

Agenda Item: Regulatory Actions - Chart of Regulatory Actions

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

Action: None – provided for information only

Board		Board of Pharmacy
Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Outsourcing facilities</u> [Action 4452]</p> <p>Emergency/NOIRA - Register Effective: 12/7/15 to 6/6/17 Comment on NOIRA ended: 1/27/16</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Prohibition against incentives to transfer prescriptions</u> [Action 4186]</p> <p>NOIRA - Register Date: 11/16/15 Comment on NOIRA ended: 12/16/15</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Addressing hours of continuous work by pharmacists</u> [Action 3755]</p> <p>Proposed - Register Date: 11/30/15 Comment on proposed ended: 1/29/16</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Collection sites for disposal of unused drugs</u> [Action 4337]</p> <p>Fast-Track - Register Date: 2/8/16 Effective: 3/24/16</p>
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	<p><u>Repackaging at PACE sites</u> [Action 4453]</p> <p>Fast-Track - Register Date: 3/7/16 Effective: 4/21/16</p>
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	<p><u>Permits for facilities</u> [Action 4451]</p> <p>Emergency/NOIRA - Register Effective: 12/7/15 to 6/6/17 Comment on NOIRA ended: 1/27/16</p>

Agenda Item: Adoption of Notice of Intended Regulatory Action

Staff Note:

The Board issued a Notice of Periodic Review with comment requested from 11/30/15 to 12/30/15. Subsequently, the Regulation Committee held two meetings to review Chapters 20 and 50 – Regulations Governing the Practice of Pharmacy and Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen.

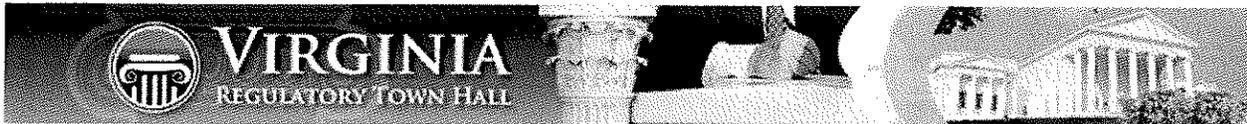
Included in your package are copies of:

- Copy of Notice of Periodic Review
- Copies of comments on the Review
- Draft substance of the Notice of Intended Regulatory Action identifying the sections for which the Board is considering amendments.

Action:

Motion to adopt the Notice of Intended Regulatory Action as recommended by the Regulation Committee.

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Logged in as

Elaine J. Yeatts

Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

Regulations Governing the Practice of Pharmacy [18 VAC 110 – 20]

[Edit Review](#)

Periodic Review of this Chapter

Includes a Small Business Impact Review

Date Filed: 11/3/2015

Review Announcement

Pursuant to Executive Order 17 (2014) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, the Board of Pharmacy is conducting a periodic review and small business impact review of VAC citation: 18VAC110-20-10 et seq., Regulations Governing the Practice of Pharmacy and 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen.

The review of this regulation will be guided by the principles in Executive Order 17 (2014). <http://dhp.virginia.gov/regs/EO17.pdf>

The purpose of this review is to determine whether this regulation should be repealed, amended, or retained in its current form. Public comment is sought on the review of any issue relating to this regulation, including whether the regulation (i) is necessary for the protection of public health, safety, and welfare or for the economical performance of important governmental functions; (ii) minimizes the economic impact on small businesses in a manner consistent with the stated objectives of applicable law; and (iii) is clearly written and easily understandable.

The comment period begins November 30, 2015, and ends on December 30, 2015.

Comments may be submitted online to the Virginia Regulatory Town Hall at <http://www.townhall.virginia.gov/L/Forums.cfm>. Comments may also be sent to Name: Elaine Yeatts, Title: Agency Regulatory Coordinator, Address: 9960 Mayland Drive, Suite 300, City: Henrico, State: Virginia, Zip: 23233, FAX: 804-527-4434, email address: elaine.yeatts@dhp.virginia.gov.

Comments must include the commenter's name and address (physical or email) information in order to receive a response to the comment from the agency. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

Public Comment Period

Begin Date: 11/30/2015 End Date: 12/30/2015

Comments Received: 2

Review Result

Pending

Attorney General Certification

Pending

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Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

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Commenter: Jon Horton, Sentara Norfolk General *

12/24/15 12:16 pm

Tech-Check-Tech

Please thoughtfully consider the addition of Tech-Check-Tech within Part X regulating Unit Dose Dispensing Systems.

Tech-Check-Tech programs have been in existence since 1978 and are currently approved for use in 12 states. In a 2009 NABP survey California, Colorado, Idaho, Iowa, Kansas, Kentucky, Michigan, Minnesota, Montana, North Dakota, South Carolina, and Washington indicated that they allowed pharmacy technicians to check the work of other technicians in hospital and institutional or community settings. Studies have demonstrated the value of these programs in providing safe and effective care in the institutional setting. They have demonstrated that a technician's accuracy of final dispensing checks is comparable to a pharmacist's accuracy in performing final dispensing checks. Allowance for implementation of Tech-Check-Tech programs would maintain the accuracy of the checking process and facilitate a pharmacists' involvement in providing direct patient care services.

Please consider addition to the Virginia Board of Pharmacy regulations the allowance for Tech-Check-Tech processes within Part X. Language found in Kansas law clearly identifies the requirements for technicians who would qualify as a checking technician as well as a process for training technicians and evaluating their competency once they have met the criteria to qualify (http://www.sos.ks.gov/pubs/kar/2013/068_68-Board%20of%20Pharmacy,%202013%20KAR%20Supp.pdf):

"...a pharmacy technician in a medical care facility may check the work of another pharmacy technician in filled floor stock, a crash cart tray, a unit dose cart, or an automated dispensing machine if the checking pharmacy technician meets each of the following criteria:

(1) Has a current certification issued by the pharmacy technician certification board or a current certification issued by any other pharmacy technician certification organization approved by the board. Any pharmacy technician certification organization may be approved by the board if the board determines that the organization has a standard for pharmacy technician certification and recertification not below that of the pharmacy technician certification board;

(2) has either of the following experience levels:

(A) One year of experience working as a pharmacy technician plus at least six months experience working as a pharmacy technician in the medical care facility at which the checking will be performed; or

(B) one year of experience working as a pharmacy technician in the medical care facility at which the checking will be performed; and

(3) has successfully completed a written training program and related examination designed by the

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pharmacist-in-charge of the medical care facility pharmacy to demonstrate competency in accurately checking whether floor stock, a crash cart tray, and an automated dispensing machine have been properly filled."

Respectfully submitted for your consideration!

* Nonregistered public user

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Agency

Department of Health Professions

Board

Board of Pharmacy

Chapter

Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

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Commenter: Jamin Engel, Pharmacy Manager at Sentara RMH Medical Center *

12/11/15 3:47 pm

Regionalization of Hospital Packaging

Please thoughtfully consider the addition of regionalization of hospital packaging within Part XI regulating Pharmacy Services to Hospitals.

ASHP Pharmacy Forecast for 2015-2019 indicates that the pharmacy departments in at least 50% of hospitals will be responsible for preparing nearly all compounding sterile products needed for the hospital's patients. An increasing amount of facilities are moving away from outsourcing facilities due to unresolved FDA 483's and subsequent warning letters.

The increasing demand on internal sterile compounding operations is exponentiated by changes in USP guidelines and CETA regulations that continue to increase demands on facility controls and compounding competencies. As health systems continue to merge and acquire additional facilities to mitigate changing financial and quality measures, there is an opportunity to utilize and capitalize sterile compounding skilled labor internally and centrally for these systems.

Insourcing through regionalization allows centralized compounding to ensure quality standards are met and consistency is established throughout the continuum of care within the system. In comparison to a manufacturing facility, consistency is established through ISO standardization that improves the quality of the end-product. As facilities and individual sites increase, the risk for inconsistency increases, thus putting our patients at risk. In addition, sterile compounding continues to involve technological resources, advances in engineering, and specific competency that is better established and implemented at a centralized location for better controls.

California board of Pharmacy 2015 Lawbook for Pharmacy Article 7.6:4128 allows "a centralized hospital packaging pharmacy may prepare medications, by performing the following specialized functions, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership"

Wisconsin Chapter Phar 7.01 (2) does not "prohibit institutional pharmacists or community pharmacists serving institutions from receiving prescription orders, dispensing and returning prescription medications consistent with accepted inpatient institutional drug distribution systems"

New Jersey also allows health system regionalization of sterile compounding under section 503A.

Please consider addition to the Virginia Board of Pharmacy regulations the allowance for regionalization of compounded products under a common ownership entity. The prescription data may be collected by the site of requisition, and can be recalled by the site of distribution allowing for receipt of a valid order prior to dispensing and administration to the end-user to comply with 503A Traditional Compounding.

Recommended addition for consideration:

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E. Centralized Hospital Packaging

A centralized hospital packaging pharmacy may prepare medications, unit dose packaging and compounded medications, for administration only to inpatients within its own general acute care hospital and one or more general acute care hospitals if the hospitals are under common ownership and share a common medical information system.

Thank you for your thoughtful consideration!

* Nonregistered public user

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Yeatts, Elaine J. (DHP)

From: Tim Musselman <Tim@virginia pharmacists.org>
Sent: Wednesday, December 30, 2015 9:12 PM
To: Yeatts, Elaine J. (DHP)
Cc: Juran, Caroline (DHP)
Subject: Periodic Review Comments

Elaine,

See below for regulations that VPhA members have suggested the Board of Pharmacy consider reviewing:

- **Prescription department enclosures for locations where the pharmacy and business open and close at the same time**
 - 18VAC110-20-190. Prescription department enclosures; access to prescription department.
 - A few pharmacies have been cited recently for not locking their prescription department. In some these cases, the pharmacy department is only open when the entire location is opened (or closed) by the pharmacist and thus do not operate the front of the store with the pharmacy department closed. The Board should consider reviewing the requirement for a secure prescription department in instances where the department and the entire location are closed and secured at the same time.
- **Lack of adequate technician help**
 - 18VAC110-20-270. Dispensing of prescriptions; certification of completed prescriptions; supervision of pharmacy technicians.
 - We hear too often that pharmacists are not provided with adequate technician help. While Section B clearly states that “a pharmacist shall determine the number....” we have heard from many pharmacists who are not willing to approach their employer about the lack of staffing support due to fear of retribution including losing their job. Thus, the decision to determine their technician support does not lie in the hands of the pharmacist on duty. We encourage the Board to consider strengthening this regulation as pharmacists are placed in unsafe staffing situations that ultimately fall out of their control.

Please feel free to contact me if you have any questions.

- Tim

Timothy S. Musselman, Pharm.D.

Executive Director

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December 15, 2015

Elaine Yeatts
Agency Regulatory Coordinator
9960 Mayland Drive
Suite 300
Henrico, VA 23233
Via email: elaine.yeatts@dhp.virginia.gov

Re: Periodic Regulatory Review: 18VAC110-50-10 et seq., Regulations Governing Wholesale Distributors, Manufacturers, and Warehousemen

Dear Ms. Yeatts:

On behalf of our members that operate approximately 1,126 chain pharmacies in the Commonwealth of Virginia, the National Association of Chain Drug Stores ("NACDS") is writing to comment to the Virginia Board of Pharmacy ("Board") on the periodic regulatory review of 18VAC110-50-10 et seq. regarding wholesale distributors, manufacturers and warehousemen and requirements for pedigree. We are concerned that the current rules are inconsistent with and preempted by provisions of the Federal Drug Quality and Security Act (DQSA) that outline requirements for an electronic, interoperable system to identify and trace drugs that are distributed in the United States.

The new federal track and trace law implements various approaches designed to promote a secure drug supply chain, including: product identification, tracing and verification; detection and response to quarantine and investigate suspect drug products; notification systems; wholesaler licensing; and third-party logistics provider licensing. There are numerous instances where the existing and proposed rule language in 18VAC110-50-10 et seq. regarding drug pedigree and recordkeeping requirements is inconsistent with the new requirements of DQSA.

Notably, the Food and Drug Administration (FDA) gave a presentation at the 2015 National Association of Boards of Pharmacy Annual Meeting on the topic of drug supply chain integrity. During this session, representatives from FDA explained how DQSA preempts states' laws and regulations on drug distribution recordkeeping.

For these reasons, NACDS urges the Board amend 18VAC110-50-10 et seq. to mirror the federal law.

Thank you for considering our comments on the periodic regulatory review of 18VAC110-50-10 et seq. Please do not hesitate to contact me with any questions or for further assistance.

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Sincerely,

A handwritten signature in black ink that reads "Jill K. McCormack". The signature is written in a cursive, flowing style.

Jill McCormack, Director
State Government Affairs

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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.”

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 “American Medical Association” 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.

18VAC110-20-100 Approval of continuing education programs

- Deleting ability for board to approve CE programs.

PART III. Requirements For Pharmacy Technician Registration.

18VAC110-20-102 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.

18VAC110-20-106 Requirements for continued competency

- Changing “certificates” to “documentation” in both sentences of subsection D.

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.

18VAC110-20-130 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, weekly 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

- Adding language in subsection A from Guidance Document 110-16 regarding clarifications for performing inventories.
- Deleting language in subsection B regarding the red "C" unless this is based on federal rules.
- 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.
- Regarding subsection F and on-hold prescriptions, revising requirement for pharmacy to pull the originally filed prescription and refile it.
- 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.
- Revising section 275 for more clarity.

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 identify 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.
- 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.

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

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

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 review all regulations that require a pharmacist's initials to determine if there is a better method for identifying the responsible pharmacist.

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, AND WAREHOUSERS

Part I General Provisions

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 if law 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.
- For consistency, considering similar requirements in 18VAC110-20-80 for responsible party of manufacturers.

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)

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 March 25, 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 March 23, 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 six (6) 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:

1. N-phenyl-N-[1-(2-phenylethyl)-4-piperidinyl]-butanamide (other name: butyryl fentanyl)

Butyryl fentanyl is a powerful synthetic opioid similar in structure to fentanyl and has been identified in DFS laboratories. Butyryl fentanyl has not been approved for medical use in the United States. DFS recommends placing butyryl fentanyl into Schedule I (§ 54.1-3446(6)).

2. Flubromazolam

Flubromazolam is classified as a benzodiazepine which is a central nervous system depressant. Flubromazolam has been identified in DFS laboratories found on blotter paper and candy. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(4)).

3. 5-methoxy-N,N-methylisopropyltryptamine (Other name: 5-MeO-MIPT)

5-MeO-MIPT is classified as a research chemical and has been identified in DFS laboratories. 5-MeO-MIPT is similar in structure to 5-MeO-DIPT which is currently a schedule I compound. Drugs of this type have been placed in Schedule I (§ 54.1-3446(3)) in previous legislative sessions.

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

ADB-FUBINACA is classified as a cannabimimetic agent, and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

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

MDMB-FUBINACA is classified as a cannabimimetic agent, and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

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

5-fluoro-ADB is classified as a cannabimimetic agent and has been identified in DFS laboratories. Other drugs of this type have been placed in Schedule I (§ 54.1-3446(7)(b)) in previous legislative sessions.

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.

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 (18 months from the effective date), unless enacted into law in the Drug Control Act.

Agenda Item: Petitions for rulemaking

Included in your package are:

3 petitions for rulemaking

Copies of the *Requests for Comment*

Copies of comment on petitions

Copies of applicable regulations

Board action: The Board will consider each petition separately:

- 1) Irwin – allow long term care facility to provide prescription information for Schedule VI drugs to a “back-up” pharmacy located near the facility (3 comments)
- 2) Gilley – allow pharmacists in hospitals or free-standing emergency departments to adjust or order medications according to clinically accepted guidelines (0 comments)
- 3) Merryfield – allow bar code and FRID scanning to extend the pharmacist check, once the bar code or RFID scan has been verified (0 comments).

The Board may reject the petition’s request. If rejected, the Board must state their reasons for denying the petition.

OR

The Board may initiate rulemaking by adoption of an amendment by publication of a Notice of Regulatory Action.

Request for Comment on Petition for Rulemaking

Promulgating Board: **Board of Pharmacy**

Regulatory Coordinator: Elaine J. Yeatts
(804)367-4688
elaine.yeatts@dhp.virginia.gov

Agency Contact: Caroline Juran
Executive Director
caroline.juran@dhp.virginia.gov
Department of Health Professions

Contact Address: 9960 Mayland Drive
Henrico, VA 23233

Chapter Affected:
18 vac 110 - 20: Regulations Governing the Practice of Pharmacy

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Petitioner Bill Irvin, for Omnicare

Petitioner's Request

To allow a pharmacy providing services to a long term care facility to provide prescription information of Schedule VI drugs to a "back-up" pharmacy located near the facility enabling the "back-up" pharmacy to provide the first dispensing of the prescription without the act constituting a transfer of the prescription.

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on December 28, 2015. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until January 27, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016.

**Comments may be posted on the Virginia Regulatory Townhall at:
www.townhall.virginia.gov**

Publication Date 12/28/2015 *(comment period will also begin on this date)*

Comment End Date 01/27/2016

From: Irvin, William [<mailto:William.Irvin@omnicare.com>]
Sent: Wednesday, October 14, 2015 2:51 PM
To: Juran, Caroline (DHP)
Cc: mark.johnston@cvscaremark.com
Subject: Follow Up Omnicare Meeting - First Fill Discussion

Good Afternoon Caroline,

During our recent meeting, we discussed Omnicare's protocol for handling "first fill" doses for patients residing in long term care facilities. In consultation with Mark Johnston, we respectfully share the language used by the Idaho Board of Pharmacy that governs this issue. We believe it is most representative of Omnicare's current process as well as those conducted in other pharmacies engaged in providing long term care pharmacy services. The specific language is noted below along with a link to the full suite of Idaho Rules. Please let me know if I can provide any additional information that may further assist with the regulation review. Last, would it be possible to participate in the regulation review meeting as a key stakeholder?

Thank you again for your time and consideration.

All the best,

Bill

<http://adminrules.idaho.gov/rules/current/27/0101.pdf>

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY. A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13) 01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13) 02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13) 03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13) 04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required.

Bill Irvin, R.Ph.
Director, Pharmacy Regulatory Affairs
13 Commerce Avenue
Londonderry, NH 03053
603-339-7846 Mobile
513-719-0433 E-fax
William.Irvin@omnicare.com

 **CVSHealth**

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Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing the Practice of Pharmacy [18 VAC 110 - 20]

All comments for this forum

[Back to List of Comments](#)

Commenter: Amy Hewett, Virginia Health Care Association *

1/20/16 2:31 pm

Support for the petition for rulemaking

The Virginia Health Care Association (VHCA), which represents over 270 long term care facilities in the Commonwealth of Virginia, supports this petition for rulemaking. Allowing a "back-up" pharmacy to initially dispense a prescription without that constituting a prescription transfer would help ensure patients receive their medication in a timely manner. This efficiency is especially important in circumstances when the patient is beginning a new, clinically critical medication.

Changing the regulations as proposed would also improve the continuity of care when patients are transferred from hospitals to nursing facilities and the on-site pharmacy may not have the new prescription on-hand.

Commenter: Hope Spencer * *

1/25/16 11:28 am

Support for change in backup pharmacy requirement for LTC

I work in a LTC, mail order pharmacy which handles many backup requests for our consumers. The vast majority of these requests are for antibiotics and other emergency meds which patients need quickly. We have been handling these requests as transfers per the Board requirement, which means we have to transfer the medication to another (local to the patient) pharmacy and then transfer it back to us if it is not a one time order or a control. This process is very time consuming and frequently results in more of a delay for start of treatment. Additionally, some of the pharmacies our patients' caregivers would like to utilize as backup pharmacies consider the extra work to be too prohibitive and refuse to accept our transfers, which causes even more of a delay in start of treatment.

Commenter: Kimberly White, Pharmacy Alternatives *

1/27/16 1:47 pm

Support for backup requirement change

I support the change for backup requirement for long term care pharmacies. I currently work at a long term care pharmacy, and we send many prescriptions to backup pharmacies every day. Our patients typically need acute care meds or new prescriptions/dose changes to begin immediately. It is very time-consuming for both us and the retail pharmacy to do a transfer of each of these prescriptions, negatively impacting patient care. In fact, many of the retail pharmacies we call will refuse to service our patients any longer due to the time/effort of transferring the prescription back and forth when they may only be filling a three day supply. My patients and their caregivers cannot

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always go the the backup pharmacy of their choice because the backup pharmacy will not fill these prescriptions. I strongly feel if change the requirements, we can benefit our patients and their caregivers.

* Nonregistered public user

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Idaho. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required. IA ADC 27.01.641

<http://adminrules.idaho.gov/rules/current/27/0101.pdf>

641. INSTITUTIONAL FACILITY: OFFSITE SERVICES -- FIRST DOSE PHARMACY. A contracted offsite pharmacy that provides prescription processing or filling services for an institutional facility without an institutional pharmacy or for patients of a home health or hospice agency may centralize these services to another pharmacy if in compliance as follows: (7-1-13) 01. Limited Purpose. Centralized pharmacy services are for the limited purpose of ensuring that drugs or devices are attainable to meet the immediate needs of patients and residents or if the originating pharmacy cannot provide services for the institutional facility on an ongoing basis; (7-1-13) 02. Institutional Facility Approval. The originating pharmacy obtains approval from the institutional facility, home health agency or hospice agency to centralize pharmacy services for its patients and residents; (7-1-13) 03. Written Contract. The originating pharmacy has a written contract with the central pharmacy outlining the services to be provided and the responsibilities and accountabilities of each party in fulfilling the terms of the contract; and (7-1-13) 04. Drug or Chart Orders. The originating pharmacy provides a valid verbal, electronic, or paper drug order to the contracted central pharmacy. A single drug order may be shared by an originating pharmacy and a central pharmacy with no transfer required.

Colorado. Pharmacist at prescription drug outlet may dispense up to 72-hour supply of non-controlled substance prescription drug pursuant to a duplicate copy of an LTCF chart order . 3 CCR 719-3.00.25

Montana. In an emergency, Montana allows a pharmacy to “transfer” original prescription order for a non-controlled substance to a second pharmacy for dispensing up to a seven day supply without adhering to the states formal prescription transfer requirements. See Mont. Admin. R. 24.174.514(6).

Florida. Florida allows a pharmacy to transmit a starter dose to another pharmacy provided that the originating pharmacy: (1) has a written authorization from the LTC facility; (2) has a written contract with the starter dose pharmacy; (3) has written authorization from the prescriber to act as the prescriber’s agent for the purpose of transmitting a starter dose prescription; (4) has a valid prescription from the prescriber p; (5) maintains a record of each starter dose prescription; and (6) maintains policies and procedures regarding starter dose prescriptions. Fla. Admin. Code Ann. r. 64B 28.503(2)(a)-(f).

18VAC110-20-520. Drugs in long-term care facilities.

Prescription drugs, as defined in the Drug Control Act, shall not be floor stocked by a long-term care facility, except those in the stat drug box or emergency drug box or as provided for in 18VAC110-20-560 within this chapter.

18VAC110-20-530. Pharmacy's responsibilities to long-term care facilities.

The pharmacy serving a long-term care facility shall:

1. Receive a valid order prior to the dispensing of any drug.
2. Ensure that personnel administering the drugs are trained in using the dispensing system provided by the pharmacy.
3. Ensure that the drugs for each patient are kept and stored in the originally received containers and that the medication of one patient shall not be transferred to another patient.
4. Ensure that each cabinet, cart or other area utilized for the storage of drugs is locked and accessible only to authorized personnel.
5. Ensure that the storage area for patients' drugs is well lighted, of sufficient size to permit storage without crowding, and is maintained at appropriate temperature.
6. Ensure that poison and drugs for "external use only" are kept in a cabinet and separate from other medications.
7. Provide for the disposition of discontinued drugs under the following conditions:
 - a. Discontinued drugs may be returned to the pharmacy for resale or transferred to another pharmacy for redispensing to the indigent if authorized by §54.1-3411.1 and 18VAC110-20-400, or disposed of by appropriate means in compliance with 18VAC110-20-210 and any applicable local, state, and federal laws and regulations.
 - b. Drug destruction at the pharmacy shall be witnessed by the PIC and by another pharmacy employee. The pharmacy may transfer the drugs for destruction to an entity appropriately licensed to accept returns for destruction. Drug destruction at the facility shall be witnessed by the director of nursing or, if there is no director, then by the facility administrator and by a pharmacist providing pharmacy services to the facility or by another employee authorized to administer medication.
 - c. A complete and accurate record of the drugs returned or destroyed or both shall be made. The original of the record of destruction shall be signed and dated by the persons witnessing the

destruction and maintained at the long-term care facility for a period of two years. A copy of the destruction record shall be maintained at the provider pharmacy for a period of two years.

d. Long term care facilities shall destroy discontinued or unused drugs or return them to the pharmacy within 30 days of the date the drug was discontinued.

8. Ensure that appropriate drug reference materials are available in the facility units.

9. Ensure that a monthly review of drug therapy by a pharmacist is conducted for each patient in long-term care facilities except those licensed under Title 63.2 of the Code of Virginia. Such review shall be used to determine any irregularities, which may include but not be limited to drug therapy, drug interactions, drug administration or transcription errors. The pharmacist shall sign and date the notation of the review. All significant irregularities shall be brought to the attention of the attending practitioner or other party having authority to correct the potential problem.

Request for Comment on Petition for Rulemaking

Promulgating Board: Board of Pharmacy

Elaine J. Yeatts

Regulatory Coordinator: (804)367-4688

elaine.yeatts@dhp.virginia.gov

Caroline Juran

Agency Contact: Executive Director

caroline.juran@dhp.virginia.gov

Department of Health Professions

Contact Address: 9960 Mayland Drive

Henrico, VA 23233

Chapter Affected:

18 vac 110 - 20: Regulations Governing the Practice of Pharmacy

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Date Petition Received 12/28/2015

Petitioner Angela Gilley

Petitioner's Request

Within a Hospital or free-standing Emergency Department setting, the medical staff may approve guidelines that are clinically accepted as the standard of care, or are approved by the Medical Staff of the hospital through the typical approval process (such as the Pharmacy and Therapeutics Committee), which allow pharmacists to change, discontinue, adjust, monitor, order pertinent labs, and make subsequent adjustments to medications as applicable to the approved guideline without requiring a physician order to implement the guideline. In addition, a practitioner may write an order for "pharmacy to dose" a medication which allows the pharmacist to dose, monitor, order pertinent labs, and make subsequent adjustments to any medication specified in the order based on the pharmacist's clinical judgment.

Agency Plan

In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on January 25, 2016. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until February 24, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. It will also be reviewed by the Assistant Attorney General who can advise the Board on whether the request requires a change in the Code of Virginia. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016.

Publication Date 01/25/2016 *(comment period will also begin on this date)*

Comment End Date 02/24/2016



COMMONWEALTH OF VIRGINIA

Board of Pharmacy

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

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

Petition for Rule-making

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

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

Petitioner's full name (Last, First, Middle initial, Suffix,)

Gilley, Angela

Street Address

5377 Blackwater Loop

Area Code and Telephone Number

757-421-3132

City

Virginia Beach

State

VA

Zip Code

23457

Email Address (optional)

Fax (optional)

Respond to the following questions:

1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending.

This is a request to amend Part XI. Pharmacy Services to Hospitals. There is a need for language in the Regulations that addresses pharmacists adjusting medication regimens per medical staff approved guidelines.

2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule.

The Centers for Medicare & Medicaid Services (CMS) updated the State Operations Manual (SOM) Appendix A (October 30, 2015) with respect to both the hospital survey process and the interpretive guidelines for the pharmaceutical services Condition of Participation (CoP), clarifying their interpretive guidance in Appendix A for existing regulations in 42 CFR Part 482.25(b)(8) as follows.

§482.25(b)(8) - Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be available to the professional staff.

Interpretive Guidelines §482.25(b)(8)

The pharmacy must be a resource for medication-related information to the hospital's health-care practitioners and other health care personnel to optimize therapeutic outcomes and minimize adverse drug events. Information must be available concerning drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration.

The pharmacy may also assist other health care professionals with the following medication-related functions:

- Identification of the presence of medication-therapy problems, both potential and actual, such as drug-drug interactions, excessive doses;
- Identification and specification of pharmaco-therapeutic goals;
- Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health-care professionals;
- Monitoring the effects of the pharmacotherapeutic regimen – could include adjusting doses based on lab values (i.e.: Coumadin dosing);
- Redesigning the regimen and monitoring plan as indicated.

For example, practitioners may write an order for "pharmacy to dose" an antibiotic. The pharmacist would then take patient-specific information, review the patient's current medication therapies for any problems, and then calculate the dose required to meet therapeutic goals.

July 10, 2012 **63**

The proposed language would read as follows:

Within a Hospital or free-standing Emergency Department setting, the medical staff may approve guidelines that are clinically accepted as the standard of care, or are approved by the Medical Staff of the hospital through the typical approval process (such as the Pharmacy and Therapeutics Committee), which allow pharmacists to change, discontinue, adjust, monitor, order pertinent labs, and make subsequent adjustments to medications as applicable to the approved guideline without requiring a physician order to implement the guideline. In addition, a practitioner may write an order for "pharmacy to dose" a medication which allows the pharmacist to dose, monitor, order pertinent labs, and make subsequent adjustments to any medication specified in the order based on the pharmacist's clinical judgment.

3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is other legal authority for promulgation of a regulation, please provide that Code reference.

Signature: *Angela Gilley*

Date: 12-23-15

Part XI. Pharmacy Services to Hospitals

18VAC110-20-440. Responsibilities of the pharmacist-in-charge.

A. The PIC in a pharmacy located within a hospital or the PIC of any outside pharmacy providing pharmacy services to a hospital shall be responsible for establishing procedures for and assuring maintenance of the proper storage, security, and dispensing of all drugs used throughout the hospital.

B. The PIC of a pharmacy serving a hospital shall be responsible for maintaining a policy and procedure for providing reviews of drug therapy to include at a minimum any irregularities in drug therapy consistent with § 54.1-3319 A of the Code of Virginia.

C. Prior to the opening of a satellite pharmacy within the hospital, the PIC shall notify the board as required by 18VAC110-20-140 and shall ensure compliance with subsections B through G of 18VAC110-20-150, 18VAC110-20-160, 18VAC110-20-170, 18VAC110-20-180 and 18VAC110-20-190. No drugs shall be stocked in a satellite pharmacy until an inspection has been completed and approval given for opening.

D. For the following list of Schedule VI controlled substances, the PIC of a pharmacy serving a hospital may authorize the storage in an area of the hospital outside the pharmacy, and may delegate the ordering and distribution within the hospital to non-pharmacy personnel provided the conditions for proper storage and adequate security and the procedures for distribution are set forth in the pharmacy's policy and procedure manual, and provided that the PIC assures that these storage areas are checked monthly for compliance. The storage areas must be locked when authorized staff is not present in the area. Except for nitrous oxide, medical gases may be stored in an unlocked area.

1. Large volume parenteral solutions that contain no active therapeutic drugs other than electrolytes;
2. Irrigation solutions;
3. Contrast media;
4. Medical gases;
5. Sterile sealed surgical trays that may include a Schedule VI drug; and
6. Blood components and derivatives, and synthetic blood components and products.

18VAC110-20-450. After-hours access to the pharmacy.

A. When authorized by the PIC, an authorized nurse may have access to a supply of drugs maintained by the pharmacy at a location outside the pharmacy in order to obtain emergency medication during hours the pharmacy is closed, provided that such drug is available in the manufacturer's original package or in units which have been prepared and labeled by a pharmacist

and provided further that a separate record shall be made and left at the location of the stock of drugs on a form prescribed by the PIC and such records are maintained within the pharmacy for a period of one year showing:

- 1 The date of withdrawal;
2. The patient's name;
3. The name of the drug, strength, dosage form and dose prescribed;
4. Number of doses removed; and
5. The signature of the authorized nurse.

B. If the after-hours supply of drugs is in an area that is continuously open and staffed, such as a patient floor or emergency room, then the area does not need to be alarmed. If the after-hours supply is maintained in an area of the hospital that is not open and continuously staffed, such as a floor that primarily houses departments that are closed daily, then an alarm that meets the requirements of 18VAC110-20-180 shall be installed and activated at all times.

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;
2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;
3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and
4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

18VAC110-20-470. Emergency room.

All drugs in the emergency department shall be under the control and supervision of the PIC and shall be subject to the following additional requirements:

1. All drugs kept in the emergency room shall be in a secure place from which unauthorized personnel and the general public are excluded.
2. Oral orders for medications shall be reduced to writing and shall be signed by the practitioner.
3. A medical practitioner may dispense drugs to his patients if in a bona fide medical emergency or when pharmaceutical services are not readily available and if permitted to do so by the hospital; the drug container and the labeling shall comply with the requirements of this chapter and the Drug Control Act.
4. A record shall be maintained of all drugs administered in the emergency room.
5. A separate record shall be maintained on all drugs, including drug samples, dispensed in the emergency room. The records shall be maintained for a period of two years showing:
 - a. Date and time dispensed;
 - b. Patient's name;
 - c. Prescriber's name;
 - d. Name of drug dispensed, strength, dosage form, quantity dispensed, and dose.

18VAC110-20-480. (Repealed)

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

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

Request for Comment on Petition for Rulemaking

Promulgating Board: **Board of Pharmacy**

Regulatory Coordinator: Elaine J. Yeatts
(804)367-4688
elaine.yeatts@dhp.virginia.gov

Agency Contact: Caroline Juran
Executive Director
carolin.juran@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Henrico, VA 23233

Chapter Affected:
18 vac 110 - 20: Regulations Governing the Practice of Pharmacy

Statutory Authority: State: Chapters 33 and 34 of Title 54.1

Date Petition Received 12/31/2015

Petitioner David Merryfield

Petitioner's Request

To allow bar code and RFID scanning to extend the pharmacist check, once the bar code or RFID scan has been verified once for each product by a pharmacist.

Agency Plan

Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov; comment will be requested until February 24, 2016. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for March 25, 2016, and the petitioner will be informed of the Board's decision on his request after that meeting

Publication Date 01/25/2016 *(comment period will also begin on this date)*

Comment End Date 02/24/2016



COMMONWEALTH OF VIRGINIA
Board of Pharmacy

RECEIVED
DEC 29 2015

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

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

Petition for Rule-making

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

Please provide the information requested below. (Print or Type)		
Petitioner's full name (Last, First, Middle Initial, Suffix) <i>Merry Field, David W.</i>		
Street Address <i>1332 Meadow Lake Road</i>	Area Code and Telephone Number <i>757-934-4699</i>	
City <i>Virginia Beach, VA 23454</i>	State <i>VA</i>	Zip Code <i>23454</i>
Email Address (optional)	Fax (optional)	
Respond to the following questions:		
1. What regulation are you petitioning the board to amend? Please state the title of the regulation and the section/sections you want the board to consider amending. <i>See attachment</i>		
2. Please summarize the substance of the change you are requesting and state the rationale or purpose for the new or amended rule. <i>See attachment</i>		
3. State the legal authority of the board to take the action requested. In general, the legal authority for the adoption of regulations by the board is found in § 54.1-2400 of the Code of Virginia. If there is <u>other</u> legal authority for promulgation of a regulation, please provide that Code reference. <i>See attachment</i>		
Signature: <i>[Signature]</i>	Date: <i>12/2/15</i>	

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RECEIVED
E 29 08

December 29, 2015

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

RE: Periodic review of Chapter 20: Regulations Governing the Practice of Pharmacy (18 VAC 110-2—10 et seq.)

This is a request to amend Part X Unit Dose Dispensing Systems and Part XI Pharmacy Services to Hospitals.

18 VAC 110-20-420

8.d. currently requires "...the initials of the pharmacist checking and certifying the contents of the drug cart..."

18 VAC 110-20-425

3 requires "Pharmacists shall verify and check...and the verifying pharmacist shall initial the record..."

5 requires "Pharmacists shall perform a daily random check...Documentation of this check shall include the pharmacist's initials..."

6 requires "All manual picks shall be checked by pharmacists."

18 VAC 110-20-460

A requires "A pharmacist shall check all Schedule II-VI drugs..."

18 VAC 110-20-490

C.1. requires "...initials of the pharmacist checking the drugs to be removed from the pharmacy..."

The purpose of this periodic review is to determine whether these regulations should be amended or retained in their current form, including whether they are necessary for the protection of public health, safety, and welfare.

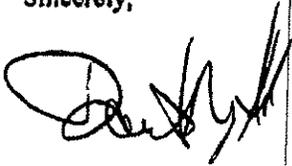
Bar coding technology has been available in pharmacy for several decades. RFID technology has become available somewhat more recently. These technologies are in wide use within pharmacy. Bar code scanning is recognized by Boards of Pharmacy in most other states. This is no longer innovative practice; this is usual and customary practice. A pharmacist should be required to verify that the bar code or RFID code assigned to a drug product is correct, but once that has been verified by the pharmacist, bar code or RFID scanning is well-established as safe for the protection of public health, safety, and welfare. Requiring a pharmacist to continue to physically check these items, each time they are dispensed, seriously limits the time that the pharmacist should be spending in other, much more valuable, contributions to the care and safety of patients.

Under the authority of the Code of Virginia 12.3-45 to promulgate regulations, this is a petition for new or amended regulations as described in the Code of Virginia Section 2.2-4007. Please give serious consideration to allowing bar code and RFID scanning to extend the pharmacist check, once the bar code or RFID scan has been verified once for each product by a pharmacist. This will be a boon to the profession of pharmacy in Virginia, freeing pharmacists to improve patient care and safety.

Although each of the above provisions could be modified separately, another way to approach this update would be to add in 18VAC110-20-10. Definitions. A new definition. (and the terms "certify" and "verify" above changed to "check"):

"check" means the pharmacist check that the product prepared by the technician or robotic technology is the correct medication, dosage form, and strength, as ordered for the patient. If electronic bar code or RFID scanning technology is used to perform the check in lieu of visual inspection by the pharmacist, the electronic scanning system must record a record of the scan. A pharmacist must have verified that each product's scan matches the correct product in the scanning database.

Sincerely,



David W. Merryfield
Pharmacist in Charge
Sentara Obici Hospital

Part X. Unit Dose Dispensing Systems

18VAC110-20-420. Unit dose dispensing system.

A. A unit dose drug dispensing system may be utilized for the dispensing of drugs to patients in a hospital or long-term care facility. The following requirements shall apply regardless of whether licensed or unlicensed persons administer medications:

1. Any equipment outside the pharmacy used to house drugs to be administered in a unit dose system shall be fitted with a locking mechanism and locked at all times when unattended.
2. A signed order by the prescribing practitioner shall accompany the requests for a Schedule II drug, except that a verbal order for a hospital patient for a Schedule II controlled substance may be transmitted to a licensed nurse or pharmacist at the hospital who shall promptly reduce the order to writing in the patient's chart. Such an order shall be signed by the prescriber within 72 hours.
3. Properly trained personnel may transcribe the prescriber's drug orders to a patient profile card, fill the medication carts, and perform other such duties related to a unit dose distribution system provided these are done under the personal supervision of a pharmacist.
4. All dosages and drugs shall be labeled with the drug name, strength, lot number and expiration date when indicated.
5. The patient's individual drug drawer or tray shall be labeled in a manner to identify the patient and his location without violating health privacy laws.
6. All unit dose drugs intended for internal use shall be maintained in the patient's individual drawer or tray unless special storage conditions are necessary.
7. A back-up dose of a drug of not more than one dose unit may be maintained in the patient's drawer, tray, or special storage area provided that the dose is maintained in the patient's drawer, tray, or special storage area with the other drugs for that patient.
8. A record shall be made and maintained within the pharmacy for a period of one year showing:
 - a. The date of filling of the drug cart;
 - b. The location of the drug cart;
 - c. The initials of the person who filled the drug cart; and
 - d. The initials of the pharmacist checking and certifying the contents of the drug cart in accordance with the provisions in 18VAC110-20-270 C.

9. A patient profile record or medication card will be accepted as the dispensing record of the pharmacy for unit dose dispensing systems only, subject to the following conditions:

a. The record of dispensing must be entered on the patient profile record or medication card at the time the drug drawer or tray is filled.

b. In the case of Schedule II through V drugs, after the patient profile record or medication card has been completed, the card must be maintained for two years.

c. In the case of the computer-based distribution system, a uniformly maintained "fill list" or other document containing substantially the same information may be accepted as the dispensing record for Schedule II through VI drugs. Records of disposition/administration for floor stock drugs as provided in 18VAC110-20-460 B will be accepted for drugs distributed as floor stock.

B. In providing unit dose systems to hospitals or long-term care facilities where only those persons licensed to administer are administering drugs, the pharmacy shall dispense not more than a seven-day supply of a drug in a solid, oral dosage form at any one given time.

C. In addition to the requirements listed in subsection A of this section, the following requirements apply to those long-term care facilities in which unlicensed persons administer drugs:

1. The pharmacy providing medications to such facility shall dispense no more than a 72-hour supply of drugs in a solid, oral dosage form at any one given time.

2. The pharmacy shall provide to persons administering medications training specific to the particular unit dose system being used.

3. The pharmacy shall provide a medication administration record to the facility listing each drug to be administered with full dosage directions to include no abbreviations.

4. The drugs in a unit dose system shall be placed in slots within a drawer labeled or coded to indicate time of administration.

18VAC110-20-425. Robotic pharmacy systems.

Consistent with 18VAC110-20-420, a pharmacy providing services to a hospital or a long-term care facility and operating a robotic pharmacy system that dispenses drugs in bar-coded unit dose or compliance packaging is exempted from 18VAC110-20-270 C, provided the accuracy of the final dispensed prescription product complies with a written quality assurance plan and requirements of this chapter. The following requirements for operation of a robotic pharmacy system shall apply: 1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

2. The packaging, repackaging, stocking and restocking of the robotic pharmacy system shall be performed by pharmacy technicians or pharmacists.

3. Pharmacists shall verify and check for the accuracy of all drugs packaged or repackaged for use by the robot by a visual check of both labeling and contents prior to stocking the drugs in the robotic pharmacy system. A repackaging record shall be maintained in accordance with 18VAC110-20-355 A, and the verifying pharmacist shall initial the record. Packaging and labeling, including the appropriate beyond-use date, shall conform to requirements of this chapter and current USP-NF standards.

4. A written policy and procedure must be maintained and shall include at a minimum, procedures for ensuring:

a. Accurate packaging and repackaging of all drugs for use in the robotic pharmacy system, to include properly labeled barcodes, and method for ensuring pharmacist verification of all packaged and repacked drugs compliant with this chapter;

b. Accurate stocking and restocking of the robotic pharmacy system;

c. Removing expired drugs;

d. Proper handling of drugs that may be dropped by the robotic pharmacy system;

e. Performing routine maintenance of robotic pharmacy system as indicated by manufacturer's schedules and recommendations;

f. Accurate dispensing of drugs via robotic pharmacy system for cart fills, first doses, and cart fill updates during normal operation and during any scheduled or unscheduled downtime;

g. Appropriately investigating, identifying and correcting sources of discrepancies or errors associated with the robotic pharmacy system; and

h. Maintaining quality assurance reports.

5. Pharmacists shall perform a daily random check of medications or compliance packaging picked by the robot for 5.0% of all patients' bins and 5.0% of all first doses or cart updates. Documentation of this check shall include the pharmacist's initials for each medication checked and a description of all discrepancies found.

6. All manual picks shall be checked by pharmacists.

7. If the robot picks an incorrect medication, the pharmacy shall immediately institute a 100% check of all doses or compliance packages and shall immediately report the error to the board. The 100% check procedure shall continue until such time as the pharmacy provides documentation to the board showing that the cause of the error has been determined and addressed and that the robot is no longer making errors, and the board allows the pharmacy to return to a reduction in checking.

8. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include:

a. A summary indicating the date and description of all discrepancies that include but are not limited to discrepancies involving the packaging, repackaging and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

b. The total number of doses packaged or compliance packages prepared for the robotic pharmacy system and total number of doses or compliance packages picked by the robot during the quarter.

c. The total number of doses or compliance packages picked by the robot that were checked in conducting the 5.0% checks.

d. Dates and time associated with any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution.

9. All unanticipated downtime shall be immediately reported to the board.

10. All records required by this section shall be maintained at the address of the pharmacy for a minimum of two years. Records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

Part XI. Pharmacy Services to Hospitals

18VAC110-20-460. Floor stock drugs; proof of delivery; distribution records.

A. A pharmacist shall check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and shall initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.

B. A delivery receipt shall be obtained for Schedule II through V drugs supplied as floor stock. This record shall include the date, drug name and strength, quantity, hospital unit receiving drug and the manual or electronic signatures of the dispensing pharmacist and the receiving nurse.

C. A record of disposition/administration shall be used to document administration of Schedule II through V drugs when a floor stock system is used for such drugs. The record shall be returned to the pharmacy within three months of its issue. The PIC or his designee shall:

1. Match returned records with delivery receipts to verify that all records are returned;

2. Periodically audit returned administration records for completeness as to patient's names, dose, date and time of administration, signature or initials of person administering the drug, and date the record is returned;

3. Verify that all additions to inventory are recorded, that all additions to and deductions from inventory are correctly calculated, that sums carried from one record to the next are correctly recorded, and periodically verify that doses documented on administration records are reflected in the medical record; and

4. Initial the returned record.

D. All records required by this section shall be filed chronologically by date of issue, and retained for two years from the date of return at the address of the pharmacy. Schedule VI records may be maintained in offsite storage or as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic storage is retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent. Schedule II-V records may only be stored offsite or electronically as described in this subsection if authorized by DEA or in federal law or regulation. The filing requirements of 18VAC110-20-240 A 1 for separation of Schedule II records shall be met for administration records if the Schedule II drugs are listed in a separate section on a page that contains other schedules of drugs.

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

A. A hospital may use automated devices for the dispensing and administration of drugs pursuant to § 54.1-3301 of the Code of Virginia and §§ 54.1-3401 and 54.1-3434.02 of the Drug Control Act and in accordance with 18VAC110-20-270, 18VAC110-20-420, or 18VAC110-20-460 as applicable.

B. Policy and procedure manual; access codes.

1. Proper use of the automated dispensing devices and means of compliance with requirements shall be set forth in the pharmacy's policy and procedure manual.

2. Personnel allowed access to an automated dispensing device shall have a specific access code which records the identity of the person accessing the device. The device may verify access codes using biometric identification or other coded identification after the initial log-on in order to eliminate sharing or theft of access codes.

C. Distribution of drugs from the pharmacy.

1. Prior to removal of drugs from the pharmacy, a delivery record shall be generated for all drugs to be placed in an automated dispensing device which shall include the date; drug name, dosage form, and strength; quantity; hospital unit and a unique identifier for the specific device receiving the drug; initials of the person loading the automated dispensing device; and initials of the pharmacist checking the drugs to be removed from the pharmacy and the delivery record for accuracy.

2. At the time of loading any Schedule II through V drug, the person loading will verify that the count of that drug in the automated dispensing device is correct. Any discrepancy noted shall be recorded on the delivery record and immediately reported to the pharmacist in charge, who shall be responsible for reconciliation of the discrepancy or properly reporting of a loss.

D. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution which shall show patient name, drug name and strength, dose withdrawn, date and time of withdrawal from the device, and identity of person withdrawing the drug. The record shall be filed in chronological order from date of issue.

2. If an automated dispensing device is used to obtain drugs for dispensing from an emergency room, a separate dispensing record is not required provided the automated record distinguishes dispensing from administration and records the identity of the physician who is dispensing.

E. Discrepancy reports.

A discrepancy report shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be resolved by the PIC or his designee within 72 hours of the time the discrepancy was discovered or, if determined to be a theft or an unusual loss of drugs, shall be immediately reported to the board in accordance with § 54.1-3404 E of the Drug Control Act.

F. Reviews and audits.

1. The PIC or his designee shall conduct at least a monthly review for compliance with written policy and procedures which are consistent with subsection A of § 54.1-3434.02 for security and use of the automated dispensing devices, to include procedures for timely termination of access codes, when applicable, and proper recordkeeping.

2. The PIC or his designee shall conduct at least a monthly audit to review distribution of Schedule II through V drugs from each automated dispensing device as follows:

a. The audit shall reconcile records of all quantities of Schedule II through V drugs dispensed from the pharmacy with records of all quantities loaded into each device to detect whether any drugs recorded as removed from the pharmacy were diverted rather than being placed in the proper device.

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedule II-V to ensure drugs dispensed from the pharmacy have been loaded into the device and not diverted, such as with the use of perpetual inventory management software, then the audit required in this subsection may be limited to the discrepancies or exceptions as identified by the method for perpetually monitoring the drugs.

3. The PIC or his designee shall conduct at least a monthly audit to review administration of Schedule II through V drugs from each automated dispensing device as follows:



a. The audit shall include a review of administration records from each device per month for possible diversion by fraudulent charting. The review shall include all Schedule II through V drugs administered for a time period of not less than 24 consecutive hours during the audit period.

b. The hard-copy distribution and administration records printed out and reviewed in the audit shall be initialed and dated by the person conducting the audit. If nonpharmacist personnel conduct the audit, a pharmacist shall review the record and shall initial and date the record.

c. The PIC or his designee shall be exempt from requirements of this audit if reconciliation software which provides a statistical analysis is used to generate reports at least monthly. The statistical analysis shall be based on:

(1) Peer-to-peer comparisons of use for that unit or department; and

(2) Monitoring of overrides and unresolved discrepancies.

d. The report shall be used to identify suspicious activity which includes, but is not limited to, usage beyond three standard deviations in peer-to-peer comparisons. A focused audit of the suspicious activity and individuals associated with the activity shall be performed whenever suspicious activity is identified from the reports.

4. The PIC or his designee shall maintain a record of compliance with the reviews and audits in accordance with subsection H of this section.

G. Inspections.

Automated dispensing devices shall be inspected monthly by pharmacy personnel to verify proper storage, proper location of drugs within the device, expiration dates, the security of drugs and validity of access codes. The PIC or his designee shall maintain documentation of the inspection in accordance with subsection H of this section. With the exception of a monthly physical review of look-alike and sound-alike drugs stored within matrix drawers or open access areas within the device, such monthly inspection shall not require physical inspection of the device if the device is capable of and performs the following:

a. At least daily monitoring of refrigerator or freezer storage with documented temperature ranges, variances, and resolutions;

b. Automatic identification and isolation of the location of each drug within the device using a machine readable product identifier, such as barcode technology, and generation of a report verifying the applicable settings;

c. Electronic tracking of drug expiration dates and generation of proactive reports allowing for the replacement of drugs prior to their expiration date; and

d. Electronic detection of the opening of the device, identification of the person accessing the device, automatic denial of access to the device during malfunctions and mechanical errors, and generation of reports of any malfunction and mechanical error.

H. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records shall be maintained at the address of the pharmacy providing services to the hospital except manual Schedule VI distribution records, reports auditing for indications of suspicious activity, and focused audits, all of which may be maintained in offsite storage or electronically as an electronic image that provides an exact image of the document that is clearly legible provided such offsite or electronic records are retrievable and made available for inspection or audit within 48 hours of a request by the board or an authorized agent.

2. Distribution and delivery records and required initials may be generated or maintained electronically provided:

a. The system being used has the capability of recording an electronic signature that is a unique identifier and restricted to the individual required to initial or sign the record.

b. The records are maintained in a read-only format that cannot be altered after the information is recorded.

c. The system used is capable of producing a hard-copy printout of the records upon request.

3. Schedule II through V distribution and delivery records may also be stored offsite or electronically in compliance with requirements of subdivision 1 of this subsection and if authorized by DEA or in federal law or regulation.

4. Hard-copy distribution and administration records that are printed and reviewed in conducting required audits may be maintained at an off-site location or electronically provided they can be readily retrieved upon request; provided they are maintained in a read-only format that does not allow alteration of the records; and provided a separate log is maintained for a period of two years showing dates of audit and review, the identity of the automated dispensing device being audited, the time period covered by the audit and review, and the initials of all reviewers.

Agenda Item: Adoption of Proposed Regulations for Permitting Facilities in which Practitioners of the Healing Arts dispense controlled substances – replacement of Emergency Regulations

Included in your agenda package are:

A copy of the 2015 legislation mandating issuance of permits to facilities in which practitioners of the healing arts dispense drugs

A copy of the emergency regulations in effect from December 7, 2015 through June 6, 2017

There were no comments on the Notice of Intended Regulatory Action.

Board action:

Adoption of proposed regulations identical to the emergency regulations currently in effect

VIRGINIA ACTS OF ASSEMBLY -- 2015 SESSION

CHAPTER 117

An Act to amend and reenact § 54.1-3304.1 of the Code of Virginia, relating to Board of Pharmacy; practitioners dispensing controlled substances.

[H 2192]

Approved March 16, 2015

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-3304.1 of the Code of Virginia is amended and reenacted as follows:

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

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.

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.

BOARD OF PHARMACY

Permits for physician selling drugs facilities

Emergency Regulations Effective: 12/7/15 to 6/6/17

18VAC110-30-15. Fees.

A. Unless otherwise provided, fees listed in this section shall not be refundable.

B. ~~Fee for initial license for a practitioner of the healing arts to sell controlled substances~~

Initial application fees.

1. ~~The application fee for initial licensure shall be \$240.~~ License for practitioner of the healing arts to sell controlled substance \$180

2. ~~The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be \$500.~~ Permit for facility in which practitioners of the healing arts sell controlled substance \$240

C. ~~Renewal of license for a practitioner of the healing arts to sell controlled substances~~

Annual renewal fees.

1. ~~The annual fee for renewal of an active license shall be \$90. For the annual renewal due on or before December 31, 2009, the fee shall be \$50.~~ License for practitioner of the healing arts to sell controlled substance \$90

2. ~~The late fee for renewal of a license within one year after the expiration date is \$30 in addition to the annual renewal fee.~~ Permit for facility in which practitioners of the healing arts sell controlled substance \$240

3. ~~The fee for reinstatement of a license expired for more than one year shall be \$210.~~

D. Late fees.

The following late fees shall be paid in addition to the current renewal fee to renew an expired license within one year of the expiration date.

1. License for practitioner of the healing arts to sell controlled substance \$30

2. Permit for facility in which practitioners of the healing arts sell controlled substance \$40

E. Reinstatement fees.

Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. License for practitioner of the healing arts to sell controlled substances \$150

2. Permit for facility in which practitioner of the healing arts to sell controlled substances \$240

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely \$500

F. 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 a facility permit.

D-G. The fee for reinspection of any facility shall be \$150.

E-H. The fee for a returned check shall be \$35.

Part II

Licensure Requirements

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 4, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

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

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

- ~~1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice; and~~
- ~~2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.~~

18VAC110-30-21. Application for facility permit.

A. After June 4, 2016, any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner shall make application for the facility permit on a form provided by the board.

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

1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.

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

C. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-30. Renewal of license or permit.

A. A license or facility permit so issued shall be valid until December 31 of the year of issue. Renewal of the license shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license or facility permit to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license or facility permit by payment of these fees for one year from the date of expiration.

C. Failure to renew the license or facility permit to sell within one year following expiration shall cause the license or permit to lapse. The selling of controlled substances with a lapsed license or permit shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license or permit, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a license or facility permit that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted ~~unless another practitioner at the same location has held an active license to sell controlled substances during that period.~~ A practitioner seeking reinstatement of a facility permit shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on expired status. If no other practitioner of the healing arts licensed to sell controlled substances intends

to sell controlled substances from the same location, the practitioner shall also surrender the facility permit, and the permit will be placed on expired status.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license or facility permit pursuant to this section may request that it be made current again at any time within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

Part III

Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

18VAC110-30-70. Maintenance of a common stock of controlled substances Practitioner in charge in a permitted facility.

Any two or more licensees who elect to maintain a common stock of A facility with a permit for practitioners of the healing arts to sell controlled substances ~~for dispensing~~ shall:

1. Designate a licensee practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;
2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for ~~licenses~~ facility permits which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a ~~license~~ facility permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

F. No ~~license~~ facility permit shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;
2. There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;
3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be

stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

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

5. A sink with hot and cold running water shall be available within ~~the immediate vicinity~~ 20 feet of the selling and storage area and not located within an examination room or restroom; and

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

Agenda Item: Adoption of ^{Proposed} ~~Emergency~~ Regulations for Outsourcing Facilities and Compounding

Included in your agenda package are:

A copy of the 2015 legislation mandating issuance of permits to resident and non-resident outsourcing facilities

A copy of the emergency regulations which are effective from December 7, 2015, through June 6, 2017

There were no comments on the Notice of Intended Regulatory Action.

Board action:

Adoption of proposed regulations to replace emergency regulations as currently in effect

VIRGINIA ACTS OF ASSEMBLY -- 2015 SESSION

CHAPTER 300

An Act to amend and reenact §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia and to amend the Code of Virginia by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5, relating to outsourcing facilities and nonresident outsourcing facilities and compounding for office-based administration.

[H 1737]

Approved March 17, 2015

Be it enacted by the General Assembly of Virginia:

1. That §§ 54.1-3401, 54.1-3406, 54.1-3410.2, and 54.1-3434.4 of the Code of Virginia are amended and reenacted and that the Code of Virginia is amended by adding in Article 2 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.05 and by adding in Article 2.1 of Chapter 34 of Title 54.1 a section numbered 54.1-3434.5 as follows:

§ 54.1-3401. Definitions.

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

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

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

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

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

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

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

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

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

"Board" means the Board of Pharmacy.

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

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

"Compounding" means the combining of two or more ingredients to fabricate such ingredients into a

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

"Controlled substance" means a drug, substance, or immediate precursor in Schedules I through VI of this chapter. The term shall not include distilled spirits, wine, malt beverages, or tobacco as those terms are defined or used in Title 3.2 or Title 4.1. The term "controlled substance" includes a controlled substance analog that has been placed into Schedule I or II by the Board pursuant to the regulatory authority in subsection D of § 54.1-3443.

"Controlled substance analog" means a substance the chemical structure of which is substantially similar to the chemical structure of a controlled substance in Schedule I or II and either (i) which has a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II or (ii) with respect to a particular person, which such person represents or intends to have a stimulant, depressant, or hallucinogenic effect on the central nervous system that is substantially similar to or greater than the stimulant, depressant, or hallucinogenic effect on the central nervous system of a controlled substance in Schedule I or II. "Controlled substance analog" does not include (a) any substance for which there is an approved new drug application as defined under § 505 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355) or that is generally recognized as safe and effective pursuant to §§ 501, 502, and 503 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 351, 352, and 353) and 21 C.F.R. Part 330; (b) with respect to a particular person, any substance for which an exemption is in effect for investigational use for that person under § 505 of the federal Food, Drug, and Cosmetic Act to the extent that the conduct with respect to that substance is pursuant to such exemption; or (c) any substance to the extent not intended for human consumption before such an exemption takes effect with respect to that substance.

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

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

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

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

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

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

"Dispenser" means a practitioner who dispenses.

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

"Distributor" means a person who distributes.

"Drug" means (i) articles or substances recognized in the official United States Pharmacopoeia National Formulary or official Homeopathic Pharmacopoeia of the United States, or any supplement to any of them; (ii) articles or substances intended for use in the diagnosis, cure, mitigation, treatment, or

prevention of disease in man or animals; (iii) articles or substances, other than food, intended to affect the structure or any function of the body of man or animals; (iv) articles or substances intended for use as a component of any article specified in clause (i), (ii), or (iii); or (v) a biological product. "Drug" does not include devices or their components, parts, or accessories.

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

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

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

"FDA" means the U.S. Food and Drug Administration.

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

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

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

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

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

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

"Manufacturer" means every person who manufactures.

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

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

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

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

of its use, or (ii) any drug, except a new animal drug or an animal feed bearing or containing a new animal drug, the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

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

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

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

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

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

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

"Outsourcing facility" means a facility that is engaged in the compounding of sterile drugs and is currently registered as an outsourcing facility with the U.S. Secretary of Health and Human Services and that complies with all applicable requirements of federal and state law, including the Federal Food, Drug, and Cosmetic Act.

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

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

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

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

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

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

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

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

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

"Radiopharmaceutical" means any drug that exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance, but does not

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include drugs such as carbon-containing compounds or potassium-containing salts that include trace quantities of naturally occurring radionuclides. The term also includes any biological product that is labeled with a radionuclide or intended solely to be labeled with a radionuclide.

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

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

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

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

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

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

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

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

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

§ 54.1-3406. Records confidential; disclosure of information about violations of federal law.

A. No agent of the Board or agent designated by the Superintendent of the Department of State Police having knowledge by virtue of his office of any prescriptions, papers, records, or stocks of drugs shall divulge such knowledge, except in connection with a criminal investigation authorized by the Attorney General or attorney for the Commonwealth or with a prosecution or proceeding in court or before a regulatory board or officer, to which investigation, prosecution or proceeding the person to whom such prescriptions, papers or records relate is a subject or party. This section shall not be construed to prohibit the Board president or his designee and the Director of the Department of Health Professions from discharging their duties as provided in this title.

B. *Notwithstanding the provisions of § 54.1-2400.2, the Board shall have the authority to submit to the U.S. Secretary of Health and Human Services information resulting from an inspection or an investigation indicating that a compounding pharmacy or outsourcing facility may be in violation of federal law or regulations with the exception of compounding for office-based administration in accordance with §54.1-3410.2.*

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

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

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

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

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

C. In accordance with the conditions set forth in subsections A and B, pharmacists shall not distribute compounded drug products for subsequent distribution or sale to other persons or to

commercial entities, including distribution to pharmacies or other entities under common ownership or control with the facility in which such compounding takes place; however, a pharmacist may distribute to a veterinarian in accordance with federal law.

Compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed by a pharmacy to a veterinarian for further distribution or sale to his own patients shall be limited to drugs necessary to treat an emergent condition when timely access to a compounding pharmacy is not available as determined by the prescribing veterinarian.

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

A pharmacist may also provide a reasonable amount of compounded products to practitioners of medicine, osteopathy, podiatry, or dentistry; or ~~veterinary medicine~~ to administer to their patients ~~in the course of their professional practice~~, either personally or under their direct and immediate supervision, *if there is a critical need to treat an emergency condition, or as allowed by federal law or regulations. A pharmacist may also provide compounded products to practitioners of veterinary medicine for office-based administration to their patients.*

Pharmacists *who provide compounded products for office-based administration for treatment of an emergency condition or as allowed by federal law or regulations* shall label all compounded products distributed to practitioners other than veterinarians for administration to their patients with (i) the statement "For Administering in Prescriber Practice Location Only"; (ii) the name and strength of the compounded medication or list of the active ingredients and strengths; (iii) the facility's control number; (iv) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (v) the name and address of the pharmacy; and (vi) the quantity.

Pharmacists shall label all compounded products for companion animals, as defined in regulations promulgated by the Board of Veterinary Medicine, and distributed to a veterinarian for either further distribution or sale to his own patient or administration to his own patient with (a) the name and strength of the compounded medication or list of the active ingredients and strengths; (b) the facility's control number; (c) an appropriate beyond-use date as determined by the pharmacist in compliance with USP-NF standards for pharmacy compounding; (d) the name and address of the pharmacy; and (e) the quantity.

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

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

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

1. Comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if such monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding; or are drug substances that are components of drugs approved by the FDA for use in the United States; or are otherwise approved by the FDA;

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

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

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

H. Pharmacists shall not engage in the following:

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

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

3. The compounding of inordinate amounts of any preparation in cases in which there is no observed historical pattern of prescriptions and dispensing to support an expectation of receiving a valid

prescription for the preparation. The compounding of an inordinate amount of a preparation in such cases shall constitute manufacturing of drugs.

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

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

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

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

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

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

K. Every pharmacist-in-charge or owner of a permitted pharmacy or a registered nonresident pharmacy engaging in sterile compounding shall notify the Board of its intention to dispense or otherwise deliver a sterile compounded drug product into the Commonwealth. Upon renewal of its permit or registration, a pharmacy or nonresident pharmacy shall notify the Board of its intention to continue dispensing or otherwise delivering sterile compounded drug products into the Commonwealth. Failure to provide notification to the Board shall constitute a violation of Chapter 33 (§ 54.1-3300 et seq.) or Chapter 34 (§ 54.1-3400 et seq.). The Board shall maintain this information in a manner that will allow the production of a list identifying all such sterile compounding pharmacies.

§ 54.1-3434.05. 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.

§ 54.1-3434.4. Prohibited acts.

A. It is unlawful for any person or entity which is not registered under this article to (i) conduct the business of shipping, mailing, or otherwise delivering Schedule II through VI controlled substances into Virginia or (ii) advertise the availability for purchase of any Schedule II through VI controlled substances by any citizen of the Commonwealth. Further, it shall be unlawful for any person who is a resident of Virginia to advertise the pharmacy services of a nonresident pharmacy ~~which~~ *or compounding services of an outsourcing facility that has not registered with the Board, with the knowledge that the advertisement will or is likely to induce members of the public in the Commonwealth to use the pharmacy or outsourcing facility to obtain controlled substances.*

B. Any controlled substance that is ordered or shipped in violation of any provision of this chapter, shall be considered as contraband and may be seized by any law-enforcement officer or any agent of the Board of 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.*

2. That the Board of Pharmacy shall promulgate regulations to implement the provisions of this act to be effective within 280 days of its enactment.