

- Guidance for whether nurses may prepare methadone take-home bottles

Mr. Rutkowski stated that the statute is specific as to what duties a pharmacist and pharmacy technician may perform. A limited-use pharmacy permit as issued to a methadone clinic gives the Board the ability to waive certain regulatory requirements, however, the Board is not able to waive statutory requirements. Because the duties of a pharmacy technician are restricted in statute, the Board may not waive these requirements to allow a nurse to prepare methadone take-home doses. However, a nurse could consider obtaining registration as a pharmacy technician which could authorize the individual to perform duties otherwise restricted to a pharmacy technician.

NEW BUSINESS:

- Amend healthcare workforce pharmacist survey

Dr. Elizabeth Carter, Director for the Healthcare Workforce Data Center, provided information regarding a request to amend the pharmacist workforce survey to include informatics in both the residency and current pharmacy practice choices on the survey.

MOTION:

The Board voted unanimously to direct the Healthcare Workforce Data Center to update the annual pharmacist workforce survey, as necessary, to ensure the residency choices and current pharmacy practice choices listed in the survey represent the current residencies recognized by the American Society of Health-Systems Pharmacists (ASHP). (motion by Allen, second by Logan)

- Amend *Protocol for*

Based on the recent FDA-approval of Narcan nasal spray, Ms. Juran

Prescribing and Dispensing of Naloxone

recommended that the Board consider amending the naloxone protocol to include this third drug option. She indicated the amendments as presented had been discussed with and agreed upon by representatives of the Board of Medicine, Department of Behavioral Health and Developmental Services, the Virginia Department of Health, and the Department of Criminal Justice Services.

MOTION:

The Board voted unanimously to amend the naloxone protocol as presented by adding reference to the recent FDA-approved Narcan nasal spray as a third naloxone delivery system. (motion by Allen, second by Shinaberry)

- Consideration for "white bagging, brown bagging" and "specialty drugs"

Ms. Juran provided an overview of the practices involving "white bagging" and "brown bagging" and indicated the practices don't appear to operate in compliance with current regulations. She referenced comments on the subject within the Pharmacy Benefit Managers (PBM) Workgroup Report. There was a unanimous recommendation from the PBM workgroup that the Board discuss promulgating regulation for these practices. Ms. Shinaberry commented that this topic will be discussed at the NABP meeting in California in May as there is a resolution for consideration. Ms. Cathcart and Mr. Saenz agreed that this is a large public health issue that needs to be addressed. Ms. Juran stated that Colorado has addressed white bagging in regulation, but that the regulation only addresses reconstitution by the receiving pharmacy, not compounding by the receiving pharmacy. It also does not address brown bagging.

A question was asked if the Board has the authority to define a "specialty drug". Counsel opined that the Board does not presently have the authority to define "specialty drug" in regulation. He recommended the term be defined in statute or that the General Assembly could give the Board of Pharmacy the authority to define "specialty drug" in regulation. Ms. Allen provided statistics about the approval of specialty drugs and that CMS is often times changing the definition of specialty drugs as well as the cost of some specialty drugs.

ACTION ITEM:

There was consensus that the Regulation Committee should further discuss the issues of white bagging, brown bagging, and the defining of specialty drug at its May meeting.

- Amend Guidance Document 110-29 *Physician Dispensing Drugs*

Ms. Juran provided background regarding the changes in statute and regulation requiring the practitioners of the healing arts to sell controlled substances to obtain a permit for the location from which they dispense or sell drugs. Thus, there is a need to conform language in the guidance document to this new oversight. Additionally, the suggested amendments reflect counsel's advice resulting from an opinion of the Attorney General as to under what circumstances a physician may dispense a prescription written by a mid-level practitioner. Suggested amendments further address counsel's advice that a physician may also dispense a refill of a

prescription written by another physician licensed to sell controlled substances. Mr. Logan asked if the physician would have the ability to refill the prescription of another physician who is practicing at a different address, but possibly within a practice with shared ownership. Mr. Rutkowski stated he would need to research this further to answer that question.

ACTION ITEM:

There was consensus that the Board would table this issue until the June board meeting to allow counsel time to research whether a physician licensed to sell controlled substance may dispense a refill of a prescription written by another physician licensed to sell controlled substances regardless if he is practicing at a different address which may or may not have shared ownership with the other physician's practice.

REPORTS:

- Chairman's Report

Ms. Warriner reported that the annual meeting of the NABP will be held in San Diego, California in May and that it is an excellent opportunity for board members to get a picture of what is happening in pharmacy around the nation. Ms. Warriner also mentioned that Ms. Juran is running for a seat on the Executive Committee with NABP and the election will be held at this meeting in May.

- Report on Board of Health Professions

Mr. Logan recently attended the Board of Health Professions meeting. It was reported at that time that the PBM workgroup report would be ready soon. Dr. Carter provided the Healthcare Workforce Data Center (HWDC) report in which pharmacists were reported to be the youngest group of healthcare professionals. The HWDC hopes to use their website to educate others on future careers in healthcare. There was also a discussion on telehealth and that a recently developed Telehealth Report was sent to all executive directors and board chairmen for comment.

- Report on Licensure Program

Mr. Johnson reported the Board currently licenses 34,423 individuals and facilities. The Board issued 942 licenses and registrations for the period of November 30, 2015 through February 29, 2016. Inspectors conducted 378 facility inspections including 185 routine inspections of pharmacies: 54 (29%) resulted in no deficiency, 74 (40%) with deficiencies and 57 (31%) with deficiencies and a consent order. Mr. Johnson also discussed a chart providing a graphic display of inspection deficiencies by quarter since September 2012. Mr. Johnson reviewed the report of Major & Minor Inspection Deficiencies. It was noted that Minor deficiency 42, regarding compliance with CQI requirements, is the most frequently cited deficiency. The Board discussed methods of educating pharmacists about the CQI requirement such as by newsletter, and "blast" email.

- Report on Disciplinary Program

Ms. Reiniers-Day provided the Board with a handout and discussed the Board's Open Disciplinary Case Report comparing the case stages between the four report dates of June 12, 2015; September 28, 2015; November 30, 2015; and March 24, 2016. For the final date, she reported

that there were no cases at the entry stage; 69 at the investigation stage; 165 at the probable cause stage; one at the administrative proceedings division stage; two at the informal stage; one at the formal stage; and 105 at the pending closure stage.

Further, Ms. Reiniers-Day advised that between December 1, 2015, and March 24, 2016, 129 cases were closed. Additionally, when a Special Conference Committee met on March 21, 2016, 40 cases were presented.

- Executive Director's Report

Ms. Juran reviewed her report with the board which was provided as a handout. She indicated that staff is nearing completion of the transition, previously approved by the board, from the Virginia Federal and State Drug Law Exam to the Multistate Pharmacy Jurisprudence Examination (MPJE). As of July 1, 2016, the Virginia Federal and State Drug Law Exam will no longer be administered and pharmacist applicants must take and pass the MPJE. Notifications to the Virginia school of pharmacy deans and current applicants will be sent this week. She also reported that staff is reviewing the recently developed NABP universal inspection form to determine if it can begin piloting the form and providing feedback to NABP. Staff will continue to research this issue and seek ability from NABP to post the inspection form on the board's website, as requested by the Board. She then reported on a recent visit to the VCU School of Pharmacy Compounding Center and that Dean DiPiro would like to provide an update on the center to the board in June. She also provided an update regarding the new licensure programs for practitioners of the healing arts and outsourcing facilities, and reported on staffing issues.

CONSIDERATION OF CONSENT ORDERS

Closed Meeting:

Upon a motion by Ms. Thornbury, and duly seconded by Mr. Boone, the Board voted 10-0 to convene a closed meeting pursuant to § 2.2-3711(A)(27) of the Code of Virginia for the purpose of deliberation to reach a decision in the matter of two Consent Orders. Additionally, she moved that Cathy M. Reiniers-Day, Caroline D. Juran, Sammy Johnson and Jim Rutkowski attend the closed meeting because their presence in the closed meeting was deemed necessary and would aid the Board in its deliberations.

Reconvene

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

MOTION:

Upon a motion by Ms. Shinaberry and duly seconded by Mr. Boone, the Board voted 7-0 in favor of accepting the Consent Orders as presented by Ms. Reiniers-Day in the matters of Matthew T. King

and Samantha L. Warren, pharmacy technicians.

ADJOURN: With all business concluded, the meeting adjourned at approximately 2:20 pm.

Cynthia Warriner, Chairman

DATE:

Caroline D. Juran, Executive Director

DATE:

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
PUBLIC HEARING FOR SCHEDULING CERTAIN SUBSTANCES

March 25, 2016
Second Floor
Board Room 4

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The public hearing was called to order at 9:05a.m.

PRESIDING: Cynthia Warriner, Chairman

MEMBERS PRESENT:
Melvin L. Boone, Sr.
Freeda Cathcart
Ryan K. Logan
Raphael Saenz
Rebecca Thornbury
Ellen B. Shinaberry
Jody H. Allen

MEMBERS ABSENT:
Sheila K. W. Elliott
Michael I. Elliott

STAFF PRESENT:
Caroline D. Juran, Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
David E. Brown, D.C., Director, DHP
Lisa Hahn, Chief Deputy Director, DHP
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General

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

Pursuant to subsection D of 54.1-3443 of the Code, a public hearing to consider placement of chemical substances in Schedule I of the Drug Control Act was held. If approved by the Board of Pharmacy, the placement of these substances in Schedule I in the Virginia Drug Control Act shall go into effect 30 days following publication of the proposed regulation and remain in effect for a period of 18 months. The chemicals will then be de-scheduled unless a general law is passed by the General Assembly placing the chemicals into Schedule I.

CALL FOR COMMENT: Ms. Warriner called for comment to consider placement of the chemical substances N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl), Flubromazolam, 5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT), N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-

fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA), Methyl 2-[1-[(4-flurophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA), and Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB and 5-Fluoro-MDMB-PINACA) into Schedule I. John Prysbylski with the Department of Forensic Science stated that these six chemicals have been identified in forensic labs within Virginia and nationally. He stated flubromazolam has been associated with one fatality, 5-methoxy-N,N-methylisopropyltryptamine (other name: 5-MeO-MIPT) is a hallucinogenic, and that N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA), Methyl 2-[1-[(4-flurophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA), and Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB and 5-Fluoro-MDMB-PINACA) are cannabimimetics. He also stated that Methyl 2-[1-[(4-flurophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA) has been associated with 40 deaths and 1,000 hospitalizations. No additional public comment was provided.

ADJOURN: The public hearing adjourned at 9:12am.

Cynthia Warriner, Chairman

Caroline D. Juran, Executive Director

Date

Date

(DRAFT/UNAPPROVED)
VIRGINIA BOARD OF PHARMACY
SPECIAL CONFERENCE COMMITTEE MINUTES

Wednesday, April 13, 2016
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 ("Board") was called to order at 9:30 a.m.
PRESIDING:	Ryan K. Logan, Committee Chair
MEMBERS PRESENT:	Rebecca Thornbury, Committee Member
STAFF PRESENT:	Cathy M. Reiniers-Day, Deputy Executive Director Mykl D. Egan, DHP Adjudication Specialist
NICHOLE F. RAFFA License No. 0202-207011	Nichole Raffa appeared with Tracy Buldiga, her sponsor, to discuss the reinstatement of her license and to review allegations that she may have violated portions of the laws and regulations governing the practice of pharmacy as stated in the March 29, 2016, Notice.
Closed Meeting:	Upon a motion by Ms. Thornbury, and duly seconded by Mr. Logan, the Committee unanimously voted to convene a closed meeting pursuant to § 2.2-3711(A)(28) of the Code of Virginia ("Code"), for the purpose of deliberation to reach a decision in the matter of Nichole Raffa. 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. Thornbury, and duly seconded by Mr. Logan, the Committee made certain Findings of Fact and Conclusions of Law and unanimously voted to issue an Order that reinstates her pharmacist license after she successfully completes the requirements of 18 VAC 110-20-80(G).

Adjourn:	With all business concluded, the meeting adjourned at 1:00 p.m.

Ryan K. Logan, Chair

Cathy M. Reiniers-Day
Deputy Executive Director

Date

Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**

Staff Note: Attached is a chart with the status of regulations for the Board as of June 1, 2016

Action: None – provided for information only

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Periodic review result of Chapters 20 and 50; Promulgation of Chapters 16 and 25 [Action 4538] NOIRA - *At Governor's Office for 34 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Addressing hours of continuous work by pharmacists [Action 3755] Proposed - *Register Date: 11/30/15* *Re-consideration at 6/14/16 meeting*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Outsourcing facilities [Action 4452] Proposed - *DPB Review in progress* [Stage 7508]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Proposed - *DPB Review in progress* [Stage 7515]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Inclusion of diazepam rectal gel in emergency kits [Action 4536] Fast-Track - *At Governor's Office for 12 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling of chemicals in Schedule I [Action 4535] Final - *Register Date: 5/16/16* *Effective: 6/14/16*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Permits for facilities [Action 4451] Proposed - *DPB Review in progress* [Stage 7507]

Agenda Item: Adoption of Regulation to Schedule certain chemicals in Schedule I of the Drug Control Act

Staff Note:

There was a Public Hearing conducted at 9:00 this morning pursuant to requirements of § 54.1-3443 of the Drug Control Act.

Included in your packet:

Notice of hearing and request for comment (none received)

Copy of regulation to schedule certain chemicals

Board action:

Adoption of amendments to section 18VAC110-20-322. Placement of chemicals in Schedule I. (Note: the action is exempt from the requirements of the Administrative Process Act pursuant to §2.2-4006)

Scheduling of Chemicals in Schedule I

18VAC110-20-322. Placement of Chemicals in Schedule I.

A. ~~Pursuant to § 54.1-3443 D of the Code of Virginia, the Board of Pharmacy places the following substances in Schedule I of the Drug Control Act:~~

~~1. Cannabimimetic agents:~~

~~a. N-(1-amino-3,3-dimethyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indazole-3-carboxamide (other names: ADB-CHMINACA, MAB-CHMINACA);~~

~~b. Methyl 2-(1-(5-fluoropentyl)-1H-indazole-3-carboxamido)-3-methylbutanoate (other name: 5-fluoro-AMB);~~

~~c. 1-naphthalenyl 1-(5-fluoropentyl)-1H-indole-3-carboxylate (other name: NM-2201); and~~

~~d. 1-(4-fluorobenzyl)-3-(2,2,3,3-tetramethylcyclopropylmethanone)indole (other name: FUB-144).~~

~~2. Substituted cathinones:~~

~~a. 4-bromomethcathinone (other name: 4-BMC); and~~

~~b. 4-chloromethcathinone (other name: 4-CMC).~~

~~The placement of drugs in this subsection shall remain in effect until February 11, 2017, unless enacted into law in the Drug Control Act.~~

~~B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:~~

~~1. Acetyl fentanyl (other name: desmethyl fentanyl).~~

~~2. Etizolam.~~

~~3. 4-Iodo-2, 5-dimethoxy-N-[(2-hydroxyphenyl) methyl]-benzeneethanamine (other name: 25I-NBOH).~~

~~4. Cannabimimetic agent:~~

~~1-(5-fluoropentyl)-3-(4-methyl-1-naphthoyl) indole (MAM-2201).~~

~~5. Substituted cathinones:~~

~~a. Alpha-Pyrrolidinohexiophenone (other name: alpha-PHP); and~~

~~b. Alpha-Pyrrolidinoheptiophenone (other name: PV8).~~

~~The placement of drugs listed in this subsection shall remain in effect until June 1, 2017, unless enacted into law in the Drug Control Act.~~

~~C.~~ Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl)
2. Flubromazolam
3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)
4. Cannabimimetic agents:

    a. N-(1-Amino-3,3-dimethyl-1-oxobutan-2-yl)-1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamide (other name: ADB-FUBINACA)

    b. Methyl 2-[1-[(4-fluorophenyl)methyl]-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other name: MDMB-FUBINACA)

    c.Methyl 2-[1-(5-fluoropentyl)-1H-indazole-3-carboxamido]-3,3-dimethylbutanoate (other names: 5-fluoro-ADB, 5-Fluoro-MDMB-PINACA)

The placement of drugs listed in this subsection shall remain in effect until December 13, 2017, unless enacted into law in the Drug Control Act.

B. Pursuant to subsection D of § 54.1-3443 of the Code of Virginia, the Board of Pharmacy places the following in Schedule I of the Drug Control Act:

1. Beta-keto-N,N-dimethylbenzodioxolylbutanamine (other names: Dibutylone, bk-DMBDB)
2. 1-(1,3-benzodioxol-5-yl)-2-(ethylamino)-1-pentanone (other name: N-ethylpentylone)
3. 1-[1-(3-methoxyphenyl)cyclohexyl]piperidine (other name: 3-methoxy PCP)
4. 1-[1-(4-methoxyphenyl)cyclohexyl]piperidine (other name: 4-methoxy PCP)
5. 4-Chloroethcathinone (other name: 4-CEC)
6. 3-Methoxy-2-(methylamino)-1-(4-methylphenyl)-1-propanone (other name: Mexedrone)
7. 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide (other name: U-47700)
8. 3,4-dichloro-N-{[1-(dimethylamino)cyclohexyl]methyl}benzamide (other name: AH-7921)

9. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-pentanamide (other name: Pentanoyl fentanyl)

10. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-2-furancarboxamide (other name: Furanyl fentanyl)

11. N-(3-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl]-propanamide (other name: 3-fluorofentanyl)

12. Clonazolam

13. Cannabimimetic agents:

a. Methyl 2-({1-[(4-fluorophenyl)methyl]-1H-indazole-3-carbonyl}amino)-3-methylbutanoate

(other names: AMB-FUBINACA, FUB-AMB)

b. N-(adamantan-1-yl)-1-(4-fluorobenzyl)-1H-indazole-3-carboxamide (other name: FUB-AKB48)

c. N-(adamantan-1-yl)-1-(5-fluoropentyl)-1H-indazole-3-carboxamide (other name: 5F-AKB48)

d. Naphthalen-1-yl 1-pentyl-1H-indazole-3-carboxylate (other name: SDB-005)

e. N-(1-amino-3-methyl-1-oxobutan-2-yl)-1-(cyclohexylmethyl)indole-3-carboxamide

(other name: AB-CHMICA)

The placement of drugs listed in this subsection shall remain in effect until (18 months from the effective date of the regulation), unless enacted into law in the Drug Control Act.

Agenda Item: Consideration for Convening a Regulatory Advisory Panel (RAP) for Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil

Included in your agenda package are:

A copy of SB701

A copy of Regulation 18VAC110-11-70 regarding allowance to appoint a regulatory advisory panel

Regulation Committee Recommendation:

Chairman to appoint members to a RAP with goal of meeting 2-3 times this summer and presenting full board with proposed regulatory language at the September full board meeting for adoption. A general notice for those interested in participating was posted.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to amend and reenact §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia and to amend the Code of Virginia by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, relating to cannabidiol oil and THC-A oil; permitting of pharmaceutical processors to manufacture and provide.

[S 701]

Approved

Be it enacted by the General Assembly of Virginia:

1. That §§ 18.2-250.1 and 54.1-3408.3 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Chapter 34 of Title 54.1 an article numbered 4.2, consisting of sections numbered 54.1-3442.5 through 54.1-3442.8, as follows:

§ 18.2-250.1. Possession of marijuana unlawful.

A. It is unlawful for any person knowingly or intentionally to possess marijuana unless the substance was obtained directly from, or pursuant to, a valid prescription or order of a practitioner while acting in the course of his professional practice, or except as otherwise authorized by the Drug Control Act (§ 54.1-3400 et seq.).

Upon the prosecution of a person for violation of this section, ownership or occupancy of the premises or vehicle upon or in which marijuana was found shall not create a presumption that such person either knowingly or intentionally possessed such marijuana.

Any person who violates this section is guilty of a misdemeanor and shall be confined in jail not more than 30 days and fined not more than $500, either or both; any person, upon a second or subsequent conviction of a violation of this section, is guilty of a Class 1 misdemeanor.

B. The provisions of this section shall not apply to members of state, federal, county, city, or town law-enforcement agencies, jail officers, or correctional officers, as defined in § 53.1-1, certified as handlers of dogs trained in the detection of controlled substances when possession of marijuana is necessary for the performance of their duties.

C. In any prosecution under this section involving marijuana in the form of cannabidiol oil or THC-A oil as those terms are defined in § 54.1-3408.3, it shall be an affirmative defense that the individual possessed such oil pursuant to a valid written certification issued by a practitioner in the course of his professional practice pursuant to § 54.1-3408.3 for treatment or to alleviate the symptoms of (i) the individual's intractable epilepsy or (ii) if such individual is the parent or legal guardian of a minor *or of an incapacitated adult as defined in § 18.2-369*, such minor's *or incapacitated adult's* intractable epilepsy. If the individual files the valid written certification with the court at least 10 days prior to trial and causes a copy of such written certification to be delivered to the attorney for the Commonwealth, such written certification shall be prima facie evidence that such oil was possessed pursuant to a valid written certification.

§ 54.1-3408.3. Certification for use of cannabidiol oil or THC-A oil to treat intractable epilepsy.

A. As used in this section:

"Cannabidiol oil" means a processed Cannabis plant extract that contains at least 15 percent cannabidiol but no more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of cannabidiol per milliliter but not more than five percent tetrahydrocannabinol.

"Practitioner" means a practitioner of medicine or osteopathy licensed by the Board of Medicine who is a neurologist or who specializes in the treatment of epilepsy.

"THC-A oil" means a processed Cannabis plant extract that contains at least 15 percent tetrahydrocannabinol acid but not more than five percent tetrahydrocannabinol, or a dilution of the resin of the Cannabis plant that contains at least 50 milligrams of tetrahydrocannabinol acid per milliliter but not more than five percent tetrahydrocannabinol.

B. A practitioner ~~of medicine or osteopathy licensed by the Board of Medicine~~ in the course of his professional practice may issue a written certification for the use of cannabidiol oil or THC-A oil for treatment or to alleviate the symptoms of a patient's intractable epilepsy.

C. The written certification shall be on a form provided by the Office of the Executive Secretary of the Supreme Court developed in consultation with the Board of Medicine. Such written certification shall contain the name, address, and telephone number of the practitioner, the name and address of the patient issued the written certification, the date on which the written certification was made, and the signature of the practitioner. Such written certification issued pursuant to subsection B shall expire no

later than one year after its issuance unless the practitioner provides in such written certification an earlier expiration.

D. No practitioner shall be prosecuted under § 18.2-248 or 18.2-248.1 for dispensing or distributing cannabidiol oil or THC-A oil for the treatment or to alleviate the symptoms of a patient's intractable epilepsy pursuant to a written certification issued pursuant to subsection B. Nothing in this section shall preclude the Board of Medicine from sanctioning a practitioner for failing to properly evaluate or treat a patient's medical condition or otherwise violating the applicable standard of care for evaluating or treating medical conditions.

E. A practitioner who issues a written certification to a patient pursuant to this section shall register with the Board. The Board shall, in consultation with the Board of Medicine, set a limit on the number of patients to whom a practitioner may issue a written certification.

F. A patient who has been issued a written certification shall register with the Board or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, a patient's parent or legal guardian shall register and shall register such patient with the Board.

G. The Board shall promulgate regulations to implement the registration process. Such regulations shall include (i) a mechanism for sufficiently identifying the practitioner issuing the written certification, the patient being treated by the practitioner, and, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian; (ii) a process for ensuring that any changes in the information are reported in an appropriate timeframe; and (iii) a prohibition for the patient to be issued a written certification by more than one practitioner during any given time period.

H. Information obtained under the registration process shall be confidential and shall not be subject to the disclosure provisions of the Virginia Freedom of Information Act (§ 2.2-3700 et seq.). However, reasonable access to registry information shall be provided to (i) the Chairmen of the House and Senate Committees for Courts of Justice, (ii) state and federal agencies or local law enforcement for the purpose of investigating or prosecuting a specific individual for a specific violation of law, (iii) licensed physicians or pharmacists for the purpose of providing patient care and drug therapy management and monitoring of drugs obtained by a registered patient, (iv) a pharmaceutical processor involved in the treatment of a registered patient, or (v) a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, the patient's parent or legal guardian, but only with respect to information related to such registered patient.

Article 4.2.

Permitting of Pharmaceutical Processors to Produce and Dispense Cannabidiol Oil and THC-A Oil.

§ 54.1-3442.5. Definitions.

As used in this article:

"Cannabidiol oil" has the same meaning as specified in § 54.1-3408.3.

"Pharmaceutical processor" means a facility that (i) has obtained a permit from the Board pursuant to § 54.1-3408.3 and (ii) cultivates Cannabis plants intended only for the production of cannabidiol oil or THC-A oil, produces cannabidiol oil or THC-A oil, and dispenses cannabidiol oil or THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian for the treatment of intractable epilepsy.

"Practitioner" has the same meaning as specified in § 54.1-3408.3.

"THC-A oil" has the same meaning as specified in § 54.1-3408.3.

§ 54.1-3442.6. Permit to operate pharmaceutical processor.

A. No person shall operate a pharmaceutical processor without first obtaining a permit from the Board. The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmaceutical processor. The Board shall establish an application fee and other general requirements for such application.

B. Each permit shall expire annually on a date determined by the Board in regulation. The number of permits that the Board may issue or renew in any year is limited to one for each health service area established by the Board of Health. Permits shall be displayed in a conspicuous place on the premises of the pharmaceutical processor.

C. The Board shall adopt regulations establishing health, safety, and security requirements for pharmaceutical processors. Such regulations shall include requirements for (i) physical standards; (ii) location restrictions; (iii) security systems and controls; (iv) minimum equipment and resources; (v) recordkeeping; (vi) labeling and packaging; (vii) quarterly inspections; (viii) processes for safely and securely cultivating Cannabis plants intended for producing cannabidiol oil and THC-A oil, producing cannabidiol oil and THC-A oil, and dispensing cannabidiol oil and THC-A oil to a registered patient or, if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian; (ix) a maximum number of marijuana plants a pharmaceutical processor may possess at any one time; and (x) the secure disposal of plant remains.

D. Every pharmaceutical processor shall be under the personal supervision of a licensed pharmacist

on the premises of the pharmaceutical processor.

E. No person who has been convicted of a felony or of any offense in violation of Article 1 (§ 18.2-247 et seq.) or Article 1.1 (§ 18.2-265.1) of Chapter 7 of Title 18.2 shall be employed by or act as an agent of a pharmaceutical processor.

§ 54.1-3442.7. Dispensing cannabidiol oil and THC-A oil; report.

A. A pharmaceutical processor shall dispense cannabidiol oil or THC-A oil only in person to (i) a patient who is a Virginia resident, has been issued a valid written certification, and is registered with the Board pursuant to § 54.1-3408.3 or (ii) if such patient is a minor or an incapacitated adult as defined in § 18.2-369, such patient's parent or legal guardian who is a Virginia resident and is registered with the Board pursuant to § 54.1-3408.3. Prior to dispensing, the pharmaceutical processor shall verify that the practitioner issuing the written certification, the patient, and if such patient is a minor or an incapacitated adult, the patient's parent or legal guardian are registered with the Board. No pharmaceutical processor shall dispense more than a 30-day supply for any patient during any 30-day period. The Board shall establish in regulation an amount of cannabidiol oil or THC-A oil that constitutes a 30-day supply to treat or alleviate the symptoms of a patient's intractable epilepsy.

B. A pharmaceutical processor shall dispense only cannabidiol oil and THC-A oil that has been cultivated and produced on the premises of such pharmaceutical processor.

C. The Board shall report annually by December 1 to the Chairmen of the House and Senate Committees for Courts of Justice on the operation of pharmaceutical processors issued a permit by the Board, including the number of practitioners, patients, and parents or legal guardians of patients who have registered with the Board and the number of written certifications issued pursuant to § 54.1-3408.3.

§ 54.1-3442.8. Criminal liability; exceptions.

In any prosecution of an agent or employee of a pharmaceutical processor under § 18.2-248, 18.2-248.1, 18.2-250, or 18.2-250.1 for possession or manufacture of marijuana or for possession, manufacture, or distribution of cannabidiol oil or THC-A oil, it shall be an affirmative defense that such agent or employee (i) possessed or manufactured such marijuana for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (ii) possessed, manufactured, or distributed such cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations. If such agent or employee files a copy of the permit issued to the pharmaceutical processor pursuant to § 54.1-3442.6 with the court at least 10 days prior to trial and causes a copy of such permit to be delivered to the attorney for the Commonwealth, such permit shall be prima facie evidence that (a) such marijuana was possessed or manufactured for the purposes of producing cannabidiol oil or THC-A oil in accordance with the provisions of this article and Board regulations or (b) such cannabidiol oil or THC-A oil was possessed, manufactured, or distributed in accordance with the provisions of this article and Board regulations.

2. That, except as provided in the third enactment of this act, the provisions of the first enactment of this act shall not become effective unless reenacted by the 2017 Session of the General Assembly.

3. That the Board of Pharmacy shall promulgate regulations to implement the provisions of the first enactment of this act within 280 days of its initial enactment. Such regulations shall not become effective unless the provisions of the first enactment of this act are reenacted by the 2017 Session of the General Assembly.

18VAC110-11-70. Appointment of Regulatory Advisory Panel.

A. The agency may appoint a regulatory advisory panel (RAP) to provide professional specialization or technical assistance when the agency determines that such expertise is necessary to address a specific regulatory issue or action or when individuals indicate an interest in working with the agency on a specific regulatory issue or action.

B. Any person may request the appointment of a RAP and request to participate in its activities. The agency shall determine when a RAP shall be appointed and the composition of the RAP.

C. A RAP may be dissolved by the agency if:

1. The proposed text of the regulation is posted on the Town Hall, published in the Virginia Register, or such other time as the agency determines is appropriate; or

2. The agency determines that the regulatory action is either exempt or excluded from the requirements of the Administrative Process Act.

Statutory Authority

§§ 2.2-4007.02 and 54.1-2400 of the Code of Virginia.

Historical Notes

Derived from Volume 25, Issue 02, eff. October 29, 2008.

Agenda Item: Fast-track Regulations for amending regulations for "Public Participation Guidelines (PPG)"

Included in your agenda package are:

A copy of the Administrative Process Act relating to PPG's

A copy of the fast-track regulations for consideration by the Regulation Committee

Board action:

Recommendation of the Regulation Committee to adopt by a Fast-track action

Code of Virginia
Title 2.2. Administration of Government
Chapter 40. Administrative Process Act

§ 2.2-4007.02. Public participation guidelines.

A. Public participation guidelines for soliciting the input of interested parties in the formation and development of its regulations shall be developed, adopted, and used by each agency pursuant to the provisions of this chapter. The guidelines shall set out any methods for the identification and notification of interested parties and any specific means of seeking input from interested persons or groups that the agency intends to use in addition to the Notice of Intended Regulatory Action. The guidelines shall set out a general policy for the use of standing or ad hoc advisory panels and consultation with groups and individuals registering interest in working with the agency. Such policy shall address the circumstances in which the agency considers the panels or consultation appropriate and intends to make use of the panels or consultation.

B. In formulating any regulation, including but not limited to those in public assistance and social services programs, the agency pursuant to its public participation guidelines shall afford interested persons an opportunity to (i) submit data, views, and arguments, either orally or in writing, to the agency, to include an online public comment forum on the Virginia Regulatory Town Hall, or other specially designated subordinate and (ii) be accompanied by and represented by counsel or other representative. However, the agency may begin drafting the proposed regulation prior to or during any opportunities it provides to the public to submit comments.

2007, cc. 873, 916; 2012, c. 795.

40

Project 4719 - none

BOARD OF PHARMACY

Conform to APA

Part III

Public Participation Procedures

18VAC110-11-50. Public comment.

A. In considering any nonemergency, nonexempt regulatory action, the agency shall afford interested persons an opportunity to (i) submit data, views, and arguments, either orally or in writing, to the agency; and (ii) be accompanied by and represented by counsel or other representative. Such opportunity to comment shall include an online public comment forum on the Town Hall.

1. To any requesting person, the agency shall provide copies of the statement of basis, purpose, substance, and issues; the economic impact analysis of the proposed or fast-track regulatory action; and the agency's response to public comments received.

2. The agency may begin crafting a regulatory action prior to or during any opportunities it provides to the public to submit comments.

B. The agency shall accept public comments in writing after the publication of a regulatory action in the Virginia Register as follows:

1. For a minimum of 30 calendar days following the publication of the notice of intended regulatory action (NOIRA).

2. For a minimum of 60 calendar days following the publication of a proposed regulation.

3. For a minimum of 30 calendar days following the publication of a reproposed regulation.

4. For a minimum of 30 calendar days following the publication of a final adopted regulation.

5. For a minimum of 30 calendar days following the publication of a fast-track regulation.

6. For a minimum of 21 calendar days following the publication of a notice of periodic review.

7. Not later than 21 calendar days following the publication of a petition for rulemaking.

C. The agency may determine if any of the comment periods listed in subsection B of this section shall be extended.

D. If the Governor finds that one or more changes with substantial impact have been made to a proposed regulation, he may require the agency to provide an additional 30 calendar days to solicit additional public comment on the changes in accordance with § 2.2-4013 C of the Code of Virginia.

E. The agency shall send a draft of the agency's summary description of public comment to all public commenters on the proposed regulation at least five days before final adoption of the regulation pursuant to § 2.2-4012 E of the Code of Virginia.

Agenda Item: Adoption of Re-Proposed Regulations on setting certain conditions on work hours for pharmacists

Included in your agenda package are:

Committee recommendation for a re-proposed amendment

Staff note:

Based on questions and interpretation of proposed language, staff is concerned that the language adopted by the Board does not accurately represent its intent in this action. The recommended re-proposed amendment is in brackets [ ] with the current language stricken.

Since this could be considered a substantive change, it is recommended that the amendment be "re-proposed" and sent for an additional 30-day comment period.

Board action:

Recommendation from the Regulation Committee to adopt the re-proposed amendment

Project 3337

BOARD OF PHARMACY

Addressing hours of continuous work by pharmacists

Part IV

Pharmacies

18VAC110-20-110. Pharmacy permits generally.

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

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day [~~without being allowed~~ with] at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

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

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

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

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

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

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

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

Agenda Item: Recommend that PMP Advance Legislative Proposal to Amend "Covered Substance" to Include Schedule V

Background: VPhA offered comment at the March 2016 full board meeting that the board should consider deeming promethazine with codeine a drug of concern which would require dispensers to report dispensations of the drug to the Prescription Monitoring Program (PMP). Promethazine with codeine is classified as a Schedule V drug. Currently, the law only requires drugs in Schedules II-IV to be reported to the PMP.

Included in your agenda package is:

A copy of relevant laws

Map of states with authority for PMPs to collect dispensation information on Schedule V drugs

Regulation Committee Recommendation:

Committee recommends not deeming promethazine with codeine a drug of concern at this time, but rather recommending to the PMP that it advance a legislative proposal to expand the definition of "covered substance" to include drugs in Schedule V.

§ 54.1-2519. Definitions.

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

"Covered substance" means all controlled substances included in Schedules II, III, and IV and all drugs of concern that are required to be reported to the Prescription Monitoring Program, pursuant to this chapter.

"Drug of concern" means any drug or substance, including any controlled substance or other drug or substance, where there has been or there is the potential for abuse and that has been identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

§ 54.1-2520. Program establishment; Director's regulatory authority.

A. The Director shall establish, maintain, and administer an electronic system to monitor the dispensing of covered substances to be known as the Prescription Monitoring Program. Covered substances shall include all Schedule II, III, and IV controlled substances, as defined in the Drug Control Act (§ 54.1-3400 et seq.), and any other drugs of concern identified by the Board of Pharmacy pursuant to § 54.1-3456.1.

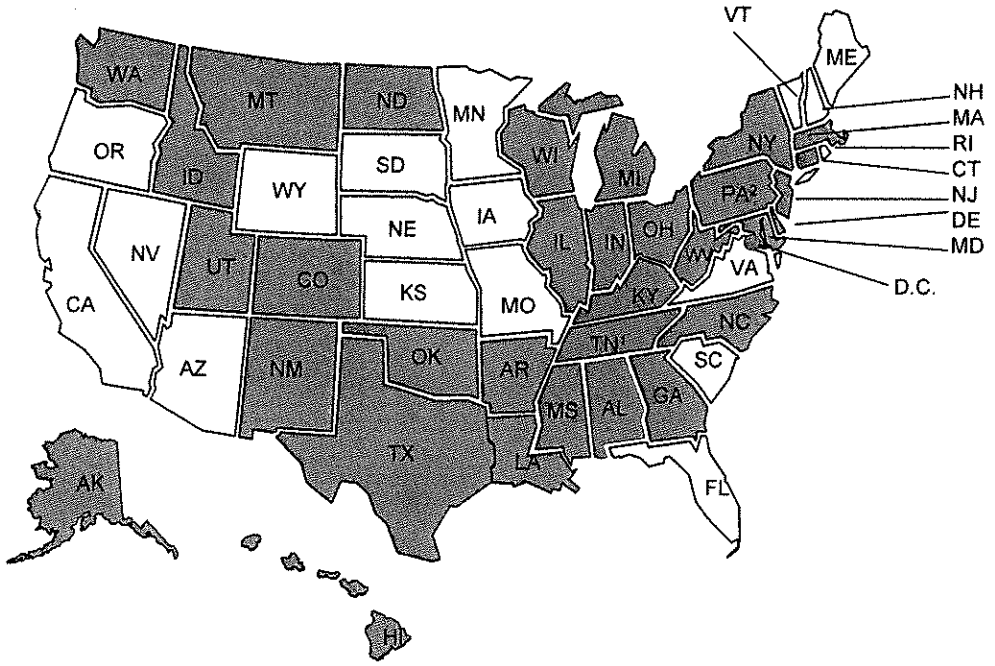
B. The Director, after consultation with relevant health regulatory boards, shall promulgate, in accordance with the provisions of the Administrative Process Act (§ 2.2-4000 et seq.), such regulations as are necessary to implement the prescription monitoring program as provided in this chapter, including, but not limited to, the establishment of criteria for granting waivers of the reporting requirements set forth in § 54.1-2521.

C. The Director may enter into contracts as may be necessary for the implementation and maintenance of the Prescription Monitoring Program.

D. The Director shall provide dispensers with a basic file layout to enable electronic transmission of the information required in this chapter. For those dispensers unable to transmit the required information electronically, the Director shall provide an alternative means of data transmission.

E. The Director shall also establish an advisory committee within the Department to assist in the implementation and evaluation of the Prescription Monitoring Program.

Prescription Drug Monitoring Programs
States With Authority to Monitor Schedule V Substances



[1]Tennessee's law authorizes the monitoring of Schedule V substances which have been identified by the controlled substances database advisory committee as demonstrating a potential for abuse. [2] Pennsylvania will begin collecting data on Schedule V substances on June 30, 2015.

This information was compiled using legal databases, state agency websites and direct communications with state PDMP representatives

Agenda Item: Recommend Gathering of Additional Information from NABP Discussions regarding White Bagging and Brown Bagging

Background: Pharmacy Benefit Manager (PBM) Workgroup agreed that the Board of Pharmacy should address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the process. Full board in March agreed that the Regulation Committee should discuss issues of white bagging and brown bagging. Staff is only aware of Oregon having addressed white bagging in regulation, however, it appears to address reconstitution, but not other forms of compounding, and does not address brown bagging.

Included in your agenda package is:

Excerpts from the PBM Workgroup Report, March 4, 2016

Oregon's Final Rule 3.00.27

NABP Resolution – passed 5/2016

Regulation Committee Recommendation:

Committee recommends gathering additional information from upcoming NABP discussions on white bagging and brown bagging based on adoption of NABP resolution on this matter.

"White bagging and brown bagging"

These are relatively new patient delivery models used by specialty pharmacies that may or may not be owned or associated with a PBM. Brown bagging involves specialty pharmacies mailing specialty drugs to the patient's residence, and white bagging involves specialty drugs being mailed to the prescriber or another pharmacy, e.g., hospital pharmacy, for subsequent administration to a specific individual in the clinical setting. A hospital pharmacist whose health system participates in white bagging indicated to the Workgroup: the specialty pharmacy dispenses the drug(s) pursuant to a patient-specific prescription; the receiving pharmacy may not be aware that drugs are being shipped to it prior to the package arriving; the receiving pharmacy may be required to further compound or reconstitute the already dispensed drug prior to administration and without reviewing the prescription, a process which may not comply with the law; the patient may be delayed in receiving the drug from the specialty pharmacy as it must be mailed from the specialty pharmacy even though the receiving pharmacy may have the prescribed drugs in stock; and the drugs appear to be delivered by the specialty pharmacy in a manner that does not comply with Board of Pharmacy Regulation 18VAC110-20-275. Mr. Gray stated there is a general lack of consistency for how these processes occur. There was consensus among the Workgroup that the Board of Pharmacy should review the practices of white bagging and brown bagging to address any issues of concern.

Parity regarding access to and requirements of plans

Comment was received from several independent pharmacy owners that there is a disparity between chain pharmacies and independent pharmacies regarding access to plans. These individuals stated patients have a right to choose their supplier of drugs, and forcing patients to use mail order pharmacies is violating that right. It was noted that Virginia law does have a freedom of choice requirement in §38.2-3407.7 regarding fully-insured health plans; and therefore, these plans cannot require a patient to use a mail order pharmacy. However, self-insured health plans may require patients to use mail order pharmacies, and both self-insured and fully-insured health plans may require drugs to be obtained from a specialty pharmacy.

Prior authorizations

Several issues related to prior authorizations were discussed. There was general consensus among the pharmacists offering comment and the pharmacy associations that the prior authorization process is overly burdensome; can delay patient access to drugs up to 7-10 days; can increase cost to the patient when the branded drug is covered and the generic drug is not, thereby pushing the patient into the Medicare "donut hole" faster; and can result in the pharmacist not being reimbursed if he or she chooses to provide the patient with the drug prior to receiving approval of the prior authorization or over a weekend when the mail order supply did not arrive in time. Those representing the health plans and PBMs indicated §38.2-3407.15:2 requires fully-insured health plans to process prior authorizations, once the required information is received, within 24 hours for emergencies and 2 business days for non-emergencies. It was also noted that the state does not have oversight of Medicare Part D. There was acknowledgement that the process is time-consuming for prescribers as well, often requiring dedicated administrative staff in the office for processing prior authorization requests. There appeared to be consensus that prior authorizations should not be eliminated, as many acknowledged there are benefits to both patients and payers for drug utilization management,

Specialty drugs

There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:

Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

Oregon's Final Rule

3.00.27 Outlet to Outlet Drug Reconstitution. A pharmacist at a prescription drug outlet may reconstitute a prescription originally dispensed in an unreconstituted form pursuant to a patient-specific order at another prescription drug outlet or nonresident prescription drug outlet provided the following conditions are met:

a. The prescription is delivered directly from the originating outlet to the receiving outlet;

b. The prescription is at no time in the physical possession of the patient until after the prescription has been reconstituted;

c. The prescription is reconstituted according to the corresponding manufacturer's directions;

d. The prescription is not a controlled substance;

e. The pharmacist at the receiving outlet does not alter the prescription or its original labeling in any way other than to reconstitute, re-label for re-dispensing for administration, and properly store the prescription; and

f. The originating outlet is ultimately accountable to the Board for the accurate dispensing of the original prescription, and the receiving outlet is ultimately accountable for the accurate reconstitution and re-dispensing of the prescription.

RESOLUTION NO: **112-1-16**

TITLE: **Study to Review the Practices of "White Bagging" and "Brown Bagging"**

MEMBERSHIP VOTE: **PASS**

WHEREAS, "white bagging" generally refers to a patient-specific medication that is distributed by a pharmacy to a hospital, clinic, physician's office, or pharmacy for later preparation and administration to a patient where allowed by law and "brown bagging" generally refers to a patient-specific medication that is dispensed by a pharmacy to the patient and then brought by the patient to the hospital, clinic, or physician's office for administration;

WHEREAS, the practices of "white bagging" and "brown bagging" are becoming more prevalent and often defined and mandated by third-party payers outside of the authority of the state boards of pharmacy; and

WHEREAS, the need exists for the boards of pharmacy to define such practices and ensure appropriate regulatory oversight in order to protect patients;

THEREFORE BE IT RESOLVED that NABP conduct a study, which may include, if appropriate, other key health care stakeholders to review and define the practices of "white bagging" and "brown bagging" and recommend regulatory language, if necessary, to the *Model State Pharmacy Act and Model Rules of the National Association of Boards of Pharmacy* to assist boards of pharmacy in overseeing and addressing the accountability and safety of medications dispensed and administered via these methods.

Agenda Item: Recommend Meeting of PBM Task Force Subgroup to Address Concerns with Designation of Specialty Drugs

Background: Pharmacy Benefit Manger (PBM) Workgroup members representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported the Board of Pharmacy considering the issue of specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug. PBM Workgroup members representing health care plans and PBMs did not support this policy option. Board counsel opined at the March 2016 full board meeting that the Board does not presently have the authority to define "specialty drug" in regulation. He recommended the term be defined in statute or that the General Assembly could give the Board the authority to define the term in regulation.

Included in your agenda package is:

Excerpts from the PBM Workgroup Report, March 4, 2016

Regulation Committee Recommendation:

Committee recommends forming a subgroup, with representation from those PBM Workgroup members who supported the Board considering the issue of specialty drugs, to identify possible actions that would effectively address the concerns involving specialty drugs as identified in the PBM Workgroup Report.

Report of the Pharmacy Benefit Managers Workgroup

Virginia Department of Health Professions

March 4, 2016

Workgroup Participants

Virginia Department of Health Professions (David E. Brown, D.C., Director, Chairman)
Virginia Board of Pharmacy (Ellen B. Shinaberry, member; Caroline D. Juran, Executive Director)
Virginia Board of Medicine (Kenneth J. Walker, MD, member; William L. Harp, MD, Executive Director)
National Community Pharmacists Association (John Beckner)
Anthem Blue Cross and Blue Shield (Geoffrey S. Ferguson)
Virginia Assbciation of Health Plans (Douglas Gray)
Virginia Department of Health, Division of Disease Prevention (Diana Jordan)
Virginia Department of Health, Office of Licensure and Certification (T.C. Jones, IV)
Medical Society of Virginia (Michael Jurgensen)
Virginia Association of Chain Drug Stores (Rusty Maney)
Pharmaceutical Care Management Association (Jessica S. Mazer, Esq)
Virginia Pharmacists Association (Timothy S. Musselman)
Virginia Department of Medical Assistance Services (Donna Proffitt)
Express-Scripts (John Sisto)
Virginia Bureau of Insurance (Van Tompkins)
Virginia Department of Human Resource Management (Sara Wilson)

Alternates

Virginia Association of Chain Drug Stores (Bill Cropper)
Virginia Board of Pharmacy (Cynthia Warriner)
Virginia Department of Human Resource Management (Walter E. Norman)
Medical Society of Virginia (Kirsten Roberts)

Staff

Laura Z. Rothrock, Executive Assistant & Operations Manager, Director's Office, Department of Health Professions

from mail order pharmacies often owned by PBMs. The Committee expressed concern for those persons employed by PBMs who determine or communicate information regarding drug coverage as this may be considered the practice of pharmacy and these individuals generally are unlicensed persons. Based on the significant amount of public comment received, complexity of issues, and impact on multiple healthcare professions, David Brown, D.C., Director of the Department of Health Professions (DHP), and Caroline Juran, Executive Director of the Board of Pharmacy, recommended that Dr. Brown discuss with William A. Hazel Jr., MD, Secretary of Health and Human Resources, the possibility of forming a workgroup of various stakeholders to review the possible lack of oversight of PBMs. At the June 15, 2015 Board of Pharmacy full board meeting, Dr. Brown reported that Secretary Hazel agreed that a broad-based workgroup should be convened and led by DHP. Any recommendations would be relayed to Secretary Hazel.

Current Oversight:

Current oversight distinguishes between self-insured and fully-insured health plans. An example of a self-insured plan is the plan offered to state employees through the Department of Human Resources Management. There is no state oversight for self-insured (Employee Retirement Income Security Act, aka ERISA) health plans. They are regulated federally. Self-insured plans may require patients to use mail order pharmacies.

Fully-insured health plans are regulated by state and federal law. The Bureau of Insurance (BOI) has the authority to oversee the administration of benefits by fully-insured health plans but does not have authority to directly oversee the PBMs with which the health plans may contract to fulfill certain functions. Oversight of PBMs is indirect, through the contracting fully-insured health plan. Fully-insured health plans may offer financial incentives to patients to use mail order pharmacies but may not require it unless the health plan deems the drug a specialty drug which the health plan may require to be obtained from a specialty pharmacy. The Virginia Department of Health Office of Licensure and Certification (VDH OLC) issues a certificate of quality assurance to fully-insured health plans and focuses more on the quality of services provided by the plan, such as reviewing whether the plan has a clear and strong utilization management/review program, its tracking of clinical performance data (for health maintenance organizations), network adequacy, and a complaint system in place. VDH OLC does not oversee PBMs. Additionally, while the Board of Pharmacy regulates the practice of pharmacy and mail order pharmacies, including specialty pharmacies, which may be associated with a PBM, it does not have direct oversight of PBMs. Oversight of PBMs is limited to the health plan being responsible for its contract PBMs as is the case with other subcontractors the health plan has contracted with to deliver health care benefits to beneficiaries, e.g., behavioral health, vision, and dental.

Role of a PBM and Specialty Pharmacy:

There is no legal definition for a pharmacy benefit manager in Virginia law. PBMs act as a third-party administrator for employers and health plans, managing the pharmacy benefits and negotiating favorable prices with pharmaceutical manufacturers and providers, e.g., pharmacies. The largest PBMs currently include Express Scripts, CVS Caremark, and OptumRx. In the last

decade, large businesses have merged, and many PBMs now have financial relationships with specialty pharmacies, mail order pharmacies, and community pharmacies. Health plans make decisions as to formulary management, plan design, and cost-sharing. The PBM administers the plan per the contract with the client. PBMs' clients include the federal government, state governments, large employers, and health plans. Common approaches in the industry for PBMs to mitigate the high costs of drugs include requiring prior authorizations of certain drugs, requiring certain drugs to be dispensed from a specialty pharmacy or mail order pharmacy, the development of pharmacy networks, disease management, and claims processing. In the 2013 National Association of Boards of Pharmacy *Report of the Task Force on the Regulation of Pharmacy Benefit Managers*, which updated and broadened information from the 1999 Task Force on Licensing of Pharmacy Benefit Managers, the following activities performed by a PBM were identified as activities which may encompass the practice of pharmacy: disease state management; disease compliance management; drug adherence management; drug interaction management; drug utilization management; formulary management; generic alternative program management; generic incentive program management; medical and/or drug data analysis; patient drug utilization review services; prior authorization services; provider profiling and outcomes assessment; refill reminder program management; therapy guidelines management; stop therapy protocol management; wellness management; maintenance of confidential patient information; and, direction or design of the clinical programs for a pharmacy or a group of pharmacies.

While there is no legal definition for a specialty pharmacy, these are mail order pharmacies that have historically been used to dispense drugs that are extremely expensive, have a restricted or limited distribution, or are complex and require special storage, handling, or ongoing monitoring for safety and efficacy. However, there appears to be an increasing trend in the industry to expand the role of specialty pharmacies and require more commonly used drugs that are not complex or expensive to be dispensed from specialty pharmacies. The plan design determines which drugs qualify as a specialty drug and therefore, must be dispensed from a specialty pharmacy. There are no standard criteria for a specialty drug; and the specialty pharmacies may have a financial relationship with the PBMs or may be operated by an independent pharmacy, chain pharmacy or a Health System.

Drugs which require prior authorization cannot be dispensed to the patient until approval is received from the health plan or the PBM, unless the patient is willing to pay the cash price. The purposes of prior authorization are decreasing overall healthcare costs as well as managing health and safety by ensuring the patient is receiving the least expensive, yet most effective drug therapy. Health plans determine which drugs require prior authorization, and this status can vary based on contractual agreements the PBM may have in place with the drug manufacturer or health plan. Patients are often informed by the dispensing pharmacist if a drug requires prior authorization. The pharmacist then notifies the prescriber who must provide the required information to the PBM for processing of the approval request.

Workgroup Activities:

The Workgroup met on October 19, 2015, November 13, 2015, and December 16, 2015. Public comment was received at each meeting; discussion focused primarily on the subjects listed below.

Specialty drugs

There were some comments by Workgroup members and the public regarding the increasing number of drugs being classified by health plans as specialty drugs which often must be dispensed by specialty pharmacies. There is no uniform definition for a specialty drug or specialty pharmacy. At one time, the practice was reserved for expensive or complex drug therapy, but presently it appears specialty drugs are no longer limited to these types of drugs. Commenters in support believe the use of specialty pharmacies increases patient safety and helps decrease overall healthcare costs. Commenters in opposition stated it appears to impact patient safety by unnecessarily delaying patients' receipt of the drug and drive business toward specialty pharmacies that are often owned by PBMs.

Potential Policy Options:

Below are potential policy options that may be taken. There was general consensus for options #1 and 2.

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

Other Possible Policy Options/Considerations:

Those representing pharmacists, pharmacies, and the Medical Society of Virginia generally supported options #3-5. VDH OLC found option #5 feasible with sufficient resources. Those representing health plans and PBMs did not support options #3-5.

3. The Board of Pharmacy will consider the issue involving specialty drugs and whether it should and has the legal authority to define the criteria for a specialty drug.
4. Future policy discussions should include the impact that the closing of pharmacies in a rural setting would have on patient care in that environment.
5. Increase oversight of the administration of pharmacy benefits by reviewing relevant statutes. Such oversight could provide VDH OLC with ability to:
    a. license PBMs;
    b. describe in regulation information which may be collected and/or prohibited from being collected by a PBM during the credentialing process of providers/pharmacies;
    c. define "specialty drug" to describe the criteria to be used in determining drug eligibility; and
    d. receive complaints against PBMs and take enforcement action when warranted.

Collaborative Practice Agreements

Background:

The statement in §54.1-3300.1 that "Nothing in this section shall be construed to supersede the provisions of §54.1-3303." appears to legally conflict with the authorization in the law for a pharmacist to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols and therefore, has led to questions as to how a pharmacist may legally perform these activities. The amendment does not intend to expand on the pharmacist's authority to participate in collaborative practice agreements, but to clarify and support the existing authority in law.

Possible actions:

* • Recommend to the full board that it adopt a legislative proposal to amend §54.1-3300.1 to clarify, notwithstanding the provisions of §54.1-3303, that a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols within a collaborative practice agreement **or**
- Take no action.

* Action recommended by Regulation Committee

§ 54.1-3300.1. Participation in collaborative agreements; regulations to be promulgated by the Boards of Medicine and Pharmacy.

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

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

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

Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and

Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

~~Nothing in this section shall be construed to supersede~~ Notwithstanding the provisions of § 54.1-3303, a pharmacist may issue a prescription to implement, modify, continue, or discontinue drug therapy pursuant to written or electronic protocols within a collaborative practice agreement.

Agenda Item: 2017 Legislative Proposal for Requiring PTCB Certification for Initial Pharmacy Technician Registration

Included in your agenda package is:

A copy of the legislative proposal adopted by the Board in 2015 with an amended effective date of July 1, 2018

Update regarding PTCB's 2020 Initiative

List of ASHP-accredited training programs

Regulation Committee Recommendation:

Committee recommends to the full board that it adopt a legislative proposal requiring PTCB certification for initial pharmacy technician registration with a delayed effective date of July 1, 2018.

Board of Pharmacy

2017 Session of the General Assembly

Draft Legislation

A BILL to amend the *Code of Virginia* by amending section § 54.1-3321 pertaining to registration of pharmacy technicians.

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3321 of the *Code of Virginia* is amended as follows:

§ 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.

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B. To be initially 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.

2. That the provisions of this act shall become effective on July 1, 2018.

Juran, Caroline (DHP)

Subject: FW: Executive Message - PTCB's 2020 Initiative To Require Accredited Education - from the Pharmacy Technician Certification Board

From: Everett McAllister, PTCB Executive Director & CEO [mailto:ptcb@ptcb.org]
Sent: Wednesday, May 11, 2016 3:29 PM
To: Board of Pharmacy
Subject: Executive Message - PTCB's 2020 Initiative To Require Accredited Education - from the Pharmacy Technician Certification Board

Click here if you are having trouble viewing this message.

Message from Executive Director & CEO Everett McAllister

PTCB's 2020 Initiative: Accredited Education Requirement

Dear Caroline,

I want to share some important news about changes in PTCB's Certification Program, including the 2020 initiative. As you know, beginning in 2020, technicians applying for certification for the first time will be required to complete an education program accredited by the American Society of Health System Pharmacists and the Accreditation Council for Pharmacy Education (ASHP/ACPE).

Success So Far

You may recall that in 2013 PTCB announced the 2020 Initiative and a number of other changes we would make in our requirements over 7 years. These are significant changes that require careful implementation to ensure our program provides continued value. I am pleased to report the process has been successful so far; we implemented updates in our continuing education (CE) requirements in 2014, 2015, and 2016 according to the phase-in schedule as planned. These include requiring 20 hours of technician-specific CE, with 1 hour of patient/medication safety CE, and a reduced number of acceptable CE hours that can be earned from college credit and in-service CE. These changes are intended to ensure technicians are educated through programs that are specific to their workplace knowledge and responsibilities.

Accredited Education Requirement in 2020

2020 is 4 years away, and PTCB continues to prepare to implement required accredited education for initial applicants. As pharmacists provide more direct patient care, technicians are being given more responsibility as they assume new and expanding roles; PTCB's new requirement reflects this evolution and is the result of years of collaboration and collective thinking among stakeholders in the pharmacy community. (Please note this requirement will not apply to already certified pharmacy technicians, only to initial certification applicants.)

Your Input: PTCB is Listening

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PTCB regularly interacts with state boards of pharmacy, and with employers, educators, and state associates. We are committed to providing various opportunities for you to inform the implementation process. PTCB also conducts regular surveys to allow our stakeholder community to have input into our program decisions.

We have hosted forums, including the 2014 stakeholder meeting which brought the community together to discuss perspectives on the ASHP/ACPE accreditation process. In 2011, we hosted a summit focused on Consumer Awareness, Resources, Education, State Policy, and Testing (CREST) which led to PTCB's decision to strengthen our certification requirements. We look forward to future events to convene stakeholders to continue to build consensus and share information. The more information we share, the better prepared the community will be for the accredited education requirement.

Preparing for Change: Growing Capacity

We have heard some concerns that the 2020 effective date may not allow enough time for the number of accredited pharmacy technician training programs to reach the level necessary to meet anticipated demand. As evidenced by the chart below, access to accredited programs continues to expand. It is important to note that a number of online education programs are taking steps toward becoming accredited. These programs show promise for employers and technicians by offering potential cost savings, increased capacity, and expanded access, particularly for technicians in rural and remote areas. PTCB will work with you to help ensure your planning allows time to prepare for the new requirement. The PTCB Board anticipated this major change would take time to implement, and thus recommended the gradual 7-year implementation.

Your Impact: Updates in Accredited Education Program Standards

The importance of participating in discussions with PTCB and other stakeholders is illustrated by the December 2015 decision by ASHP/ACPE (collaborating as the Pharmacy Technician Accreditation Commission, PTAC) to adjust the standards for accreditation of technician programs, effective January 1, 2016. These updates include expanded flexibility for training programs to meet requirements regarding the number and types of student experiential activities that must be performed, requiring at least one and encouraging two different contemporary pharmacy practice experiences. The updates, in large part, resulted from stakeholders voicing their views.

Your Participation: Please Contact Us

As always, PTCB requests your input to guide us. The transition to accredited education calls for your involvement and participation. We recently welcomed Miriam Mobley Smith, PharmD, FASHP as PTCB's new Director of Strategic Alliances. Please reach out to her at any time to share your questions or comments at: mmobleysmith@ptcb.org.

Dr. Mobley Smith and/or I are available to meet with you or present at meetings. If you would like us to participate in your conference or lead an information session, please contact Dr. Mobley Smith. We look forward to joining you.

Thank you for your interest. Please share this message with other decision-makers in your organization.

Best regards,

Everett

Everett B. McAllister, MPA, RPh
Executive Director & CEO

Growth in ASHP/ACPE-Accredited Pharmacy Technician Education Programs

(Source: ASHP)

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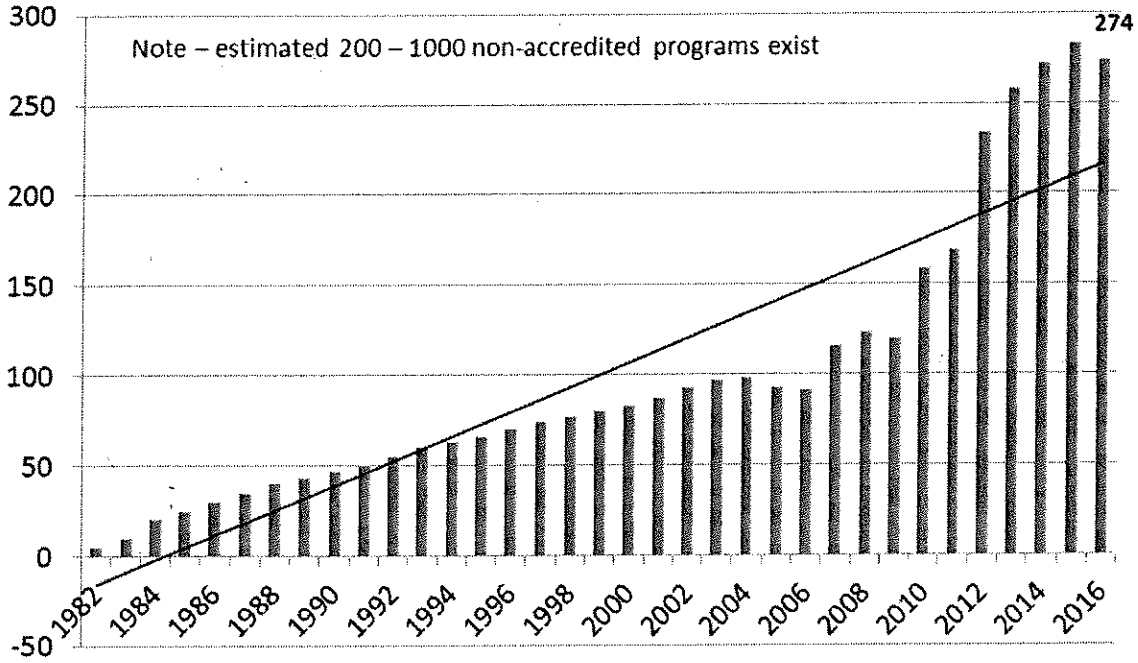


Note: 2016 decrease is due in large part to Corinthian College closures

Join PTCB's Group and follow PTCB's Company Page on LinkedIn.
Like PTCB on Facebook.
Follow PTCB on Twitter!

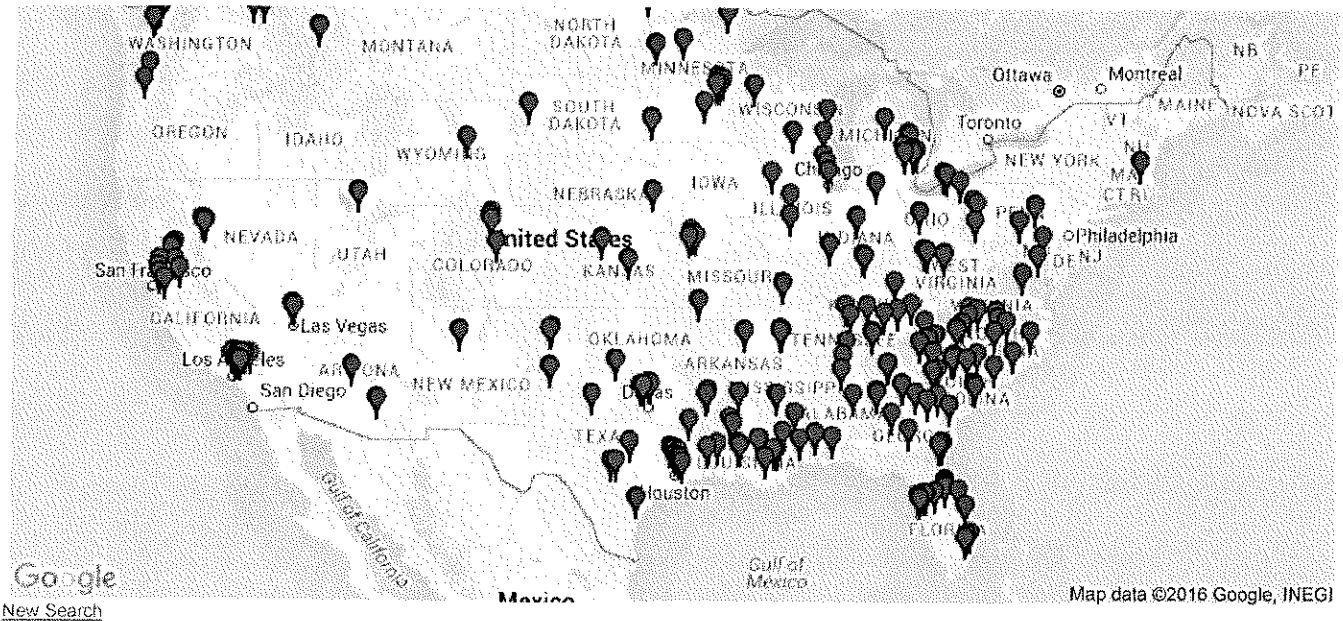
Pharmacy Technician Certification Board
2215 Constitution Avenue, NW
Suite 101
Washington, DC 20037
www.ptcb.org

Pharmacy Technician Training Program Directory

Institution Name:

Location: Select a State/Country

SEARCH



New Search

Name of Site	Type	Code
Alabama		
George C. Wallace State Community College - Hanceville	Community College	AL-01
Remington College - Mobile	Technical College	AL-06
Virginia College - Birmingham	Technical College	AL-05
Virginia College - Huntsville	Technical College	AL-04
Virginia College - Montgomery	Community/Technical College	AL-02
Virginia College of Mobile	Technical College	AL-03
Arkansas		
Arkansas State University - Beebe	University	AR-01
Walmart Stores, Inc	Chain Based Retail Pharmacy	AR-04
Arizona		
Arizona College of Allied Health	Technical College	AZ-03
Carrington College - Mesa	Technical College	AZ-06
Carrington College - Phoenix	Technical College	AZ-05
Carrington College - Tucson	Technical College	AZ-04
Central Arizona College - San Tan Campus	Technical College	AZ-07
Pima Community College	Community College	AZ-01
California		
American Career College - Anaheim	Technical College	CA-27
American Career College - Los Angeles	Technical College	CA-18
American Career College - Ontario	Technical College	CA-33
Career Networks Institute	Technical College	CA-02
Carrington College - Citrus Heights	Vocational/Tech School	CA-32
Carrington College - Pleasant Hill	Vocational/Tech School	CA-26
Carrington College - Pomona	Vocational/Tech School	CA-52
Carrington College - Sacramento	Vocational/Tech School	CA-06

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Carrington College - San Jose	Vocational/Tech School	CA-20
Carrington College - San Leandro	Vocational/Tech School	CA-13
Carrington College - Stockton	Vocational/Tech School	CA-31
Cerritos College	Community College	CA-17
Charles A. Jones Career and Education Center, Sacramento City Unified School District	Technical College	CA-19
Cosumnes River College	Technical College	CA-47
Fast Response Safety Training Center, Inc DBA Fast Response School of Health Care	Other	CA-55
Foothill College (Middlefield Campus)	Community College	CA-23
Modesto Junior College	Technical/Community	CA-01
North Orange County Community College District, School of Continuing Education	Community College	CA-30
North-West College - Glendale	Vocational/Tech School	CA-12
North-West College - Pasadena	Vocational/Tech School	CA-10
North-West College - Pomona	Vocational/Tech School	CA-11
North-West College - West Covina	Vocational/Tech School	CA-04
San Bernardino Valley College	Technical College	CA-53
Santa Ana College	Community College	CA-03
Therapeutic Research Center	Other	CA-54
Unitek College	Technical College	CA-56
Colorado		
Arapahoe Community College	Community College	CO-02
Everest College - Thornton College	Private University Technical/Community	CO-06
Exempla Pharmacy Technician Training Academy	Medical Center	CO-01
Front Range Community College	Community College	CO-03
Pikes Peak Community College	Community College	CO-04
Florida		
Broward College	Technical College	FL-34
Everest College - Brandon Campus	Technical College	FL-28
Everest College - Orange Park	Technical College	FL-30
Everest University - Jacksonville Campus	Technical College	FL-24
Everest University - Lakeland	Technical College	FL-29
Everest University - Largo	Technical College	FL-15
Everest University - Melbourne	Community/Technical College	FL-06
Everest University - Orlando	Technical College	FL-18
Everest University - Orlando	Technical College	FL-23
Everest University - Pompano Beach	Technical College	FL-25
Everest University - Tampa	Technical College	FL-21
Henry W. Brewster Technical Center	Vocational/Tech School	FL-02
McFatter Vocational Technical Center	Vocational/Tech School	FL-03
Orange County Public Schools	Vocational/Tech School	FL-10
Pasco Hernando State College	University	FL-33
Pinellas Technical Education Center	Vocational/Tech School	FL-01
Southeastern College - Clearwater Campus	Vocational/Tech School	FL-14
Southeastern College - Miami Lakes Campus	Vocational/Tech School	FL-13
Southeastern College -West Palm Beach Campus	Vocational/Tech School	FL-12
Technical Education Center Osceola	Technical College	FL-17
Virginia College - Fort Pierce	Technical College	FL-31
Virginia College - Jacksonville	Technical College	FL-27
Virginia College in Pensacola	Technical College	FL-22
Georgia		
Albany Technical College	Technical College	GA-10
Atlanta Technical College	Technical College	GA-07
Augusta Technical College	Technical College	GA-13
Central Georgia Technical College	Technical College	GA-08
Columbus Technical College	Technical College	GA-06
Everest College - Atlanta West	Technical College	GA-14
Oconee Fall Line Technical College	Technical College	GA-15
Ogeechee Technical College	Technical College	GA-04
Southeastern Technical College	Technical College	GA-03
Southern Crescent Technical College	Technical College	GA-16
Virginia College - Augusta	Technical College	GA-05
Virginia College - Columbus		

	Technical College	GA-12
Virginia College - Macon	Technical College	GA-09
Virginia College - Savannah	Technical College	GA-11
Wiregrass Georgia Technical College	Technical College	GA-01
Idaho		
Carrington College - Boise	Technical College	ID-03
Lewis-Clark State College	Technical College	ID-02
North Idaho College	Technical College	ID-01
Illinois		
Malcolm X College	Vocational/Tech School	IL-03
Midwest Technical Institute - East Peoria	Technical College	IL-01
Midwest Technical Institute - Moline	Technical College	IL-14
Midwest Technical Institute - Springfield	Technical College	IL-06
South Suburban College	Community College	IL-02
Walgreen Co.	Other	IL-05
Indiana		
Indiana University Health	Health System	IN-01
Ross Medical Education Center - Fort Wayne	Community/Technical College	IN-04
Vincennes University	Technical College	IN-05
Kansas		
Hutchinson Community College	Community College	KS-03
Johnson County Community College	Technical College	KS-04
North Central Kansas Technical College	Technical College	KS-02
Kentucky		
Ashland Community and Technical College	Technical College	KY-05
Jefferson Community and Technical College	Community/Technical College	KY-03
KCTCS Somerset Community College	Community College	KY-04
Ross Medical Education Center - Bowling Green	Technical College	KY-06
Sullivan University	University	KY-02
Louisiana		
Allied Prep Technical Institute	Technical/Community	LA-21
Ayers Career College	Technical College	LA-07
Bossier Parish Community College	Community College	LA-02
Delgado Community College	Community College	LA-04
Fortis College Baton Rouge	Technical College	LA-22
Healthcare Training Institute	Technical College	LA-20
Infinity College	Technical College	LA-18
Louisiana State University at Alexandria	Community College	LA-03
Northshore Technical Community College	Community College	LA-08
Remington College - Baton Rouge	Technical College	LA-11
Remington College - Lafayette	Technical/Community	LA-10
Remington College - Shreveport	Technical College	LA-09
Unitech Training Academy - Houma	Vocational/Tech School	LA-15
Unitech Training Academy - Lake Charles	Vocational/Tech School	LA-13
Unitech Training Academy - Metairie	Vocational/Tech School	LA-12
Unitech Training Academy - West Monroe	Vocational/Tech School	LA-16
Unitech Training Academy-Alexandria	Vocational/Tech School	LA-14
Unitech Training Academy-Lafayette	Vocational/Tech School	LA-17
Virginia College - Baton Rouge	Technical College	LA-01
Virginia College - Shreveport/Bossier City	Technical/Community	LA-05
Maryland		
Anne Arundel Community College	Community College	MD-04
Hagerstown Community College	Community College	MD-02
Michigan		
Everest Institute - Detroit	Technical College	MI-07
Henry Ford College	Community College	MI-02
MedCerts	Technical College	MI-11
Mid Michigan Community College - Mt. Pleasant	Community College	MI-04
Ross Medical Education Center - Brighton	Technical College	MI-09
Ross Medical Education Center - Davison	Technical College	MI-08
Ross Medical Education Centers LLC - Saginaw		

	Technical College	MI-10
Washtenaw Community College	Community College	MI-03
Wayne County Community College	Community College	MI-01
Minnesota		
Hennepin Technical College	Technical College	MN-11
Hibbing Community College	Community College	MN-04
Minnesota State Community and Technical College	Community/Technical College	MN-03
National American University - Bloomington	University	MN-08
National American University - Brooklyn Center	University	MN-09
National American University - Roseville	University	MN-05
Northland Community and Technical College	Community/Technical College	MN-02
Saint Paul College	Technical College	MN-15
South Central College	Technical College	MN-10
Missouri		
Concorde Career College - Kansas City	Technical College	MO-06
National American University - Independence	Technical College	MO-04
National American University - Zona Rosa	Technical College	MO-03
Mississippi		
Jones County Junior College	Community College	MS-02
Virginia College - Biloxi	Technical College	MS-04
Virginia College - Jackson	Technical College	MS-03
Montana		
Missoula College at the University of Montana	Technical College	MT-01
North Carolina		
Asheville-Buncombe Technical Community College	Technical/Community	NC-09
Cabarrus College of Health Sciences	Vocational/Tech School	NC-05
Cape Fear Community College	Community College	NC-03
Central Piedmont Community College	Community College	NC-11
Craven Community College	Community/Technical College	NC-06
Davidson County Community College	Community College	NC-07
Durham Technical Community College	Community College	NC-01
Fayetteville Technical Community College	Community College	NC-14
Forsyth Technical Community College	Community/Technical College	NC-04
Johnston Community College	Community College	NC-12
Southeastern Institute - Charlotte	Technical/Community	NC-10
Virginia College - Greensboro	Technical College	NC-08
Wake Technical Community College	Technical/Community	NC-13
North Dakota		
North Dakota State College of Science	Community/Technical College	ND-01
Turtle Mountain Community College	Community College	ND-02
Nebraska		
Southeast Community College	Community College	NE-01
New Jersey		
Everest Institute - South Plainfield	Technical College	NJ-02
New Mexico		
Carrington College - Albuquerque	Technical College	NM-02
Central New Mexico Community College	Community College	NM-01
Nevada		
Career College of Northern Nevada	Technical/Community	NV-05
Carrington College - Las Vegas	Technical College	NV-09
College of Southern Nevada	Technical College	NV-02
Kaplan College - Las Vegas	Vocational/Tech School	NV-03
Milan Institute - Las Vegas	Technical College	NV-07
Milan Institute - Sparks	Technical College	NV-01
Pima Medical Institute	Technical College	NV-04
Sierra Nevada Job Corps	Vocational/Tech School	NV-08
Ohio		
Cleveland Clinic	Health System	OH-06
Cuyahoga Community College	Community College	OH-01
Everest Institute - Gahanna	Technical College	OH-08
Ross Education, LLC - Niles Campus 207	Technical College	OH-09

Oklahoma		
Tulsa Technology Center	Technical College	OK-01
Oregon		
Carrington College - Portland	Technical College	OR-06
Central Oregon Community College	Community College	OR-07
Chemeketa Community College	Community College	OR-01
Everest College - Portland	Technical College	OR-05
Everest College - Tigard	Technical College	OR-04
Pennsylvania		
Bidwell Training Center, Inc.	Vocational/Tech School	PA-05
Community College of Allegheny County	Community College	PA-03
Rite Aid Pharmacy	Other	PA-06
Rhode Island		
CVS/pharmacy	Other	RI-01
South Carolina		
Aiken Technical College	Technical College	SC-08
Central Carolina Technical College	Technical College	SC-16
Greenville Technical College	Technical College	SC-02
Horry-Georgetown Technical College	Technical College	SC-05
Midlands Technical College	Technical College	SC-01
Piedmont Technical College	Technical College	SC-06
Remington College - Columbia	Technical College	SC-17
Southeastern Institute	Vocational/Tech School	SC-15
Spartanburg Community College	Community/Technical College	SC-04
Tri-County Technical College	Community/Technical College	SC-07
Trident Technical College	Technical College	SC-03
Virginia College - Columbia	Technical College	SC-12
Virginia College - Florence	Technical College	SC-18
Virginia College - Greenville	Community/Technical College	SC-09
Virginia College - North Charleston	Technical College	SC-13
Virginia College - Spartanburg	Technical/Community	SC-14
South Dakota		
National American University	Vocational/Tech School	SD-03
Southeast Technical Institute	Technical College	SD-02
Western Dakota Technical Institute	Technical College	SD-01
Tennessee		
Chattanooga State Technical Community College	Community/Technical College	TN-05
Concorde Career College - Memphis	Vocational/Tech School	TN-03
Fortis Institute - Cookeville	Technician Institute	TN-14
Remington College - Memphis	Technical College	TN-16
Remington College - Nashville	Technical College	TN-15
Roane State Community College	Community College	TN-09
Southwest Tennessee Community College	Community College	TN-10
Tennessee College of Applied Technology Murfreesboro	Technical College	TN-04
Tennessee College of Applied Technology-Memphis	Technical College	TN-06
Virginia College - Knoxville	Technical College	TN-13
Virginia College School of Business and Health - Chattanooga	Vocational/Tech School	TN-12
Walters State Community College	Community College	TN-08
Texas		
Amarillo College	Vocational/Tech School	TX-22
Angelina College	Community College	TX-05
Austin Community College	Community College	TX-12
Carrington College - Mesquite	Technical College	TX-42
Cisco Junior College	Community College	TX-08
College of the Mainland	Community College	TX-30
Del Mar College	Vocational/Tech School	TX-23
El Paso Community College	Community College	TX-06
Everest College - Dallas Mid-Cities Campus	Technical College	TX-36
HCC Coleman College for Health Sciences	Community College	TX-02
Lamar State College - Orange	Community College	TX-10
Lone Star College - Tomball		

	Community College	TX-24
Lone Star College-North Harris	Community College	TX-18
Medical Education and Training Campus	Military School	TX-33
Milan Institute - Amarillo	Technical College	TX-34
Northwest Vista College	Community College	TX-11
Remington College - Dallas Campus	Technical College	TX-35
Remington College - Fort Worth	Vocational/Tech School	TX-40
Remington College - Houston	Technical College	TX-38
Remington College - Webster	Technical College	TX-39
Richland College	Community College	TX-03
San Jacinto College, North	Community College	TX-14
San Jacinto College, South	Community College	TX-17
South Texas College	Technical College	TX-09
Vernon College	Community/Technical College	TX-20
Virginia College - Austin	Vocational/Tech School	TX-26
Virginia College in Lubbock	Technical College	TX-37
Utah		
Eagle Gate College	Technical College	UT-04
Granite Technical Institute	Technical College	UT-03
Virginia		
Everest College - Chesapeake	Technical College	VA-04
Virginia College in Richmond	Technical College	VA-03
Washington		
Carrington College - Spokane	Technical College	WA-10
Clover Park Technical College	Technical College	WA-04
Edmonds Community College	Community College	WA-11
Everest College - Bremerton	Technical College	WA-08
Everest College - Everett	Community/Technical College	WA-07
Everest College - Renton	Private University Technical/Community	WA-06
Everest College - Tacoma	Technical College	WA-09
North Seattle College	Community College	WA-05
Renton Technical College	Technical College	WA-02
Spokane Community College	Community College	WA-03
Wisconsin		
Chippewa Valley Technical College	Technical College	WI-03
Gateway Technical College	Technical College	WI-07
Lakeshore Technical College	Technical College	WI-05
Milwaukee Area Technical College	Technical College	WI-01
UW Health	Health System	WI-06
West Virginia		
Carver Career and Technical Education Center	Vocational/Tech School	WV-01
Mountwest Community and Technical College	Technical/Community	WV-02
Ross Medical Education Centers LLC - Charleston	Technical College	WV-04
Ross Medical Education Centers LLC - Morgantown	Technical College	WV-03
Wyoming		
Casper College	Community/Technical College	WY-01

Consider 2017 Legislative Proposal for Addressing Compounding Best Practices

Included in agenda package:

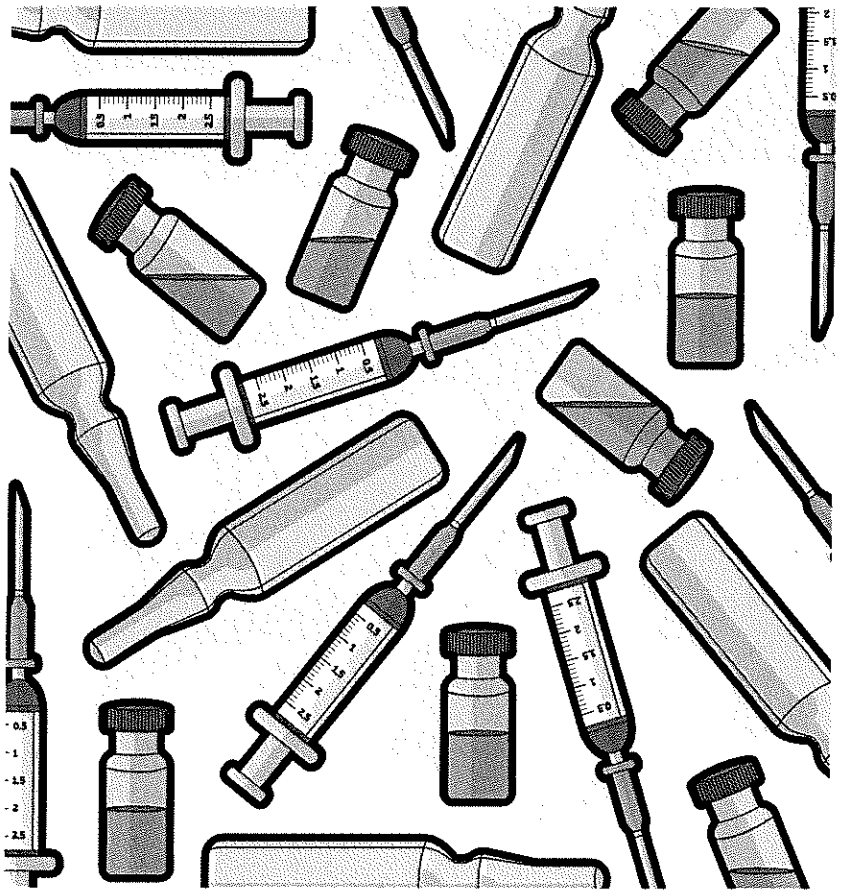
A copy of the Appendix from the Pew Charitable Trusts report summarizing Best Practices for State Oversight of Drug Compounding

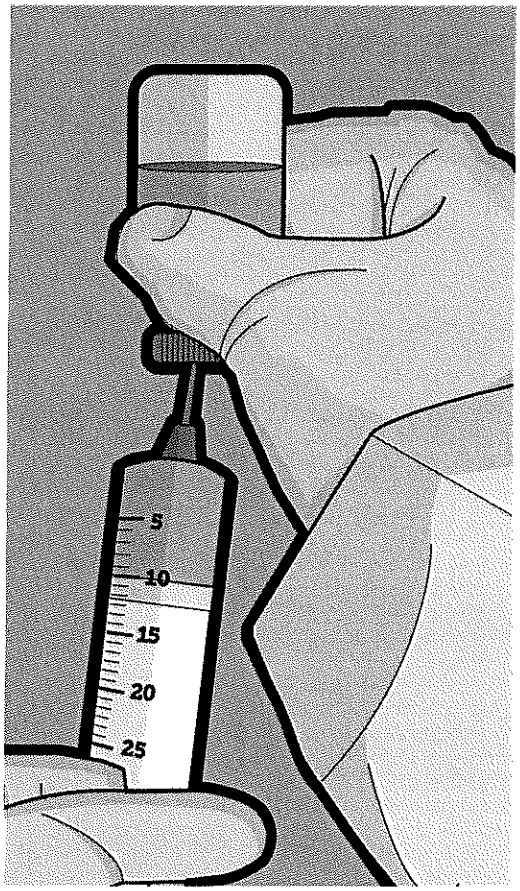
Possible actions:

- Recommend to the full board that it adopt a legislative proposal for any identified possible gaps in oversight, e.g., recalls, seizures of drug, quarantine **or**
- Take no action.

* Regulation Committee recommended no action

A report from THE PEW CHARITABLE TRUSTS | March 2016





Best Practices for State Oversight of Drug Compounding

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The Pew Charitable Trusts

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Appendix

Best Practices for State Oversight of Drug Compounding

Quality standards

States should require traditional compounding pharmacies to comply, at minimum, with all applicable U.S. Pharmacopeial (USP) Convention standards, including general chapters <795> and <797>, new chapter <800> when complete, and other referenced chapters.

States should hold out-of-state traditional compounding pharmacies that ship into the state to USP standards at a minimum.

States should ensure that revisions of USP standards are reflected in state requirements.

Equipment certification and lab accreditation

States should require that all sterile compounding facilities and critical air control devices be certified by a qualified individual at least every six months (as required by USP <797>) using standard testing protocols such as those endorsed by the Controlled Environment Testing Association (CETA).

States should require that sterile compounders use only external testing labs that are clinical or environmental labs with appropriate accreditation.* Labs should also meet the International Organization for Standardization and the International Electrotechnical Commission 17025:2005† quality standard, General Requirements for the Competence of Testing and Calibration Laboratories.

Pharmacist training

In addition to USP <797> training expectations, states should require pharmacists who perform or supervise sterile compounding to receive regular specialized training in the practice, whether through continuing education or certification programs.

Training must include classroom and practical components and must cover core elements of USP <797> (see section on quality standards).

States should require compounders to document that all personnel engaging in or supervising sterile compounding are qualified and have had appropriate training. Compounders should provide such documentation upon request.

Recommendation for other stakeholders: Accreditation Council for Pharmacy Education (ACPE) should adopt core curriculum standards for schools of pharmacy that include training on nonsterile and sterile compounding, in conformance with USP requirements.

* Appropriate accreditation for clinical labs could include, for example, Clinical Laboratory Improvement Amendments accreditation or College of American Pathologists accreditation. Appropriate accreditation for environmental labs could include, for example, review by the American Association for Laboratory Accreditation, American Industrial Hygiene Association's Laboratory Accredited Programs LLC, or National Environmental Laboratory Accreditation Conference accreditation.

† The nonprofit International Organization for Standardization creates standardized international specifications for numerous types of business operations and products across many industry sectors.

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Inspections

Frequency

States should inspect nonsterile compounding facilities at least every two years and sterile compounding facilities yearly. States should have sufficient staff and funding to achieve these frequencies.

When resources are constrained, states should use a risk-based assessment to prioritize inspections, emphasizing high-risk compounding (e.g., preparing sterile drugs from nonsterile ingredients). States may also review documents to supplement in-person inspections.

States should also conduct facility inspections if the compounding pharmacy remodels or relocates, and such changes must be reported to the state. Before sterile products can be released from a remodeled or relocated facility, a successful inspection should be required.

Out-of-state pharmacies should be subject to the same frequency of inspections as in-state pharmacies, whether conducted by the state or a third party.

Process

Inspections should be conducted by the state or by a trusted, qualified third party approved by the state.

Inspections should include examinations specific to the compounding activity, such as sterile or high-risk compounding, with sterile compounding activities assessed for minimum core components of USP <797> (see section on quality standards).

States should utilize a formalized inspection document that adequately describes what was observed on an inspection to ensure compounder adherence to appropriate quality standards for the activities being conducted.

Inspections should be unannounced.

Inspections should be long enough (or include return visits) to permit direct observation of the highest risk compounding activity performed at the site. If this is not possible, states should require compounders to simulate, or compound for observation, the sterile products most challenging to make. States should also review the results of prior media fill (compounding simulations) tests that simulate the compounder's most challenging sterile product processes.

States should have the ability to take and test samples of sterile compounded drugs when needed, such as for inspections or investigations. States should have sufficient funding and, if needed, authority to support these activities. States should have a relationship with a qualified lab to perform analysis.

Recommendation for other stakeholders: The National Association of Boards of Pharmacy, or other similar credible organization, should work with states to create a standardized inspection form to support harmonization of state oversight.

Inspections by regulators in other states or by third parties

If the state relies on another state or a third party to perform inspections, the inspection process must sufficiently assess, and the inspection report must demonstrate compliance with, USP standards at minimum. Inspection reports must describe the specific criteria reviewed and whether compliance was met.

States should approve in advance any third parties permitted to conduct inspections and regularly confirm that these inspectors are meeting qualification criteria.

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Third-party inspectors should provide the state with timely notification of any compliance failures and with all documentation related to the inspection.

Inspector qualifications

State and third-party inspectors should be competent to examine the type of facility they are reviewing. This includes pharmacies engaging in traditional sterile compounding or handling nuclear/radiopharmaceuticals (knowledge of and experience in inspecting for applicable USP requirements), or outsourcing facilities for those states that elect to inspect them (knowledge of and experience in inspecting for relevant current Good Manufacturing Practices). States may also choose to rely on FDA inspections of outsourcing facilities (see outsourcing facilities section).

Inspectors should receive initial training before conducting inspections and ongoing follow-up training to stay current with updated standards. Training should include a classroom component and practical experience. States should allocate sufficient financial resources to support both initial and follow-up training for state inspectors. Third-party inspectors must be able to show proof of training.

Documentation of inspections and findings

States should document all inspections and inspectional findings in writing, which should include an inspection report form or checklist clearly indicating the standards reviewed and observed; documentation may also include additional narrative as needed.

States should give compounders a written description of any problems discovered during inspections and request a written response describing how problems will be addressed. States should follow up with facilities to ensure appropriate responses and actions.

Pharmacy licensure

Pre-licensure inspection

States should conduct an inspection before initial licensure of a traditional compounding pharmacy and before compounding activity begins at a licensed traditional pharmacy.

States may rely on FDA licensure and inspections for outsourcing facilities. However, if the state elects to license and inspect outsourcing facilities before licensure, inspections must be to cGMP standards (see outsourcing facilities section).

Specific licensure requirements for sterile compounding

States should have a mechanism to identify facilities that engage in sterile compounding that ship or dispense drugs in the state and must have a targeted ability to enforce standards specific to sterile compounding. The optimal way to achieve this is through separate licensure for sterile compounders.

Licensure requirements should include quality standards for sterile compounding (i.e., USP <797>).

Out-of-state pharmacies

States should independently license out-of-state pharmacies, which should be inspected before initial licensure or before compounding activity begins at a licensed traditional pharmacy.

If the state cannot conduct an inspection before initial licensure, it may rely on an inspection report by the state where the pharmacy is located or on an inspection by a qualified third party. In either case, the inspection must have been performed in the previous year, and the report must sufficiently demonstrate compliance with USP standards at minimum and describe the specific criteria reviewed and whether compliance was met.

Outsourcing facilities

States should recognize outsourcing facilities in regulation or statute and incorporate a state law definition that is aligned with federal law.

If states wish to formally track outsourcing facilities that do business in their state via separate registration or licensure, registration with FDA should be a prerequisite.

All production at an outsourcing facility must meet applicable cGMPs. States may:

- Rely on FDA to conduct oversight.
- Require an inspection report demonstrating compliance with cGMPs.
- Conduct their own inspections. States that wish to inspect outsourcing facilities must ensure inspectors have the appropriate training to assess adherence to applicable cGMP standards.

Outsourcing facilities that conduct patient-specific compounding and dispensing must also be licensed as a pharmacy with the state, but the quality standard applied to the facility must be cGMP, not USP <797>. Records of compounded products prepared based on a patient-specific prescription must be maintained separately from records of non-patient-specific compounded products, so that these distinct records are readily retrievable.

Compounding without prescriptions, violations of federal law

Compounding without prescriptions

States should align laws and regulations with federal laws and regulations on compounding and dispensing/distributing without prescriptions.

States should prioritize enforcement oversight on higher-risk activities—such as compounding pharmacies producing products without prescriptions on a larger scale—that in the event of contamination can affect more patients.

States should establish policies that support provider purchasing of compounded drugs without prescriptions only from FDA-registered outsourcing facilities.

Compounding in violation of federal law

State regulators should identify any compounding entities that operate in violation of federal law and either require them to cease this activity or, if appropriate, register with FDA as an outsourcing facility. State regulators should report to FDA any facilities that refuse to either cease activities in violation of federal law or, if appropriate, register with FDA as an outsourcing facility.

Physician's office compounding

Physicians' offices that compound should be held to the same standards as other compounding facilities, including quality standards (e.g., USP <797>) and reporting standards.

The state should have a mechanism for knowing which doctors' offices are conducting sterile compounding and should inspect these offices to ensure compliance. This oversight can be done by the state medical board or state board of pharmacy. If by the state medical board, inspectors must receive appropriate training.

Continued on next page

There should be an exemption for compliance by physicians' offices with full USP <797> for immediate-use drugs (which are administered within the hour, as defined by USP). However, practitioners compounding in doctors' offices must still have training and be held to a standard of care that includes good hand hygiene and aseptic technique, per USP standards. The immediate-use exemption cannot apply to hazardous drugs.

Recommendation for other stakeholders: The Federation of State Medical Boards should work with the National Association of Boards of Pharmacy to address physician's office compounding and identify appropriate oversight systems, whether through state medical boards, state boards of pharmacy, or other appropriate entities.

Activity and adverse event reporting

Activity reporting

States should be able to track the type of compounding activities conducted by pharmacies in the state including sterile, nonsterile, and high-risk compounding. States should require compounders to report this information to the state, whether through licensure application or renewal, or through a separate activity reporting mechanism.

States should have the authority to request reports from traditional compounding pharmacies on the number and volume of compounded products sold or dispensed in the state and, for in-state pharmacies, outside the state in the previous year, including the drug's active ingredients, strength, and dosage form. States should be able to request this information outside of an inspection.

States should have the authority to request the reports outsourcing facilities give to FDA identifying the drugs compounded in the previous six months, including the drug's active ingredients, strength, and dosage form.

Adverse event and recalls reporting

Traditional compounding pharmacies should be required to report serious adverse events (as defined by FDA)[1] to the state board of pharmacy within 24 hours.

Traditional compounding pharmacies should be required to report voluntary recalls to the state and FDA within 24 hours. The state should review voluntary recalls to ensure that actions taken to communicate with providers and/or remove products from the market sufficiently mitigate risk to patients.

States that elect to license outsourcing facilities may also decide to require these facilities to report serious adverse events to the state.

[1] U.S. Food and Drug Administration, "What Is a Serious Adverse Event?" updated Jan. 10, 2014, http://www.fda.gov/Safety/MedWatch/HowToReport/ucm053087.htm. FDA defines a serious adverse event associated with the use of a medical product in a patient as a death, life-threatening event, hospitalization, disability or permanent damage, congenital anomaly or birth defect, or an event that may require medical or surgical intervention to prevent one of these outcomes.

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State authorities and sanctions

State authorities

States should have the authority to quarantine products.

States should have the authority to seize products.

States should have the authority to suspend activity the state believes to be in violation of applicable law or regulation in advance of a hearing when the potential for serious patient harm exists.

States should have the authority to mandate recalls of compounded drugs when there is potential or confirmed harm to a patient.

States should have the authority to require compounders to notify providers and patients about recalled products to protect public health.

States should have the authority to share information with other regulators, both federal and state, to support oversight and investigations.

Sanctions and penalties

States should post sanctions and disciplinary actions on a public website.

Recommendation for other stakeholders: An independent third party, such as the National Association of Boards of Pharmacy, should establish a central resource of public enforcement actions taken against compounding pharmacies and outsourcing facilities by state regulators, as well as product recalls. FDA enforcement actions, which the agency already posts publicly, could also be incorporated.

One Prescription per Blank Prohibition

Background:

Constituent of Senator Ebbins requested Board of Pharmacy to remove the one prescription per blank prohibition. Ms. Juran informed the Senator and constituent that it would require an amendment of §54.1-3408.01 and that she would bring the issue to the Board's attention.

Possible actions:

- Recommend to the full board that it adopt a legislative proposal to amend §54.1-3408.01 by removing the prohibition that a written prescription shall not include more than one prescription, **or**
- Take no action.

* Regulation Committee's recommendation

2017 DRAFT Legislative Proposal

§ 54.1-3408.01. Requirements for prescriptions.

A. The written prescription referred to in § 54.1-3408 shall be written with ink or individually typed or printed. The prescription shall contain the name, address, and telephone number of the prescriber. A prescription for a controlled substance other than one controlled in Schedule VI shall also contain the federal controlled substances registration number assigned to the prescriber. The prescriber's information shall be either preprinted upon the prescription blank, electronically printed, typewritten, rubber stamped, or printed by hand.

The written prescription shall contain the first and last name of the patient for whom the drug is prescribed. The address of the patient shall either be placed upon the written prescription by the prescriber or his agent, or by the dispenser of the prescription. If not otherwise prohibited by law, the dispenser may record the address of the patient in an electronic prescription dispensing record for that patient in lieu of recording it on the prescription. Each written prescription shall be dated as of, and signed by the prescriber on, the day when issued. The prescription may be prepared by an agent for the prescriber's signature.

This section shall not prohibit a prescriber from using preprinted prescriptions for drugs classified in Schedule VI if all requirements concerning dates, signatures, and other information specified above are otherwise fulfilled.

~~No written prescription order form shall include more than one prescription. However, this provision shall not apply (i) to prescriptions written as chart orders for patients in hospitals and long-term care facilities, patients receiving home infusion services or hospice patients, or (ii) to a prescription ordered through a pharmacy operated by or for the Department of Corrections or the Department of Juvenile Justice, the central pharmacy of the Department of Health, or the central outpatient pharmacy operated by the Department of Behavioral Health and Developmental Services; or (iii) to prescriptions written for patients residing in adult and juvenile detention centers, local or regional jails, or work release centers operated by the Department of Corrections.~~

B. Prescribers' orders, whether written as chart orders or prescriptions, for Schedules II, III, IV, and V controlled drugs to be administered to (i) patients or residents of long-term care facilities served by a Virginia pharmacy from a remote location or (ii) patients receiving parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion therapy and served by a home infusion pharmacy from a remote location, may be transmitted to that remote pharmacy by an electronic communications device over telephone lines which send the exact image to the receiver in hard copy form, and such facsimile copy shall be treated as a valid original prescription order. If the order is for a radiopharmaceutical, a physician authorized by state or federal law to possess and administer medical radioactive materials may authorize a nuclear medicine technologist to transmit a prescriber's verbal or written orders for radiopharmaceuticals.

C. The oral prescription referred to in § 54.1-3408 shall be transmitted to the pharmacy of the patient's choice by the prescriber or his authorized agent. For the purposes of this section, an authorized agent of the prescriber shall be an employee of the prescriber who is under his immediate and personal supervision, or if not an employee, an individual who holds a valid license allowing the administration or dispensing of drugs and who is specifically directed by the prescriber.

Agenda Item: Possible 2017 Legislative Proposal Requiring Temperature Monitoring Devices

Included in your agenda package is:

A copy of the draft minutes from the March 2016 full board meeting

Information on TransTracker CF provided by TempTime

HB 886 Enacted by the Georgia Governor (bill replaced HB132)

Regulation Committee Recommendation:

Take no action.

- December 1, 2015 Full Board Meeting
- December 1, 2015 Public Hearing for Hours of Continuous Work by Pharmacists
- December 15, 2015 Special Conference Committee
- December 29, 2015 Pilot Informal Conference Committee
- January 5, 2016 Regulation Committee
- March 21, 2016 Special Conference Committee

MOTION: **The Board voted unanimously to approve the minutes as presented for the meetings held between November 23, 2015 and March 21, 2016. (motion by Allen, second by Saenz)**

PUBLIC COMMENTS: Tim Musselman, Executive Director for the Virginia Pharmacists Association, provided a request by membership input for the Board to consider adding promethazine with codeine as a drug of concern so that it may be reported to the Prescription Monitoring Program.

Michael Rush, Executive Director of Global Health Policy at Temptime Corporation requested the Board consider legislative or regulatory changes to require temperature sensitive medications that are shipped via mail to be accompanied with a device to monitor temperature during shipping. He indicated Georgia recently passed such a law. Mr. Rush provided background on how this type of temperature monitoring has vastly reduced waste in third world countries, specifically in terms of vaccines. Mr. Rush provided examples of factors contributing to drug waste in today's society which included delays in patients receiving mailed packages containing temperature-sensitive drugs. Mr. Rush stated the temperature devices that his corporation provides fall within USP guidelines.

DHP DIRECTOR'S REPORT: Dr. David Brown introduced the recently appointed Chief Deputy Director, Lisa Hahn. He then provided a summary of the report generated by the Pharmacy Benefits Manager Workgroup, stating that he believes Virginia is in a good position having now completed this work should legislators need information on the subject of the oversight of pharmacy benefit managers. The report summarizes the discussion on several issues identified by the workgroup and provides potential policy options. He stated there was consensus among the workgroup members that:

1. The Medical Society of Virginia along with the Virginia Pharmacists Association will meet with the Virginia Health Plans and other key stakeholders with technical expertise to address current concerns with the prior authorization process and develop a strategy for implementing electronic prior authorizations in the near future and encourage the use of e-prescribing by prescribers.
2. The Board of Pharmacy will review the practices of white bagging and brown bagging to address any identified issues of concern, including the promulgation of regulations to reduce the potential for patient harm and promote consistency within the processes.

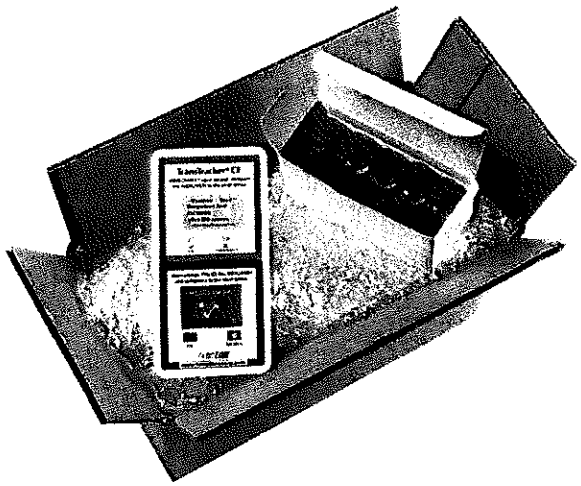
TransTracker® CF

Performance and Use

- Response Temperatures
  - Heat: 25°C(±1)
  - Freeze: -1°C(±1) 0°C(±1) -6°C(±2)
- Response Time:
  - Heat: Short Delay within 2 hours or Long Delay in 5-10 hours
  - Freeze: Within 30 minutes
- Storage Temperature: Refrigerated Storage (2°C to 8°C)
- Shelf Life: 18 months to 4 years determined by category
- Usage: Single use
- Temperature Monitoring: Continual
- Device Size: 56mm x 108mm
- Additional Features: Adhesive backing available / card design customization

Quality System

- Temptime's quality management system is consistent with FDA Quality System Requirement (QSR) 21 CFR 820 (GMP for medical devices).
- ISO 9001:2008
- ISO 13485:2003



Temptime is the world leader in time-temperature indicators that protect patients by alerting the user that a medical product has been exposed to potentially damaging temperatures. Temptime performs a vital role in the improvement of global health by providing manufacturers and distributors with heat and freeze indicators that monitor each medical product or multiple unit packages.

Temptime Corporation, 116 The American Road, Morris Plains, NJ 07950

TT-CF-001

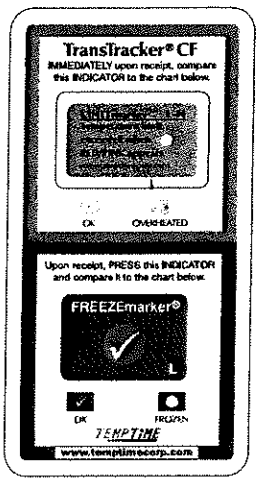
TransTracker® CF

Performance and Use

Heat and Freeze indicators for Monitoring Multiple Unit Boxes

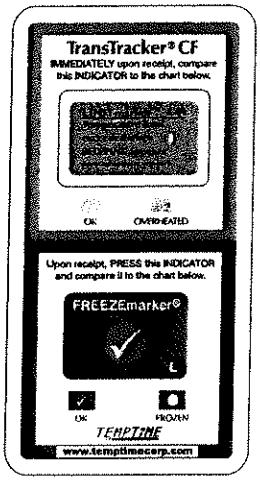
Temptime's TransTracker® indicators can be combined so that heat excursions and freeze events) can be monitored during shipping. TransTracker indicators change color to signal a freeze event, a threshold heat excursion, or that a customer defined cumulative exposure has occurred. TransTracker dual indicators are placed inside multiple units secondary packages or shipping boxes to monitor temperature events during transportation.

Leading medical product manufacturers and distributors use TransTracker dual devices to ensure compliance with regulatory guidelines (e.g. Freeze events and threshold heat events), extend their quality systems into the distribution system and communicate their commitment to cold chain best practices.



OK

FROZEN



OVERHEATED

Features

- Irreversible
- Single-use
- Easy to read
- Easy to understand
- Time-delay heat excursion
- Range of monitoring capabilities
- Combined indicators
- Superior monitoring reliability
- Device activation not required
- Nontoxic materials used in product

Benefits

- Cost effective versus all electronic and chemical indicators
- Environmentally friendly (no battery or hazardous waste disposal)
- Easily integrated into the existing packing process
- Reduce unnecessary waste - limit the destruction of products incorrectly suspected of temperature damage
- Identify and avoid administration of heat damaged medications to patients
- Enhance quality risk management and support continual quality improvement
- Strengthen conformance to International Code on Harmonization (ICH) Q9 and Q10

House Bill 886 (AS PASSED HOUSE AND SENATE)

By: Representatives Cooper of the 43rd, Martin of the 49th, Smith of the 134th, and Rogers of the 29th

A BILL TO BE ENTITLED

AN ACT

To amend Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to grounds for suspension, revocation, or refusal to grant pharmacy licenses, so as to revise a provision relating to employing the mails or common carriers to sell, distribute, and deliver prescription drugs; to provide for related matters; to repeal conflicting laws; and for other purposes.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

SECTION 1.

Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to grounds for suspension, revocation, or refusal to grant pharmacy licenses, is amended by revising paragraph (11) of subsection (a) as follows:

"(11) Regularly employing the mails or other common carriers to sell, distribute, and deliver a drug which requires a prescription directly to a patient; provided, however, that this provision shall not prohibit the use of the mails or other common carriers to sell, distribute, and deliver a prescription drug directly to:

(A) A patient or directly to a patient's guardian or caregiver or a physician or physician acting as the patient's agent for whom the prescription drug was prescribed if:

(i) Such prescription drugs are prescribed for complex chronic, terminal, or rare conditions;

(ii) Such prescription drugs require special administration, comprehensive patient training, or the provision of supplies and medical devices or have unique patient compliance and safety monitoring requirements;

(iii) Due to the prescription drug's high monetary cost, short shelf life, special manufacturer specified packaging and shipping requirements or instructions which require temperature sensitive storage and handling, limited availability or distribution, or other factors, the drugs are not carried in the regular inventories of retail

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pharmacies such that the drugs could be immediately dispensed to multiple retail walk-in patients;

(iv) Such prescription drug has an annual retail value to the patient of more than $10,000.00;

(v) The patient receiving the prescription drug consents to the delivery of the prescription drug via expedited overnight common carrier and designates the specialty pharmacy to receive the prescription drug on his or her behalf;

(vi) The specialty pharmacy utilizes a shipping method, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other ~~standards adopted by the State Board of Pharmacy;~~ recognized standards. The shipping method may include the use of temperature tags, time temperature strips, insulated packaging, or a combination of these; ~~and~~

(vii) The specialty pharmacy establishes and notifies the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs; and

(viii) Except as otherwise provided in division (vi) of this subparagraph, the specialty pharmacy complies with the rules and regulations of the State Board of Pharmacy regarding delivery by mail;

(B) An institution or to sell, distribute, or deliver prescription drugs, upon his or her request, to an enrollee in a health benefits plan of a group model health maintenance organization or its affiliates by a pharmacy which is operated by that same group model health maintenance organization and licensed under Code Section 26-4-110 or to a patient on behalf of a pharmacy. Any pharmacy using the mails or other common carriers to dispense prescriptions pursuant to this paragraph shall comply with the following conditions:

(i) The pharmacy shall provide an electronic, telephonic, or written communications mechanism which reasonably determines whether the medications distributed by the mails or other common carriers have been received by the enrollee and through which a pharmacist employed by the group model health maintenance organization or a pharmacy intern under his or her direct supervision is enabled to offer counseling to the enrollee as authorized by and in accordance with his or her obligations under Code Section 26-4-85, unless the enrollee refuses such consultation or counseling pursuant to subsection (e) of such Code section. In addition, the enrollee shall receive information indicating what he or she should do if the integrity of the packaging or medication has been compromised during shipment;

(ii) ~~In accordance with clinical and professional standards;~~ Except as otherwise provided in division (iii) of this subparagraph, the pharmacy complies with the rules and regulations of the State Board of Pharmacy regarding delivery by mail, including special conditions on the mailing of certain drugs and if necessary, restriction from delivery of certain substances by mail; provided, however, that the State Board of Pharmacy shall not promulgate a list of medications which may not be delivered by the mails or other common carriers. If, however, the State Board of Pharmacy bans a medication from being sold in this state, either over the counter or otherwise, then such medication shall not be delivered by mail. ~~However, until such list is promulgated, the group model health maintenance organization shall not deliver by use of the mails or other common carriers Class II controlled substance medications, medications which require refrigeration, chemotherapy medications deemed by the federal Environmental Protection Agency as dangerous, medications in suppository form, and other~~ Nothing herein shall require a dispensing pharmacy to deliver by mail those medications which, in the professional opinion of the dispensing pharmacist, may be clinically compromised by distribution through the mail or other common carriers;

(iii) The pharmacy shall utilize a shipping method, as appropriate and in accordance with standards of the manufacturer, United States Pharmacopeia, and Federal Drug Administration and other ~~standards adopted by the State Board of Pharmacy,~~ recognized standards. The shipping method may include the use of temperature tags, time temperature strips, insulated packaging, or a combination of these; and

(iv) The pharmacy shall establish and notify the enrollee of its policies and procedures to address instances in which medications do not arrive in a timely manner or in which they have been compromised during shipment and to assure that the pharmacy replaces or makes provisions to replace such drugs.

For purposes of this subparagraph, the term 'group model health maintenance organization' means a health maintenance organization that has an exclusive contract with a medical group practice to provide or arrange for the provision of substantially all physician services to enrollees in health benefits plans of the health maintenance organization; or

(C) A pharmacist or pharmacy to dispense a prescription and deliver it to another pharmacist or pharmacy to make available for a patient to receive the prescription and patient counseling according to Code Section 26-4-85. The State Board of Pharmacy shall adopt any rules and regulations necessary to implement this subparagraph;"

SECTION 2.

All laws and parts of laws in conflict with this Act are repealed.

Georgia General Assembly

2015-2016 Regular Session - HB 886
Pharmacy licenses; employing mails or common carriers to sell, distribute, and deliver prescription drugs; revise a provision

Sponsored By

(1) Cooper, Sharon 43rd
(2) Martin, Chuck 49th
(3) Smith, Richard 134th
(4) Rogers, Carl 29th

Sponsored In Senate By

Watson, Ben 1st

Committees

HC: Health & Human Services
SC: Health and Human Services

First Reader Summary

A BILL to be entitled an Act to amend Code Section 26-4-60 of the Official Code of Georgia Annotated, relating to grounds for suspension, revocation, or refusal to grant pharmacy licenses, so as to revise a provision relating to employing the mails or common carriers to sell, distribute, and deliver prescription drugs; to provide for related matters; to repeal conflicting laws; and for other purposes.

Status History

Jul/01/2016 - Effective Date
Apr/27/2016 - Act 468
Apr/27/2016 - House Date Signed by Governor
Mar/28/2016 - House Sent to Governor
Mar/11/2016 - Senate Passed/Adopted
Mar/11/2016 - Senate Third Read
Mar/08/2016 - Senate Read Second Time
Mar/07/2016 - Senate Committee Favorably Reported
Feb/22/2016 - Senate Read and Referred
Feb/19/2016 - House Passed/Adopted By Substitute
Feb/19/2016 - House Third Readers
Feb/10/2016 - House Committee Favorably Reported By Substitute
Feb/04/2016 - House Second Readers
Feb/03/2016 - House First Readers
Feb/02/2016 - House Hopper

Footnotes

02/19/2016 Modified Structured Rule

Votes

Mar/11/2016 - Senate Vote #582	Yea(50)	Nay(0)	NV(5)	Exc(1)
Feb/19/2016 - House Vote #566	Yea(155)	Nay(4)	NV(12)	Exc(9)

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Virginia Board of Pharmacy

Physicians Dispensing Drugs

Dispensing by a physician means the providing of drugs to patients to take with them away from the physician's place of practice. Physicians in Virginia may dispense under certain circumstances without being required to obtain a license to dispense from the Board of Pharmacy. Those circumstances include the dispensing of manufacturer's samples appropriately labeled as samples and not for sale, dispensing in a bona fide medical emergency, and dispensing when pharmaceutical services are not otherwise available. Any other type of dispensing by a physician requires the physician to obtain a license from the Board of Pharmacy. The Board offers two types of license to physicians.

Permitted Physicians – Practice as a pharmacy

One type of license, pursuant to § 54.1-3304 authorizes the Board to license a physician to practice pharmacy when good cause is shown that pharmacy services are not otherwise readily available. This type of license is usually granted to physicians working in rural areas where there is not a pharmacy within at least 15 to 20 miles and there are only a handful of these types of licenses still current. With this type of license, a physician may also fill prescriptions of other practitioners.

Physicians Selling Drugs

The second and more common type of dispensing license for physicians is the license for a practitioner of the healing arts to sell controlled substances. The term "controlled substances" in Virginia includes any drug in Schedule I through VI which is all prescription drugs, not just those drugs which are DEA controlled substances. Another confusing term is the term "sell" or "sale". Many physicians question why they are required to have this license if they do not charge a patient for the drugs dispensed. The term "sale" is defined in the Drug Control Act as "gift, barter, or exchange". Therefore a charge is not required in order for dispensing to become a "sale". With this license a physician ~~may only dispense to his own patients,~~ must comply with a set of regulations which relate specifically to this license~~, and dispensing under this license may not be delegated to anyone else, such as to a nurse practitioner, physician assistant, nurse, or pharmacy technician~~. If there is more than one physician dispensing within a single practice, each dispensing physician must obtain this license ~~and may only dispense to his own patients.~~ Effective June 4, 2016, a permit from the Board of Pharmacy must also be obtained for the facility from which practitioners of the healing arts dispense controlled substances and it shall meet compliance with the regulations for practitioners of the healing arts to sell controlled substances. Physicians licensed to sell controlled substances may dispense from any facility permitted for this purpose.

A physician licensed to sell controlled substances may only dispense to his own patients. However, with this license the physician may dispense pursuant to a prescription written by a nurse practitioner or physician assistant under the following conditions:

- The physician has a bona fide practitioner-patient relationship with the patient whom the nurse practitioner or physician assistant has prescribed a drug; and,
- The physician is the supervising physician of the physician assistant or the physician who has entered into a practice agreement with the nurse practitioner.

A physician may also dispense a refill of a prescription written by another physician licensed to sell controlled substances if the physician has a bona fide practitioner-patient relationship with the patient.

While the regulation allows for a pharmacy technician, or trained nurse or trained physician assistant to assist the licensed physician in preparing the drug for dispensing, the physician is responsible for conducting a prospective drug review, offering to counsel the patient, inspecting the prescription product to verify its accuracy in all respects, and placing his initials on the record of sale as certification of the accuracy of, and the responsibility for, the entire transaction. The physician may not delegate the responsibility of dispensing a drug to a nurse practitioner or physician assistant; hence, no drug may be dispensed when a physician is not on-site.

Within this category of licensure, it is possible to request a **limited-use license.** Pursuant to Regulation 18VAC110-30-20 and the delegation of authority to the Executive Director as set forth in Bylaws of the Board, a physician may apply for a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. Under a limited-use license, 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.

There is one other exception to the pharmacy act which allows physicians acting on behalf of the state or a local health department to dispense without having to obtain licensure from the Board of Pharmacy. It has been interpreted that this authority can be delegated to other persons authorized to prescribe within the health department system, such as nurse practitioners, since there is no direct prohibition against such delegation, as is the case with the physician selling drugs license.

Excerpts from the Code of Virginia—Pharmacy Act and Medical Practice Act related to physician dispensing

~~**§ 54.1-3301. Exceptions.**~~

~~This chapter shall not be construed to:~~

~~1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;~~

~~2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408;~~

~~3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;~~

~~4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;~~

~~5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;~~

~~6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;~~

~~7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in §/n 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary or providing manufacturers' samples of these drugs to his own patients;~~

~~8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;~~

~~9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written agreement with a physician;~~

~~10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;~~

~~11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or~~

~~12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other~~

~~jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.~~

~~This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.~~

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;

2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408, except that a veterinarian shall only be authorized to dispense a compounded drug, distributed from a pharmacy, when (i) the animal is his own patient, (ii) the animal is a companion animal as defined in regulations promulgated by the Board of Veterinary Medicine, (iii) the quantity dispensed is no more than a 72-hour supply, (iv) the compounded drug is for the treatment of an emergency condition, and (v) timely access to a compounding pharmacy is not available, as determined by the prescribing veterinarian;

3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;

4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;

5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;

6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;

7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to

prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;

8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;

9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written or electronic agreement with a physician;

10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy, including a pharmacy participating in bulk donation programs, may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;

11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the

limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

This section shall not be construed as exempting any person from the licensure, registration, permitting and record keeping requirements of this chapter or Chapter 34 of this title.

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

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

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

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

~~**§ 54.1-3304.1. Authority to license and regulate practitioners.**~~

~~The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts.~~

§ 54.1-3304.1. Authority to license and regulate practitioners.

A. The Board of Pharmacy shall have the authority to license and regulate the dispensing of controlled substances by practitioners of the healing arts. Except as prescribed in this chapter or by Board regulations, it shall be unlawful for any practitioner of the healing arts to dispense controlled substances within the Commonwealth unless licensed by the Board to sell controlled substances.

B. Facilities from which practitioners of the healing arts dispense controlled substances shall obtain a permit from the Board and comply with the regulations for practitioners of the healing arts to sell controlled substances. Facilities in which only one practitioner of the healing arts is licensed by the Board to sell controlled substances shall be exempt from fees associated with obtaining and renewing such permit.

§ 54.1-2914. Sale of controlled substances and medical devices or appliances; requirements for vision care services.

A. A practitioner of the healing arts shall not engage in selling controlled substances unless he is licensed to do so by the Board of Pharmacy. However, this prohibition shall not apply to a doctor of medicine, osteopathy or podiatry who administers controlled substances to his patients or provides controlled substances to his patient in a bona fide medical emergency or when pharmaceutical services are not available. Practitioners who sell or dispense controlled substances shall be subject to inspection by the Department of Health Professions to ensure compliance with Chapters 33 (§ 54.1-3300 et seq.) and 34 (§ 54.1-3400 et seq.) of this title and the Board of Pharmacy's regulations. This subsection shall

not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

B. A practitioner of the healing arts who may lawfully sell medical appliances or devices shall not sell such appliances or devices to persons who are not his own patients and shall not sell such articles to his own patients either for his own convenience or for the purpose of supplementing his income. This subsection shall not apply to physicians acting on behalf of the Virginia Department of Health or local health departments.

C. A practitioner of the healing arts may, from within the practitioner's office, engage in selling or promoting the sale of eyeglasses and may dispense contact lenses. Only those practitioners of the healing arts who engage in the examination of eyes and prescribing of eyeglasses may engage in the sale or promotion of eyeglasses. Practitioners shall not employ any unlicensed person to fill prescriptions for eyeglasses within the practitioner's office except as provided in subdivision A 6 of § 54.1-2901. A practitioner may also own, in whole or in part, an optical dispensary located adjacent to or at a distance from his office.

D. Any practitioner of the healing arts engaging in the examination of eyes and prescribing of eyeglasses shall give the patient a copy of any prescription for eyeglasses and inform the patient of his right to have the prescription filled at the establishment of his choice. No practitioner who owns, in whole or in part, an establishment dispensing eyeglasses shall make any statement or take any action, directly or indirectly, that infringes on the patient's right to have a prescription filled at an establishment other than the one in which the practitioner has an ownership interest.

Disclosure of ownership interest by a practitioner as required by § 54.1-2964 or participation by the practitioner in contractual arrangements with third-party payors or purchasers of vision care services shall not constitute a violation of this subsection.

Agenda Item: Consideration for Accepting Inspections or Documentation, in lieu of FDA Inspection of Outsourcing Facility or Nonresident Outsourcing Facility from:

- **Bestech GMP Contracting, Inc.**
- **Florida Department of Health**

Included in your agenda package is:

A copy of relevant statutes

Presentation and Resumes Provided by Bestech GMP Contracting, Inc.

Possible Action:

- Approve acceptance of an otherwise qualifying inspection report or other documentation from Bestech GMP Contracting, Inc. and/or the Florida Department of Health, in lieu of an FDA inspection report when the outsourcing facility or nonresident outsourcing facility has not been inspected by the FDA within the required period pursuant to §54.1-3434.05 and/or §54.1-3434.5 or,
- Take no action.

MOCK FDA INSPECTIONS

Virginia Board of Pharmacy,
14 June 2016

BESTECH GMP CONTRACTING

PRESENTATION OVERVIEW

- INTRODUCTION
- EXPERIENCE
- FDA MOCK INSPECTION
  - Inspection Approach
  - SOP Procedures
  - Scope and Duration
  - The Inspection
  - Inspection Documentation
- BESTECH CONSULTANTS
- Q&A

BESTECH GMP CONTRACTING

INTRODUCTION

BESTECH GMP CONTRACTING, INC.

- CAPABILITIES:
  - cGMP Compliance Improvement
  - Validation
- SIMILAR PROJECTS:
  - Mock FDA Audits
  - FDA Pre-Approval Inspection (PAI) preparation
  - Comprehensive systems assessments
  - Due diligence audits
  - Regulatory response letters

BESTECH GMP CONTRACTING

EXPERIENCE

Pharmaceutical Manufacturing and Compounding Pharmacies

Projects

- FDA Pre-Approval Inspection Readiness
- Current Good Manufacturing Practices (cGMPs) Due Diligence Audits
- Comprehensive GMP Assessments – triggered by regulatory action

BESTECH GMP CONTRACTING

FDA INSPECTION APPROACH

GMP Inspection approach

- FDA uses the following reference materials:
  - cGMP's – 21CFR Parts 210 & 211
  - CPG Manual – Drug Manufacturing Inspections
  - CPG Manual – Sterile Drug Process Inspections
  - Guidance – cGMP Compounding Outsourcing Facilities under Section 503B of the FD&C Act
  - Six-System Approach (next page)

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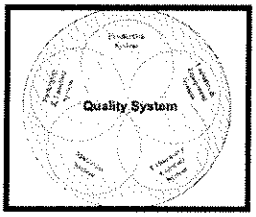
SYSTEM INSPECTION APPROACH



BESTECH GMP CONTRACTING

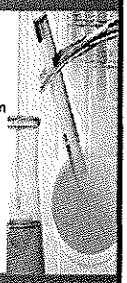
INSPECTION SCOPE

Full vs. Abbreviated

- Full inspections typical for:
  - New firms
  - Firms with short-lived compliance and recidivism
- Abbreviated – follows FDA style for routine, biennial inspections
  - Two systems are inspected (the Quality System and one other system)

Rotation of Systems

- Inspection history is an important consideration



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503B OUTSOURCING FACILITIES - SCOPE

Sub-System	
❑ Facility Design	❑ Components
❑ Control Systems and Procedures for Maintaining Suitable Facilities	❑ Release Testing
❑ Environmental and Personnel Monitoring	❑ Laboratory Controls
❑ Equipment, Containers and Closures	❑ Packaging and Labels
❑ Production and Process Controls • General • Aseptic Drug Processing	❑ Quality Assurance Activities/Complaint Handling

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THE INSPECTION

- DAY 1: Meet with key company personnel, review audit plan, facility tour, review quality files
- DAY 2-4: Complete review of quality files and at least one other system
- DAY 5: Wrap up audit activities and hold close out meeting. Issue the audit report, similar to the layout of an FDA Form 483 and provide verbal suggestions for remediation

- *Each day has a daily wrap up of the day's activities and findings and a look ahead at the next day's areas of inspection*

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INSPECTION DOCUMENTATION

- Report notes – inspectors utilize report notes to record observances and compare to regulatory guidance's.
  - Link to EXAMPLE notes
- Mock 483 report (similar to 483). Example

BESTECH CONSULTING

CONSULTANTS

OVERVIEW:

- Senior Level
- All have pharmaceutical manufacturing industry experience
- Some ex-FDA inspectors
- Multi-disciplinary (Microbiologists, Cleanroom Engineers, Pharmacists, Chemists)

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CONSULTANTS - HIGHLIGHTS

Shirley Berryman (CV)

- 35 year veteran of US FDA
- Compliance Investigator of pharmaceutical, biotechnology and compounding pharmacies

Gwyn Dickinson (CV)

- 30 year veteran of US FDA as a Consumer Safety Officer
- Attained Level III Certification as a Drug Investigator
- 5 years industry consultant, over 100 mock inspections

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Consultants – Highlights (cont.)

Matt Bestercy (CV)

- 25 years industry and consulting in GMP pharmaceuticals as a Quality manager and Clean Room Engineer
- 9 successful FDA inspections, 3 FDA approved plant startups
- Remediation of 10 firms (including compounding pharmacies) 483's (3), Warning Letters (4) and Consent Decrees (3)

Lee Kealner (CV)

- Pharmacist with over 30 years pharmaceutical industry experience as a Senior Quality Director/VP and Consultant
- Significant experience inspecting compounding pharmacies including remediation plans

BESTECH CONTRACTING

CONCLUSION

WHY USE BESTECH?

- Use of ex-FDA Inspectors and Industry Experts
- Have been executing same/similar projects for over 25 years
- Proven, step-wise approach
- Focus on areas with known higher risk and impact on patient safety

BESTECH CONTRACTING

QUESTIONS?

BESTECH GMP CONTRACTING

www.bestgmp.net (631) 338-9063 mbestercy@bestgmp.net

Change Management System:

- Acted as Change Control Technical Subject Matter Expert in QA Change Control Department
- Create, review and approve electronic and paper based CC documents across all GMP Systems at two manufacturing sites.
- Develop and conduct training sessions on the use of Trackwise and QTS CC tracking systems

Large Pharmaceutical Manufacturer, Pennsylvania (2010-2014)
Remediation project for FDA Consent Decree

- Third party Engineering/GMP oversight of $200MM rebuild of a pharmaceutical liquids manufacturing facility
- Consulted on the development of Critical Aspect Risk Assessments, VMP's (Site, Cleaning, Process, Equipment/Facility/Utilities, Computer Systems, Lab), Qualification/Validation Protocols and Reports.
- Provided guidance and review on the complete rewrite of all site engineering maintenance, calibration and operating procedures and policies.

Mid-Size Rx Drug Product Manufacturer, New Jersey (2011-2013)
Warning Letter Remediation – Warning Letter lifted

- Cleaning Validation: preparation of Master Plan, including matrix scheme. Drafted sampling plans, including MAC acceptance criteria.
- Process Validation: PV program gap assessment and remediation
- Packaging Validation: Drafted Master Plan, Gap Assessment and Remediation

Sterile Injectable Manufacturer, Ohio (2010)

- Performed training of Aseptic Operators in aseptic practices
- Monitored and enforced aseptic practices in the sterile core of a three-shift operation in three different manufacturing facilities manufacturing critical, life-saving products on drug shortage lists.

Large Rx Pharmaceutical Manufacturer, New Jersey (2010-2011)

- Commissioning and Qualification of Equipment, facilities and Utilities related to the move of an entire stability facility and labs from one location to another (within state)

Mid-Size OTC Drug Product Manufacturer, New York (2010-2011)

- Developed Cleaning Validation Master Plan, Cleaning Validation protocol master design
- Developed Process Validation Procedure design and implementation, drafted Process Validation Protocols/Reports

Large Generic Drug Manufacturer, New Jersey (2009-2010)

- Led the qualification of equipment, facilities and utilities related to two major manufacturing area additions.
- Qualifications included Water Systems, Fluid Bed Dryers, High Shear Mixer, V-Blenders, Mills, HVAC Systems and Production Suites. Produced Protocols, execution, reports.

Large Topical Rx Drug Product Manufacturer, Canada (2009)

- Remediation project for FDA inspectional observations.
- Restructured the Process Validation Program. Drafted Master Plans, PV SOP's and Protocols.
- Built revalidation strategy based on documented risk assessments. Initiated the revalidation plan and trained/passed on to internal staff for execution.
- Performed Gap Assessment and Remediation Plan for the Cleaning Validation of equipment across a variety of creams, ointments and lotions, totaling over 90 products.
- Optimized Filling Process and Operational parameters through use of HACCP. Established formal Filler setup sheets.
- Authored and completed overdue quality investigational reports that internal staff could not complete due to resource constraints.

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Mid-Size OTC Topical Drug Product Manufacturer, New York (2009)

- Remediation project for FDA inspectional observations.
- Drafted response to the FDA-483 inspection report. Attended meeting with company senior management at FDA field office to present the Corrective Action Plan.
- Implemented Corrective Action Plan, including Product Assessment Reports, GMP Quality Systems Appraisal and Process Validations.

Large Vaccine Manufacturer, Pennsylvania (2008-2009)

- Commissioning, Qualification and Validation Project Leader for the renovation of a vaccine manufacturing facility utilizing ISPE C&Q and ASTM E2500.
- Authored Project Commissioning and Qualification Plan, Commissioning and Validation Project Plans, Commissioning Test Plans and other related project documentation.

Stem Cell Processing Facility, New York (2008-2009)

- Commissioning and Qualification of a new facility and laboratories for the processing and testing of Umbilical Cord Blood into stem cells for use in Cancer Patients.
- The ISPE Commissioning and Qualification approach was utilized from the outset realizing time and dollar savings.
- Troubleshooting and repair of many of the systems. Coordinated major move of the LN_2 units (full of product inventory) from Manhattan to Long Island City, working with NYPD and Riggers. Coordinated temperature testing, equipment qualification, etc.
- Timely project execution enabled company to have most profitable quarter in history.

Large Pharmaceutical Manufacturer, Pennsylvania (2006-2007)

Liquid and solid dose pharmaceutical manufacturing

- Drafted over 40 equipment cleaning validation protocols for the various oral solids and liquids products manufactured by the site.
- Gap Assessment and remediation on 18 HVAC units servicing the GMP manufacturing areas of the plant. Includes drafting of the protocol, identification of gaps in the qualifications, assessing impact of gaps and preparing remediation plan.
- Performance Qualification protocol for the USP Purified Water plant which serves to produce the water used for the manufacturing operations at the site.
- Performance Qualification of the label inspection system at the label manufacturer for all clients' labels.

Anderson Packaging, Inc., Rockford, Illinois

Large Contract Packaging House

- On-site Validation and Quality Assurance representative for the owner drug manufacturer of the contract packager during Packaging Validation and the product launch volume of Zyrtec (Cetirizine HCL), a billion dollar drug product transitioning from Rx to OTC.
- Review and approve all packaging validation documents (IQ, OQ, PQ & PV) for all 7 different packaging presentations (e.g. blisters, bottles, pouches, clamshells)
- Review and approve all executed batch records for the validation lots and the remaining volume of launch lots.
- Inspect the packaging lines daily for GMP compliance.

LEE KENTNER

SUMMARY

Quality Operations leader with expertise in both Pharmaceutical (Prescription and OTC) and Biopharmaceutical industries. Demonstrated success in a variety of complex situations accomplished by balancing compliance and business risk, collaboration, effective communication, and strong leadership.

PROFESSIONAL EXPERIENCE

COMPLIANCE SERVICES & SOLUTIONS, LLC **2009 - Present**
Owner and principal consultant
Providing QA and Manufacturing services to the Pharmaceutical and Biopharmaceutical industries. Key services include Quality System (QS) design and implementation, pre-approval inspection preparation, supplier audits, writing responses to FDA 483 observations and Warning Letters, contract manufacturing organization (CMO) selection and qualification including auditing and follow up, internal GMP assessments, detailed compliance review of documents (Protocols, Reports, Batch records, etc.), and interim leadership. Recent projects include:

- Assessment of Compounding Pharmacy practices for compliance with FDA Guidance documents & USP
- Team lead for third party Batch Record review activity as mandated by Consent Decree
- Team Lead for cGMP auditing of Consent Decree required remediation activities at multi-site company
- Established QS and led the development of a comprehensive set of Quality Standards for a multi-site company
- Wrote first Quality Manual and Quality Policy, and established the development of selected SOPs for multi-site company utilizing cross functional teams
- Audits of oral dosage, aseptic, and clinical packaging facilities
- Developed and delivered training program for preparing for and managing FDA inspections
- Served as part-time Head of Quality for over 4 years at start-up pharmaceutical product development company
- Writing responses to FDA 483 observations and remediation of related Quality Systems
- Detailed compliance assessment of Process Validation Reports and Batch Records to determine if products should remain on the market

GPC BIOTECH, Princeton, NJ **2007 - 2009**
Vice President, Worldwide Quality Assurance
Responsible for all strategic and tactical QA activities (GXP) at Munich Germany and Princeton, NJ sites. Products include sterile and oral dosage forms.

- Led launch preparation for first commercial product including establishment of commercial Quality Systems.
- Managed related FDA inspection resulting in no Form 483 observations.
- Established a Quality Plan resulting in clear strategic and tactical priorities and effective use of resources.

WYETH PHARMACEUTICALS, Collegeville, PA **2000 - 2006**
***Assistant Vice President, Vaccines External Supply* (2004-2006)**
Led the strategic and tactical operational activities to successfully implement product outsourcing program.

- Established the Vaccines External Supply team including the development and implementation of strategies to ensure successful US and EU launches and ongoing product production resulting in increased vaccine supply generating $500 million in revenue in 2005 and $1 billion in revenue in 2006. Provided leadership and direction to the Technology Transfer Team including compliance related guidance.

***Senior Director, Vaccines Quality – Contracting Manufacturing* (2003-2004)**
Accountable for quality and compliance of all activities associated with the outsourcing of products.

- Developed and implemented strategies to ensure that the manufacturing of externally sourced vaccine products met the quality and compliance standards necessary for product launch and continuity of supply. Resulted in FDA product approval at contract manufacturer successfully alleviating a significant supply constraint generating an additional $350 million in revenue per year.

Senior Director, Quality **(2001-2003)**
Created and managed a program office to address specific corporate wide Quality and Operations deficiencies.

- Developed and launched global process for reporting key metrics from over 30 sites to Senior Corporate Management resulting in improvements in quality, safety, and customer service.
- On time completion of regulatory commitments, stability testing and APR completion from 80% to over 99%; investigation completion in less than 30 days from 30% to 80%; Customer service fill rate from 90% over 95%.

Senior Director, Vaccines Compliance **(2000-2001)**
Selected as Interim Head of QA/QC at Wyeth vaccine manufacturing site for 12 months.

- Reorganized the department of 200 staff and developed processes to ensure numerous Consent Decree and FDA 483 compliance commitments were met, thus avoiding significant fines and loss of credibility with FDA.
- QA lead for re-start of aseptic filling building
- Prepared for and hosted the first post-Consent Decree follow up inspection. The inspection was successful and was a significant step in re-establishing credibility with the FDA.
- Organized and initiated the implementation of consistent Quality Systems across vaccine sites.

RHONE POULENC RORER/AVENTIS (SANOFI AVENTIS), Collegeville, PA **1996-2000**
Director, Global Audit Services **(1999-2000)**
Directed audit team responsible for assessing 12 primary and 20 secondary RPR manufacturing sites and key External Manufacturers and Suppliers to ensure their compliance with RPR standards and BOH requirements.

- Oversaw a GMP compliance enhancement program that was designed to systematically implement corporate compliance policies and Quality Systems at manufacturing sites. As a result, numerous regulatory agency inspections yielded no or only minor observations and numerous successful Pre-Approval Inspections.

Director Quality – North America **(1996-1998)**
Provided Quality direction and oversight to a Corporate Quality group, two RPR sites, and 12 contract manufacturers to ensure compliance with regulatory requirements and RPR standards.

- Developed a Corporate Quality group to support RPR's U.S. Pharmaceutical business. This included the people and processes for Distribution Quality, Computer Validation, Customer Product Complaints and contract manufacturing support including: Supplier Auditing, Product Release, and Change Control.
- Key contributor in development of and implementation lead for Quality System compliance enhancement program at U.S. manufacturing site. Project subsequently rolled out to 12 strategic sites globally.

FISONS PHARMACEUTICS (Formerly PENNWALT), Rochester, NY **1984-1996**
Director, QA/QC **(1996)**
Led all QA/QC activities for the site including final accountability for an operating budget exceeding $10 million and a 115 employee work force.

EDUCATION

MBA – Manufacturing Strategy and General Management, Rochester Institute of Technology, Rochester, NY
BS – Pharmacy, Albany College of Pharmacy, Albany, NY

PROFESSIONAL DEVELOPMENT

Quality Engineer Certification (Quality Improvement Methodologies), American Society for Quality
Total Quality Management, Rochester Institute of Technology
Aseptic Processing Training Program (2 week program), Parenteral Drug Association, Baltimore, MD
Lean Six Sigma Training (Various Programs)
Change Management Training (Various Organizations)

BESTECH GMP CONTRACTING

CHRONOLOGICAL PROJECT LIST

Contract Manufacturer of Sterile Injectables, Northern Italy (2016)

- Evaluation of client GMP operations in preparation of FDA Pre-Approval Inspection for first US-approved product
- Review and develop recommendations for the following:
  - Key validation documents and engineering design elements of clean rooms, HVAC, clean utilities, sterilization/depyrogenation processes, vial/ampule filling.
  - Overall Validation program: Validation policy and Validation Master Plan. Procedures: Process Validation, Cleaning Validation, Equipment Qualification
  - Engineering Programs – Calibration and Preventative Maintenance

Outsourcing Compounding Pharmacy, New York (2016-current)

- Drafted company response to FDA Warning Letter
- Performed a Quality Management System Assessment against FDA cGMP Interim Guidance for Outsourcing Facilities and draft USP General Chapter <797> "Pharmaceutical Compounding". Developed a remediation plan outlining all activities to correct identified gaps.

Various Sterile Compounding Pharmacy Organizations (503A and 503B), Nationwide (2015-present)

Companies under FDA Warning Letter and/or possess 483 inspectional gaps

- Perform audit of facilities for cGMP compliance against FDA Guide for Sterile Outsourcing Facilities
- Evaluate compliance of sterile operations, quality systems, aseptic practices, gowning practices, environmental monitoring, microbiology, process flows, HVAC Systems, clean room/Laminar flow hood design and maintenance
- Draft remediation plans for recommended corrective actions against identified gaps
- Establish corporate policies and procedures pertaining to cGMPs
- Assist in training and implementation

Large OTC Manufacturer, New York (2014-2015)

483 Remediation – Complete

- Established Global Validation programs (policies and SOPs) for Process Validation and Equipment/Facility/Utility Qualification applicable to OTC manufacturing sites in the US, Canada, UK and Belgium
- Developed global Process Performance Qualification (PPQ) protocols and PPQ reports for Bulk Manufacturing and Filling of products
- Mentored and advised on new product launches as related to Equipment/Facilities/Utilities Qualification, critical process parameters (CPP's) and Process Validation (PPQ's)
- Drafted Site Validation Master Plans for four North American Sites and two EU sites. Established local Validation teams to plan and track Validation progress for new and legacy products and related systems

Mid-Size Sterile Drug Product Manufacturer, Midwest US (2014-2015)

FDA Warning Letter Remediation

Event Investigations

- Provided guidance, coaching and coordination for all aspects related to the initiation, tracking, trending and management of all investigations, corrective and preventive actions (CAPA), and CAPA effectiveness.
- Worked with the operations leadership team and Quality Assurance to facilitate the consistent and disciplined execution of the investigation system ensuring the completeness and comprehensiveness of the investigations while determining the most probable root cause. Analyze CAPA effectiveness through appropriate tracking and trending methods in order to prevent reoccurrence.

Engineering

- Retrospective evaluations of Technical Specifications for critical equipment, facilities and utilities to support requalification project.

Gwyn G. Dickinson

Knowledge, Skills, and Abilities

- Superior knowledge of the laws, regulations, and procedures that apply to U.S. Food and Drug Administration (FDA) inspections in the areas of food, drugs, biologics, cosmetics, medical devices, and veterinary products.
- Thorough familiarity with pharmaceutical industry operations in the U.S. and worldwide. Extensive knowledge of data-analysis methods and skill at analyzing inspection-related data to identify patterns and trends.
- Expertise in identifying policy and procedural problems and how to eliminate them.
- Proven ability to recognize critical but sometimes less obvious quality and regulatory issues, and to place inspectional focus on those issues.
- Good oral and written communications skills, whether discussing scientific, technical, operational, policy, or other matters related to FDA inspections and investigations.

Experience

Dickinson Consulting, Inc., 2011 to present

- Has conducted in excess of 100 audits of manufacturing facilities for firms in the pharmaceutical, biotechnology, and vaccines industry.
- Performs mock audits to prepare companies for FDA inspections.
- Trains personnel on FDA expectations and perspectives, and other topics including investigations, corrective and preventive actions, and annual product reviews.
- Provides guidance on how to comply with applicable laws and regulations.
- Provides guidance for implementing appropriate corrective actions based on FDA inspectional findings.

U.S. Food and Drug Administration (FDA), 1986-2010

Inspections and Investigations

- Served as a Consumer Safety Officer (Drug Specialist). In 2006, became a Level-III Certified Drug Investigator, one of only about 20 throughout FDA, and began serving as a member of the FDA Pharmaceutical Inspectorate, a corps of highly trained investigators who inspect complex and high-risk pharmaceutical operations, and conduct pre-approval inspections and other investigations that require the highest level of expertise.
- Planned and conducted inspections in China, India, Israel, and a number of European and South American countries. Many of these inspections included the review of New Drug Applications (NDAs) and New Animal Drug Applications (NADAs) with emphasis on the evaluation of a firm's ability to manufacture products in accordance with these applications.

- Inspected drug manufacturing operations, such as small and large volume parenterals, ophthalmics, sustained/immediate release tablets and capsules, boluses, liquids, suspensions, ointments, sterile/non-sterile powders, medical gases, and bulk pharmaceutical chemicals.
- Inspected a wide range of products, including, for example: antibiotics, antibacterials, anesthetics, anticancer drugs, antiparasitic drugs, hormone implants, and AIDS-related treatment drugs.
- Inspected firms that manufacture sterile and non-sterile bulk pharmaceutical chemicals (active ingredients), many of which involve complex chemical synthesis processes and/or aerobic fermentation processes. The majority of these inspections involved operations outside the U.S.
- Inspected facilities that use a variety of sterilizing processes, including: steam, dry heat, sterile filtration and aseptic filling, gamma irradiation or a combination of these processes. Several of the firms I inspected further process their sterile products by lyophilization. Many of the sterile and some of the non-sterile facilities I inspected require "clean rooms" or other environmentally controlled production and testing areas.
- Evaluated things like: process validation; air handling and other environmental control systems; water purification; equipment and facility cleaning; depyrogenation; fermentation; various forms of sterilization; aseptic processing; and finished product testing (both chemical and microbiological testing).
- Participated in FDA Compliance Branch meetings with industry to assess a firm's proposed corrective actions in response to inspectional findings.

Presentations and Training Given

- Regularly participated in and presented at FDA and industry-wide meetings (Human and Veterinary Drug) on FDA regulations and guidelines. Served as a member of the Pharmaceutical Technology Exchange Association (PTEA), which consists of companies in the human and veterinary pharmaceutical industry. The PTEA mission is to promote dialogue between the FDA and industry to enhance mutual understanding of the scientific, technical, and regulatory compliance issues that challenge the industry. My presentations at PTEA meetings covered such things as:
    - The regulatory requirement that, following approval of a New Animal Drug Application (NADA)/ Abbreviated New Animal Drug Application (ANADA), applicants must establish and maintain records and make reports to the Agency.
    - An overview of the systems approach to conducting inspections and an update on FDA's Pharmaceutical Inspectorate Certification program for drug investigators.
    - "An Investigator's Approach to Pharmaceutical Equipment Cleaning" and "Strategies for Success 21 CFR 211 Subpart J – Records and Reports."
- Co-developed the Kansas City District Drug Manufacturing and Quality Control training curriculum and trained investigators in the Kansas City District on the inspection of Microbiology Laboratories and Aseptic Processing Inspections.
- As a recognized source of guidance within the Kansas City District on human and veterinary drugs, provided formal classroom and on-the-job training on drug manufacturing operations to new employees, journeymen investigators, and headquarters personnel.

- In 2005, I was invited to present my approach to the inspection process to FDA headquarters staff. In a series of presentations, I described my approach as a Field Investigator to conducting routine GMP inspections of pharmaceutical facilities and discussed the most commonly cited deficiencies in the pharmaceutical industry.

Training Received

- Therapeutics Biotech Update (DG-306), Feb 2008.
- Maintenance and Cleaning of Drug Manufacturing Equipment (PHA44 Ver. 2.1), Feb 2008
- PAT (Process Analytical Technology) Practical Training, Sept 2007
- CDER/ORA Program Series, Topic 5: Handling Out of Specification (OOS) Results Guidance, Jul 2007
- Inspection of Microbiology Laboratories, Apr 2007
- Computer Aided Inspections (MP 143), Dec 2006
- Pharmaceutical Inspectorate, Module 6 – Technology (Process Analytical Technology) and Module 7 – Investigational, Aug 2005
- Pharmaceutical Inspectorate, Module 4 – Pharmaceutical Sciences and Module 5 – Current Regulatory Programs and Procedures, Feb, 2005
- Pharmaceutical Inspectorate, Module 1 – Regulating Pharmaceutical Quality, Module 2 – Risk Management, and Module 3 – Advanced Quality Systems, Aug 2004
- Writing Validation Protocols, Mar 2004
- A Step-by-Step Approach to Process Validation, Mar 2004
- Approach to Computerized Systems Validation and Compliance, Mar 2004
- Using TURBO EIR for Establishment Inspections, Jan 2001
- Active Pharmaceutical Ingredient Manufacturing, Jun 2000
- Computer Systems Validation, Mar 2000
- Basic Radiation Safety, May 2000

Awards

- Commissioner's Special Citation for heading the Generic Drug Pharmaceutical Injunction Team, Jun 2010
- Outstanding 2007 work performance, May 2008
- Certificate of Achievement "for continued focus on consumer protection and significant accomplishments as a vital member of the Kansas City Investigations Branch during a time of competing priorities," Sep 2007
- Group award for serving as a member of the Collaborative Effort Assessing Widespread Impact of a Sterility Failure Group, May 2007
- Certificate of Appreciation for working to improve interaction between chemistry, manufacturing, and controls (CMC) Reviewers and Field Investigators, Jun 2006
- Certificate of Appreciation for monitoring drug field alert notifications/investigations and handling pre-approval requests and approvals, May 2006
- Certification of Appreciation for contributing to the overall success of the April 2006 Pharmaceutical Technical Exchange Association (PTEA), Jun 2006

Matthew Bestercy

Summary

Matt has 25 years experience in GMP manufacturing environments in Pharmaceutical, Biotechnology and Medical Device companies. He possesses validation and quality assurance expertise in the manufacture of drug products (oral solids, powders, creams, ointments), aseptic/sterile processing, cell culture and fermentation.

Matt has established key quality, validation and engineering systems and procedures. He has managed validation department staffs at large and mid sized companies and has started up two plants as the validation project manager.

Additionally, he has represented his corporation's validation department during successful regulatory inspections (FDA, MHRA) and on-site presentations at FDA.

Capabilities

Equipment, Facilities/Utilities Qualification and Validation

- Process Validation
- Cleaning Validation
- Commissioning and Qualification
- Oral Solids, Liquids, Semi Solids Equipment
- Packaging Equipment and Line PQ's
- Temperature Mapping
- Auditing of cGMP Operations
- Sterilization/Depyrogenation
- Critical Utilities- WFI, USPPW, gases
- Sterile Media Fill Programs
- HVAC Systems, BMS and Clean Rooms
- Cryopreservation

Systems

- Master Plans (Process, Packaging, Cleaning)
- Validation Policies and Procedures for Process, Aseptic, Packaging and Cleaning
- Calibration Programs/procedures/training
- Maintenance Programs/procedures/training
- Risk-based gap assessments and remediation
- Commissioning Programs, FAT/SAT's
- Revalidation/Periodic Review Programs
- Change Control Programs
- Validation, Quality Training
- Investigations/Deviations
- Vendor Audit Programs
- CAPA Programs
- Inspectional Readiness

Experience	
Bestech GMP Contracting, Inc., New York	2006-Present **Owner and Principal Consultant** Consulting firm specializing in Technical Services and Quality Systems support in the manufacturing of drug products and biologics for human use. **LIST OF RECENT PROJECTS:** **Contract Manufacturer of Sterile Injectables, Italy (2016)** • Evaluate client GMP operations in preparation of FDA Pre Approval Inspection (PAI) for first US-approved product • Review and develop recommendations for the following: o Key validation documents and design elements of clean rooms, HVAC, clean utilities, sterilization/depyrogenation processes, vial/ampule filling. o Overall Validation program: Validation policy and Validation Master Plan. Procedures: Process Validation, Cleaning Validation, Equipment Qualification o Engineering Programs – Calibration and Preventative Maintenance **Outsourcing Compounding Pharmacy, New York (2016-current)** • Drafted company response to FDA Warning Letter • Performed an Assessment against FDA cGMP Interim Guidance for Outsourcing Facilities and draft USP General Chapter <797> "Pharmaceutical Compounding". Developed a remediation plan outlining all activities to correct identified gaps. **Various Sterile Compounding Pharmacies (503B & 503A), Nationwide (2015-2016)** *Companies under FDA Warning Letter and/or possess 483 inspectional gaps* • Auditing for cGMP compliance against FDA Guide for Sterile Outsourcing Facilities and USP Chapter <797> • Draft remediation plans for corrective actions against identified gaps • Evaluate sterile operations, quality systems, aseptic practices, gowning practices, environmental monitoring, microbiology, process flows, facility design, media fills, HVAC Systems, clean room/Laminar flow hood design and maintenance. • Establish corporate policies and procedures pertaining to cGMPs **Large OTC Manufacturer, New York (2014-2015)** *FDA 483 Remediation* • Established global policies and SOPs for Process Validation and Equipment/Facility/Utility Qualification, Calibration/PM for sites in North America, EU • Developed global Process Performance Qualification (PPQ) protocols and reports • Mentored on new products launches as related to Qualification and PPQ's • Drafted Site Validation Master Plans for four North American Sites and two EU sites. **OTC Manufacturer, Pennsylvania (2010-2014)** *FDA Consent Decree Remediation* • Lead Engineering Consultant for Third Party review, support and certification of the design, construction, commissioning/qualification and validation of a new $200 million manufacturing facility • Performed FMEA's, drafted policies and procedures, validation master plans • Lead consultant on C&Q and Cleaning Validation work streams. Audited documentation for accuracy and completeness. Mentored staff. **Rx Creams and Ointments Manufacturer, Florida (2010)** *FDA Warning Letter Remediation* • Performed Gap Assessments and Established the following programs: a) Facility and Utility Qualification, b) Cleaning Validation and c) Calibration and PM programs

Pfizer Global Manufacturing Brooklyn, NY	2002-2006 **Validation Manager/Team Leader, Quality Operations** ▪ Manufacturer of prescription pharmaceuticals - oral solids, liquids, ointments and sterile injectables Equipment, Facilities and Utilities: Led qualification of ~$500MM in new equipment/Facility/Utility and upgrades. Led ISPE Commissioning & Qualification Program at site including Manufacturing equipment, packaging PQ's, HVAC, Purified Water, Compressed Air and Nitrogen systems IQ/OQ/PQ. Process Validation: Validated and launched the following new products: Elitripthan Hbr (Relpax), Vfend (Voriconazole), Doxazosin Mesylate (Cardura XL) and Darifenacin (for Novartis). Process validation of SUPAC, excipient and API changes. Cleaning Validation: Maintained the CV program for actives and detergents on all equipment trains, including microbial CV (for EU). Implemented worst-case matrix approach for all products. Computer and Lab Equipment: GAMP4 Risk based gap assessment project, CFR21 Part-11, Validation of new Process Analytical Technology instrumentation. Aseptic Validation: Aseptic Media Fill program, Depyrogenation, Sterilization (Steam & Filter), Process Validation, Revalidation. Change Control: Administer and control program for evaluation of all changes that may impact validation Training: Validation training of all site individuals such as Validation Committee members, Technical Specialists, Project Engineers, Contractors and Validation Specialists. Administration: Staff development and performance reviews, Validation Master Planning and performance metrics. Develop and maintain the site validation procedures and policies Regulatory: Full-time Quality (Validation) representative during all regulatory inspections by the USFDA, UK/EU MHRA and corporate QA
Advance Biofactures Lynbrook, NY	1999-2002 **Director of Validation and Technical Services** *Manufacturer of Biopharmaceutical Collagenase Santyl Enzymatic Ointment* • Validation Project Manager for the new API facility in Curacao, Netherlands Antilles and the renovations in the Lynbrook, NY facility. Both projects involved additions of clean rooms, new USP Purified water systems, Lyophilization, and process/equipment/facility validation. Drafted associated protocols and reports. • Established various new quality-related programs such as Process Validation, Facility Preventative Maintenance, Instrument Calibration and Engineering Change Control. • Procured subcontractors, developed project scopes, negotiated contracts and managed personnel, budget and activities. • Prepared and delivered the presentation of the Curacao facility/equipment qualification plan before FDA CBER Rockville, MD in January 2000. Submitted with the PAI team, the PAS for the Curacao renovations.

Organogenesis Canton, MA	1993-1999 **Manager of Validation and Calibration** • Oversaw and performed validation on process systems related to the manufacture of biotechnologically engineered tissue constructs. • Designed/implemented IQ/OQ/PQ protocols, SOP's and calibration procedures. • Validation activities: sterilization, cryopreservation, tissue/cell culture incubators, WFI and USPPW systems, HVAC, Control Systems, SCADA, Class 100/10k clean room qualifications and equipment requalification. • Validation Project Manager for the Canton Facility expansion. Drafted Master plan, procured subcontractors, managed personnel, budget and activities. • Represented Validation/Calibration in FDA GMP inspections. • Created in-house calibration program from the ground up. Converted program from 100% out-sourced calibration labor to 100% in-house.
Barry Controls Boston, MA	1988-1993 **Senior Electronic Lab Technician** Repair/calibration support of the Engineering Test Lab. Established programs, audits, procedures. Systems included: materials testing, tension/compression, vibration/shock. Test equipment: oscilloscopes, DMM's, accelerometers, RVDT's, LVDT's and load cells.
United States Navy	1980-1988 **Electronic Technician First Class** Electronic Calibration and test equipment repair to Atlantic Surface and Submarine fleets. Electronic equipment support for coastal survey operations in Haiti and Morocco.

Education

SUNY Albany Albany, NY	1992-1994	Bachelor of Science Electronic Engineering
Northeastern University, Boston, MA	1987-1992	Electrical and Electronic Engineering

Applications

• MS Word, Excel, Power Point, Access, Project • MiniTab	• Blue Mountain Calibration Manager, other CMMS's • Kaye Validator and Validator 2000

Affiliations

International Society of Pharmaceutical Engineers	Subject Matter Expert on ISPE's Commissioning and Qualification Guideline 2008 rewrite committee.
International Academy of Compounding Pharmacists	Corporate Partner, Bestech GMP Contracting, Inc. ▪ Developed and presented Webinar – "GMP's for the Outsourcing Pharmacy" 2014

Curriculum Vitae

Shirley J. Berryman

Former FDA Pre-Approval Program Manager/Pharmaceutical Inspectorate/Investigator

Education:

Degree of Associate in Arts, The Metropolitan Community College with over 30 hours in general science classes, 1994

Degree of Bachelor of Arts, Columbia College/Criminal Justice Administration, 1997

Drug Inspectional Experience:

- Quality Systems Inspections for all pharmaceutical dosage forms
- Pre-Approval Inspections
- Compounding Pharmacy Inspections
- Positron Emission Tomography (PET) Inspections

Summary of Work Experience:

1973-1985 Various clerical positions with FDA, Kansas City District for Administrative Branch and Investigations Branch.

1985-1989 FDA Inspector/FDA Investigator - inspecting all industries including but not limited to the following industries: drugs, medical devices, biologics, tissue residue, medicated feeds, and foods.

1989-1994 I conducted criminal investigations while a member of the National Animal Drug Investigation team member. I worked directly with Department of Justice (DOJ) attorneys. I assisted attorneys at their table during one trial. I also testified in front of a grand jury.

1994 FDA Compliance Officer one year detail where I reviewed compliance cases. When appropriate I wrote and issued Warning Letters.

1995-1999 FDA Investigator inspecting all industries including but not limited to the following industries: drugs, medical devices, biologics, tissue residue, medicated feeds, and sponsor/monitor/bioresearch. I had a detail as Acting Supervisory Investigator in 1999 where I supervised Investigators.

2000 - Jan 2015 I was the Kansas City District Pre-Approval Manager (PAM) and Investigator. As the pre-approval manager I was responsible for human and veterinary drugs and medical devices. I obtained my Pharmaceutical Inspectorate status in June 2011 and continued with that status through my employment ending with retirement in January 2015. In addition, I conducted local and international Drug cGMP and Pre-Approval Inspections (PAIs) for the following types of drugs: tablets, capsules, liquids, creams, sterile, and APIs. Also I inspected compounding

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pharmacies, PET facilities and provided assistance with other industry inspections when emergencies arose. As the PAM, I made the decision whether to inspect a facility for compliance or approve/ withhold based on firm's history for our district. I reviewed previous inspection reports, interviewed the investigator, consulted with CDER, Compliance Branch & Investigation Branch management and reviewed portions of the NDA/ANDA/NADA/ANADA etc. drug application to determine if a Pre-Approval Inspection (PAI) was needed. When I assigned a PAI, I assisted Investigators and Analysts with their preparation for their PAI both domestic and international. I have provided answer to questions for foreign travelers for other district Investigators as well. I routinely provided training and presentations on the Pre-approval program to new hires. As the PAM, I worked closely with CDER, CVM, CDRH, Compliance Branch, Supervisors and Investigators. I also was back-up for handling NDA Field Alerts.

March-April 2014, I was on detail as Consumer Safety Officer (Pre-Approval Manager) where I planned Drug International Inspection trips for field Investigators for the Medical Products and Tobacco Trip Planning Branch, ORA. I planned highly technical, complex inspections and in-depth investigations related to NDA products. I reviewed previous inspection, interviewed the investigator, consulted with CDER, and reviewed the NDA drug application to determine if an inspection was needed. I then scheduled the inspections to meet time frames. I contacted drug manufactures to get the required information. I worked with drug investigators and provided them documentation for their inspection including applicable NDA applications.

January 2015 – present, I have conducted several audits for the drug industry.

Awards:

- FDA Award of Merit, 1994
- FDA Group Recognition Award, June 11, 1999
- FDA CDER Team Excellence, May 30, 2003
- Pharmaceutical Technical Exchange Association, PTEA Award of Excellence as FDA advisory member, April 2011
- Excellent or Outstanding Performance Ratings 2000 to 2014
- Numerous Monetary and Time Off Performance Awards for various work activities throughout the years

Certifications:

FDA Level I Investigator Certification, July 22, 2003

FDA Level II Certification in Drugs, February 7, 2011

FDA Level III Certification in Drugs, June 30, 2011

FDA Committee Membership:

FDA Advisory member of the Pharmaceutical Technical Exchange Association (PTEA) for several years.

August 2015 – I rejoined the PTEA as a committee member to assist in planning annual PTEA one day conference in the Kansas City area.

Presentations:

Presentations regarding the Pre-approval Program at Parenteral Technical Association (PTEA) Kansas City, MO

Presentation to Centers for Medicare and Medicaid Services (CMS) July 21, 2004 regarding the Pre-approval Program

Presentations at Basic Drug School/DG-230-Systems Based Drug Inspection regarding 21 CFR 211 Sub Part J, Records and Reports, 2007-2014

Presentations regarding the Pre-approval Program at District New Hire training for both Investigators and Analysts, 2010-2014

From *The Pharmacy Act and Drug Control Act with Related Statutes*, July 1, 2015

§ 54.1-3434.05. Permit to act as an outsourcing facility.

A. No person shall act as an outsourcing facility without first obtaining a permit from the Board.

B. Applications for a permit to act as an outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the outsourcing facility and who will be fully engaged in the compounding performed at the location designated on the application. Such application shall be accompanied by a fee determined by the Board in regulation. All permits shall expire annually on a date determined by the Board in regulation. No permit shall be issued or renewed for an outsourcing facility unless the facility can demonstrate compliance with all applicable federal and state laws and regulations governing outsourcing facilities.

C. As a prerequisite to obtaining or renewing a permit from the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for a permit to the Board or (b) no more than two years prior to the date of submission of an application for renewal of a permit to the Board. However, if the outsourcing facility has not been inspected by the U.S. Food and Drug Administration 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.

D. Every outsourcing facility shall compound in compliance with the requirements of state and federal law and regulations except § 54.1-3410.2, to include all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

E. An outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a permit to operate a pharmacy.

§ 54.1-3434.5. Nonresident outsourcing facilities to register with the Board.

A. Any outsourcing facility located outside the Commonwealth that ships, mails, or delivers in any manner Schedule II through VI drugs or devices into the Commonwealth shall be considered a nonresident outsourcing facility and shall be registered with the Board.

B. Applications for registration to act as a non-resident outsourcing facility shall be made on a form provided by the Board and signed by a pharmacist who is licensed as a pharmacist in Virginia and who is

in full and actual charge of the outsourcing facility, is fully engaged in the compounding performed at the location stated on the application, and is fully responsible for the outsourcing facility's compliance with state and federal law and regulations. Such application shall be accompanied by a fee determined by the Board in regulation. All registrations shall expire annually on a date determined by the Board in regulation.

C. As a prerequisite to registering or renewing a registration with the Board, the outsourcing facility shall (i) register as an outsourcing facility with the U.S. Secretary of Health and Human Services in accordance with 21 U.S.C. § 353b and (ii) submit a copy of a current inspection report resulting from an inspection conducted by the U.S. Food and Drug Administration that indicates compliance with the requirements of state and federal law and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration.

The inspection report required pursuant to clause (ii) shall be deemed current for the purposes of this section if the inspection was conducted (a) no more than one year prior to the date of submission of an application for registration with the Board or (b) 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 outsourcing facility has not been inspected by the U.S. Food and Drug Administration 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.

D. A nonresident outsourcing facility shall not engage in compounding of drug products to be dispensed pursuant to a valid prescription for a specific patient without first obtaining a registration to operate a nonresident pharmacy. The nonresident pharmacy shall comply with all state and federal laws, regulations, and requirements except § 54.1-3410.2.