COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Regulation Committee Meeting

May 3, 2022

9AM

TOPIC	**PAGES**

Call to Order: Dale St.Clair, Jr., Committee Chair

- Welcome & Introductions
- Approval of Agenda

Call for Public Comment

Agenda Items

Adjourn

******The Board will have a working lunch at approximately 12pm.******

Board **Board of Pharmacy**

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Remote processing of drugs in automated dispensing devices for hospitals [Action 5868] NOIRA - *Register Date: 1/17/22* [Stage 9466]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of 2021 Periodic Review [Action 5925] NOIRA - *At Secretary's Office* [Stage 9563]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of legislation for pharmacists initiating treatment [Action 5604] Proposed - *Register Date: 1/3/22* [Stage 9242]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of 2021 legislation for pharmacists initiating treatment [Action 5861] Proposed - *DPB Review in progress* [Stage 9562]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office* [Stage 7888]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] Final - *At DPB* [Stage 9584]
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and	Implementation of 2021 Periodic Review [Action 5926] NOIRA - *At Secretary's Office* [Stage 9564]

	Registration of Pharmacy Technicians	
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	Implementation of legislation for registration of pharmacy technicians [Action 5603] Proposed - *Register Date: 1/3/22* [Stage 9243]
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Implementation of 2021 Periodic Review [Action 5927] NOIRA - *At Governor's Office* [Stage 9565]
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Changes to access and labeling requirements [Action 5928] Final - *Register Date: 4/25/22* [Stage 9566]

Department of Health Professions
Regulatory/Policy Actions – 2022 General Assembly

EMERGENCY REGULATIONS:

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB1324	Working conditions regulations	Pharmacy	9/6/22	
HB1323/SB672	Pharmacists treating	Pharmacy	9/6/22	

EXEMPT REGULATORY ACTIONS

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB193/SB759	Repeal of drugs/chemicals scheduled in Drug Control Act	Pharmacy	9/6/22	11/9/22
HB933/SB671	Numerous amendments to pharmaceutical processor regs	Pharmacy	6/6/22 - propose 9/6/22 – final	9/15/22

NON-REGULATORY ACTIONS

Legislative source	Affected agency	Action needed	Due date
SB14	Pharmacy	Workgroup on prescription drug donation program	12/1/22 – if Gov amendment accepted
HB1187/SB317	All boards	System for record of temporary authorization	
HB1323/SB672	Protocols for pharmacists treating	Medicine (in collaboration with Pharmacy and VDH)	Expanded protocol list if Gov amendment accepted

Policy Actions at SHHR:

HB2559 (2019) - requires the Secretary of Health and Human Resources to convene a work group to identify successes and challenges of the electronic prescription requirement and offer possible recommendations for increasing the electronic prescribing of controlled substances that contain an opioid and to report to the Chairmen of the House Committee on Health, Welfare and Institutions and the Senate Committee on Education and Health by **November 1, 2022**.

Agenda Item: Consideration of recommendation to full Board regarding petition for rulemaking concerning automated dispensing systems.

Included in your agenda package are:

Petition for rulemaking from Renae M. Cregger.

Initial letter of response from Ms. Juran.

Regulatory Town Hall summary page showing no comments on petition.

Action needed:

- Consider whether to recommend that the Board (1) initiate a rulemaking or (2) take no action on the petition.

- Consider any similarities to centralized pharmacy verification action currently underway.

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, RPh
Executive Director
(804)367-4456
caroline.juran@dhp.virginia.gov

Contact Address: Department of Health Professions
9960 Mayland Drive
Suite 300
Richmond, 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 02/22/2022

Petitioner Renae M. Cregger

Petitioner's Request

To exempt automated dispensing systems exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use from the requirements of 18VAC110-20-555(1), (4)(a), and (4)(b).

Agency Plan

The petition will be published on March 14, 2022 in the Register of Regulations and also posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov to receive public comment ending April 13, 2022. The request to amend the regulations and any comments for or against the petition will be considered by the Board at its meeting scheduled for June 6, 2022. The petitioner will receive information on the Board's decision after that date.

Publication Date 03/14/2022 *(comment period will also begin on this date)*

Comment End Date 04/13/2022

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. If the board has not met within that 90-day period, the decision will be issued no later than 14 days after it next meets.

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

Petitioner's full name (Last, First, Middle initial, Suffix,)		
Cregger, Renae M.		
Street Address 860 Stafford Umberger Dr	**Area Code and Telephone Number** 866-768-8479 ext 6001	
City Wytheville	**State** VA	**Zip Code** 24382
Email Address (optional) renae.cregger@southrx.com	**Fax (optional)** 866-928-3983	

Respond to the following questions:

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

   18VAC110-20-555 Use of automated dispensing devices
   Sections 1, 4a, 4b

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

   See attached.

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

   54.1-2400 of the Code of Virginia authorizes the board to take action on this regulation

Signature: Renae M Cregger **Date:** 1-17-22

Since the introduction of automated dispensing systems in hospitals which provide ready access to medications and improved patient care, the long-term care industry embraced the use of these systems as a way to provide emergency and stat medications through a more secure and trackable platform. I propose the following changes to 18VAC110-20-555 when automated dispensing systems are exclusively stocked with medications that would be kept in an emergency or stat-drug kit and are used for emergency or stat administration.

18VAC110-20-555 Sections 1, 4a, and 4b currently read as follows:

Section 1 – *"Drugs placed in an automated drug dispensing system in a nursing home shall be under the control of the pharmacy providing services to the nursing home, the pharmacy shall have online communication with and control of the automated drug dispensing system, and access to any drug for a patient shall be controlled by the pharmacy."*

Sections 4a and 4b – *"Removal of drugs from any automated drug dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber under the following conditions:*

> *a. A drug, including a drug that would be stocked in a stat-drug box pursuant to subsection B of 18VAC110-20-550, may not be administered to a patient from an automated dispensing device until a pharmacist has reviewed the prescription order and electronically authorized the access of that drug for that particular patient in accordance with the order.*
>
> *b. The PIC of the provider pharmacy shall ensure that a pharmacist who has online access to the system is available at all times to review a prescription order as needed and authorize administering pursuant to the order reviewed."*

The same requirements as in Sections 1, 4a, and 4b do not exist in the regulation for a "tackle-box" style stat-drug box (18VAC110-20-550); therefore, these requirements encourage facilities to opt for the tackle-box which is less secure in terms of access and record keeping. Advantages of automated dispensing systems over tackle boxes include increased security in terms of access and increased trackability of medications removed from the system. The regulations as currently written can also lead to a delay in patient care. If the nurse has a valid order from a prescriber for a medication in the automated dispensing system, the nurse should be able to access the system to obtain the medication for the resident as quickly as possible when the medications in the system are drugs that would be kept in a stat-drug box. The contents of the automated dispensing system being medications that would be kept in an emergency or stat-drug box and the administration of such medications in an emergency or stat/first dose manner should dictate

which regulations apply to such systems rather than whether the stat-drug "box" is an electronic system or a tackle box.

I would propose an exception be added to 18VAC110-20-555 Sections 1, 4a, and 4b as currently written in 18VAC110-20-555 Section 2:

"unless the system is exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency administration."

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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

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TEL (804) 367-4400
FAX (804) 527-4475

February 23, 2022

Renae M. Cregger
860 Stafford Umberger Dr.
Wytheville, Virginia 24382

Dear Ms. Cregger,

The Virginia Board of Pharmacy would like to thank you for submission of a petition for rule-making relating to automated dispensing systems exclusively stocked with drugs that would be kept in a stat-box or an emergency drug kit and are solely administered for stat or emergency use.

In accordance with Virginia law, the petition will be filed with the Register of Regulations and published on March 14, 2022 and posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov. Comment on the petition will be requested until April 13, 2022 and may be posted on the Townhall or sent to the Board.

Following receipt of all comments on the petition to amend regulations, the matter will be considered by the Board at its meeting scheduled for June 6, 2022.

The Board appreciates your interest in amending the regulations governing the practice of pharmacy and will notify you of its decision on the petition after the June meeting.

Very truly yours,

Caroline Juran
Executive Director
Virginia Board of Pharmacy

cc: Elaine J. Yeatts
Agency Regulatory Coordinator

Virginia.gov Agencies | Governor

Secretariat **Health and Human Resources**

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Edit Petition

Petition 361

Petition Information	
Petition Title	Use of automated dispensing systems exclusively stocked with emergency or stat-drug kits
Date Filed	2/22/2022 [Transmittal Sheet]
Petitioner	Renae M. Cregger
Petitioner's Request	To exempt automated dispensing systems exclusively stocked with drugs that would be kept in a stat-drug box pursuant to 18VAC110-20-550 or an emergency drug kit pursuant to 18VAC110-20-540 and are solely administered for stat or emergency use from the requirements of 18VAC110-20-555(1), (4)(a), and (4)(b).
Agency's Plan	The petition will be published on March 14, 2022 in the Register of Regulations and also posted on the Virginia Regulatory Townhall at www.townhall.virginia.gov to receive public comment ending April 13, 2022. The request to amend the regulations and any comments for or against the petition will be considered by the Board at its meeting scheduled for June 6, 2022. The petitioner will receive information on the Board's decision after that date.
Comment Period	Ended 4/13/2022 0 comments
Agency Decision	Pending

Contact Information	
Name / Title:	Caroline Juran, RPh / *Executive Director*
Address:	9960 Mayland Drive Suite 300 Richmond, 23233
Email Address:	caroline.juran@dhp.virginia.gov
Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

This petition was created by Erin Barrett on 02/22/2022 at 8:13am

Agenda Item: Consideration of Proposed Regulations for Centralized Warehouser or Wholesale Distributor to Verify Schedule VI drugs for Automated Dispensing Devices in Hospitals

Included in your agenda package are:
NOIRA Agency Background Document.
2015 Consent Order for Pilot.
DRAFT Proposed Regulations.

Action needed:
• Motion to recommend the Board adopt proposed regulations at the June 2022 meeting as presented or amended.

townhall.virginia.gov

Notice of Intended Regulatory Action (NOIRA)
Agency Background Document

Agency name	Board of Pharmacy, Department of Health Professions
Virginia Administrative Code (VAC) Chapter citation(s)	18VAC110-20
VAC Chapter title(s)	Regulations Governing the Practice of Pharmacy
Action title	Allowance for centralized pharmacy to verify Schedule VI drugs
Date this document prepared	10/7/21

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1VAC7-10), and the *Form and Style Requirements for the Virginia Register of Regulations and Virginia Administrative Code*.

Brief Summary

Provide a brief summary (preferably no more than 2 or 3 paragraphs) of the subject matter, intent, and goals of this this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation.

In response to a petition for rulemaking, the Board is issuing a Notice of Intended Regulatory Action to amend sections 460 and 490 to allow a pharmacist at a central distribution company to verify Schedule VI drugs to be placed in an ADD prior to delivery to the receiving hospital and pharmacy technicians at the hospital to load the drugs directly into the ADD without further verification by a pharmacist at the hospital.

Acronyms and Definitions

Define all acronyms or technical definitions used in this form.

ADD = automated dispensing device

Mandate and Impetus

Identify the mandate for this regulatory change and any other impetus that specifically prompted its initiation (e.g., new or modified mandate, petition for rulemaking, periodic review, or board decision). For purposes of executive branch review, "mandate" has the same meaning as defined in Executive Order 14 (as amended, July 16, 2018), "a directive from the General Assembly, the federal government, or a court that requires that a regulation be promulgated, amended, or repealed in whole or part."

The impetus for the change is response to a petition for rulemaking by updating of regulations to facilitate new technologies in the practice of pharmacy. Since the technologies have already been approved for pilot programs in several hospital systems and have shown to be safe and effective, the Board's decision was to incorporate the allowances into regulation.

Legal Basis

Identify (1) the promulgating agency, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia and Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating agency to regulate this specific subject or program, as well as a reference to the agency's overall regulatory authority.

Regulations are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400, which provides the Board of Pharmacy the authority to promulgate regulations to administer the regulatory system:

§ 54.1-2400 -General powers and duties of health regulatory boards

The general powers and duties of health regulatory boards shall be:

6. To promulgate regulations in accordance with the Administrative Process Act (§ 2.2-4000 et seq.) that are reasonable and necessary to administer effectively the regulatory system, which shall include provisions for the satisfaction of board-required continuing education for individuals registered, certified, licensed, or issued a multistate licensure privilege by a health regulatory board through delivery of health care services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those health services. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.).

The specific authority for the Board to regulate the dispensing of prescription drugs is found in:

§ 54.1-3307. Specific powers and duties of Board.
A. The Board shall regulate the practice of pharmacy and the manufacturing, dispensing, selling, distributing, processing, compounding, or disposal of drugs and devices. The Board shall also control the character and standard of all drugs, cosmetics and devices within the

Commonwealth, investigate all complaints as to the quality and strength of all drugs, cosmetics, and devices and take such action as may be necessary to prevent the manufacturing, dispensing, selling, distributing, processing, compounding and disposal of such drugs, cosmetics and devices that do not conform to the requirements of law.
The Board's regulations shall include criteria for:
1. Maintenance of the quality, quantity, integrity, safety and efficacy of drugs or devices distributed, dispensed or administered.
2. Compliance with the prescriber's instructions regarding the drug, its quantity, quality and directions for use.
3. Controls and safeguards against diversion of drugs or devices.
4. Maintenance of the integrity of, and public confidence in, the profession and improving the delivery of quality pharmaceutical services to the citizens of Virginia.
5. Maintenance of complete records of the nature, quantity or quality of drugs or substances distributed or dispensed, and of all transactions involving controlled substances or drugs or devices so as to provide adequate information to the patient, the practitioner or the Board.
6. Control of factors contributing to abuse of legitimately obtained drugs, devices, or controlled substances.
7. Promotion of scientific or technical advances in the practice of pharmacy and the manufacture and distribution of controlled drugs, devices or substances.
8. Impact on costs to the public and within the health care industry through the modification of mandatory practices and procedures not essential to meeting the criteria set out in subdivisions 1 through 7 of this section.
9. Such other factors as may be relevant to, and consistent with, the public health and safety and the cost of rendering pharmacy services.
B. The Board may collect and examine specimens of drugs, devices and cosmetics that are manufactured, distributed, stored or dispensed in the Commonwealth.

Purpose

Describe the specific reasons why the agency has determined that this regulation is essential to protect the health, safety, or welfare of citizens. In addition, explain any potential issues that may need to be addressed as the regulation is developed.

The purpose of this regulatory action is to update regulations for utilization of newer technologies in the practice of pharmacy in a hospital system and for facilitating time for pharmacists to be more involved in direct patient care. Two pilots for central distribution (involving more than a dozen facilities) have been approved by the Board and have been shown to protect the health and safety of the drug supply and patients in hospitals.

Substance

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

Section 460 A currently requires a pharmacist to check all Schedule II-VI drugs delivered to a hospital unit as floor-stock before the drugs leave the pharmacy and to initial or sign manually or electronically the record of distribution verifying the accuracy of the distribution.
Section 490 C currently requires drugs in an ADD in a hospital to include the initials of the pharmacist at the hospital who checked the drugs removed from the pharmacy and the delivery record for accuracy.
Amendments to sections 460 and 490 would allow a pharmacist at a central distribution company to verify Schedule VI drugs to be placed in an ADD prior to delivery to the receiving hospital and pharmacy technicians at the hospital to load the drugs directly into the ADD without further verification by a pharmacist at the hospital.

Alternatives to Regulation

Describe any viable alternatives to the regulatory change that were considered, and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the regulatory change. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulatory change.

The Board of Pharmacy received a petition for rulemaking on May of 2021 and published a request for comment until July 7, 2021. There were 40 comments posted on the Townhall; all were in favor of the petitioner's request as being a safer and more cost-effective delivery method. The proposal would constitute a less burdensome and intrusive alternative to the current regulation.

Periodic Review and Small Business Impact Review Announcement

This NOIRA is not being used to announce a periodic review or a small business impact review.

Public Participation

Indicate how the public should contact the agency to submit comments on this regulation, and whether a public hearing will be held, by completing the text below. In addition, as required by § 2.2-4007.02 of the Code of Virginia describe any other means that will be used to identify and notify interested parties and seek their input, such as regulatory advisory panels or general notices.

The agency is seeking comments on this regulatory action, including but not limited to: ideas to be considered in the development of this proposal, the costs and benefits of the alternatives stated in this background document or other alternatives, and the potential impacts of the regulation.

The agency is also seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include: projected reporting, recordkeeping, and other administrative costs; the probable effect of the regulation on affected small businesses;

and the description of less intrusive or costly alternatives for achieving the purpose of the regulation.

Anyone wishing to submit comments may do so via the Regulatory Town Hall website (**http://www.townhall.virginia.gov**) or by mail to Elaine Yeatts, 9960 Mayland Drive, Suite 300, Henrico, VA 23233; by email to elaine.yeatts@dhp.virginia.gov; by fax to (804) 527-4434. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by midnight on the last day of the public comment period.

A public hearing will be held following the publication of the proposed stage of this regulatory action and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

A Regulatory Advisory Panel will not be used for development of regulatory changes; the amendments will be drafted by the Regulation Committee.

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

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Board of Pharmacy
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June 17, 2015

Daniel Honerbrink, Chief Executive Officer
Central Shared Services, LLC
Distribution Center
200 Wadsworth Drive
Richmond, VA 23236

Dear Mr. Honerbrink:

Enclosed please find a certified true copy of the Consent Order that was entered by the Board on June 17, 2015. This Consent Order approves with terms and conditions the application for an innovative (pilot) program bearing the name "Pharmacist Central Distribution" for the period of three (3) years, following the date this Order was entered by the Board.

Should you have any questions, please do not hesitate to contact me at (804) 367-4456.

Sincerely,

Caroline D. Juran
Executive Director

Enclosure
cc: Paul Dalby, Deputy Director of Enforcement

VIRGINIA:

BEFORE THE BOARD OF PHARMACY

IN RE: **Central Shared Services, LLC; Chippenham Medical Center Pharmacy; Dominion Hospital; Hanover Emergency Center Pharmacy; Henrico Doctors' Hospital; John Randolph Medical Center Pharmacy; Johnston-Willis Hospital Pharmacy; LewisGale Hospital Alleghany, LewisGale Hospital Montgomery; Pulaski Community Hospital d/b/a Lewis Gale Hospital-Pulaski; LewisGale Medical Center; Parham Doctors' Hospital-A Campus of Henrico Doctors' Hospital; Reston Center Hospital Pharmacy; Retreat Doctors' Hospital-A Campus of Henrico Doctors' Hospital; Spotsylvania Regional Medical Center; Stone Spring Emergency Center; Westcreek Medical Center Pharmacy Pharmacy Central Distribution**
Innovative Program Applicant

Permit No: 0216-000033, 0201001086, 0201003779, 0201004579, 0201001260, 0201001203, 0201001107, 0201001632, 0201002591, 0201001187, 0201001043, 0201003014, 0201002401; 0201001231, 0201004327, 0201004533, 0201004644

CONSENT ORDER

Now comes the Virginia Board of Pharmacy ("Board") and Central Shared Services, LLC, as evidenced by the signatures affixed below, and enter into this Consent Order affecting the application of Central Shared Services, LLC for approval of an innovative (pilot) program, Pharmacist Central Distribution, and waiver of compliance with certain provisions of Board of Pharmacy Regulations ("Regulations") 18 VAC 110-20-490 (C) and 18 VAC 110-20-460 (A).

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. Central Shared Services, LLC holds wholesale distributor license number 0216-000033 issued by the Board on April 14, 2000.

2. On December 29, 2014, the Board received an application from Central Shared Services, LLC, requesting approval of an innovative program.

3. Central Shared Services, LLC is requesting a waiver of 18 VAC 110-20-490 (C) of the Regulations that requires the delivery record of drugs placed into an automated dispensing device (ADD) in a hospital to

DCH

include the initials of the pharmacist at the hospital that checked the drugs to be removed from the pharmacy and the delivery record for accuracy and 18 VAC 110-20-460 (A) that requires a pharmacist to check all Schedule II - VI drugs prior to delivery as nursing unit floor stock, plus the requirement of initialing or signing manually, or electronically, the record of distribution verifying the accuracy of distribution of Schedule II - IV drugs.

4. Central Shared Services, LLC intends to distribute Schedule VI drugs to hospitals to be placed in specific automated dispensing devices. A Virginia licensed pharmacist at Central Shared Services, LLC will verify all Schedule VI drugs to be placed in an ADD prior to delivery to the pharmacy department at each hospital. Pharmacy technicians at each hospital will load the drugs into the specific ADD.

5. The Application is properly before this Committee, and it is within its sound discretion to approve or deny said Application.

CONSENT

Daniel Honerbrink, as the Chief Executive Officer, Central Shared Services, LLC, and on behalf of Central Shared Services, LLC, by affixing his signature hereon, agrees to the following:

1. Central Shared Services, LLC has been advised specifically to seek the advice of counsel prior to signing this document;

2. Central Shared Services, LLC admits the truth of the above Findings of Fact; and

3. Central Shared Services, LLC consents to the following Order.

ORDER

WHEREFORE, on the basis of the foregoing Findings of Fact and Conclusions of Law, it is hereby ORDERED that the Board APPROVES the Application for a period of three (3) years from the date this Order is entered by the Board with the following terms and conditions:

1. The approval of this innovative (pilot) program is limited to Schedule VI drugs

2. The Central Shared Services warehouse shall deliver the drugs directly to the pharmacy at each facility.

3. A pharmacist at the Central Shared Services, LLC warehouse shall verify 100% of all drugs distributed to the pharmacy at a facility to be placed into an ADD.

4. The requirement in 18 VAC 110-20-490 C of the Regulations that requires the delivery record for the drugs to be removed from a pharmacy to be placed in an ADD to include the initials of the pharmacist checking shall be waived for those drugs received from the Central Shared Services, LLC warehouse.

5. The requirement in 18 VAC 110-20-460 (A) of the Regulations for a pharmacist to check all 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 shall be waived for the drugs received from the Central Shared Services, LLC warehouse to be placed in an ADD.

6. The Central Shared Services, LLC warehouse shall maintain a record of all drugs distributed to facilities to be placed in a specific ADD. The record shall include the date; drug name, dosage form, and strength; quantity; facility name, hospital unit, a unique identifier for the specific device receiving the drug; and initials of the pharmacist checking the drugs for accuracy.

7. The pharmacy at each facility shall maintain a record of the initials of the person loading the automated dispensing device.

8. All records required by this section shall be maintained at the address of the applicable warehouse or facility 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. Central Shared Services, LLC shall provide each hospital with an invoice for drugs delivered to the hospital to be placed in a specific ADD.

9. Each facility receiving drugs from the Central Shared Services, LLC warehouse to be placed in an ADD shall maintain at least a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking automated dispensing devices at a facility is less than 90% for any quarter, the pharmacy at that facility shall immediately reinstitute a 100% pharmacist verification process at the receiving pharmacy until the Board approves Central Shared Services, LLC resuming the allowances within the innovative (pilot) program.

10. The assignment of the Meditech and Pyxis ID code shall be performed by a Virginia-licensed pharmacist employed by Parallon.

11. Central Shared Services, LLC shall submit to the Board a quarterly report which indicates for each facility the restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from Central Shared Services, LLC. These reports shall be submitted in March, June, September, and December.

12. The innovative (pilot) program shall be subject to two random, unannounced inspections by the Board or its designated representative within three (3) years following implementation of the program, one inspection to take place within the first twelve (12) months of implementation. Central Shared Services, LLC shall be solely responsible for the payment of an inspection fee of $150.00 each to be paid to the Board within thirty days from the date of the statement of monies owed which will be mailed following the inspection.

13. Reports of significant errors or other problems, or failure to comply with the terms and conditions described above shall constitute grounds for the rescission of the approval, and an administrative proceeding shall be convened to determine whether the approval should be rescinded or modified.

14. Except as specifically waived in the Consent Order, Central Shared Services, LLC and the facilities shall maintain compliance with all applicable federal and State laws and regulations.

15. Any operational changes or modifications to the innovative (pilot) program shall be approved by the Board prior to initiation of the modification.

Pursuant to § 2.2-4023 of the Code of Virginia (1950), as amended, the signed original of this Consent Order shall remain in the custody of the Department of Health Professions as a public record and shall be made available for public release, inspection and copying upon request.

FOR THE BOARD:

Caroline D. Juran
Executive Director

ENTERED: 6/17/15

SEEN AND AGREED TO:

Daniel Honerbrink, as the Chief Executive Officer, Central Shared Services, LLC, and on behalf of Central Shared Services, LLC

COMMONWEALTH OF VIRIGINA
CITY/COUNTY OF Chesterfield

Subscribed and sworn to before me, a Notary Public in and for the city/county of Chesterfield, this 17 day of June, 2015, by Daniel Honerbrink, Chief Executive Officer, Central Shared Services, LLC. My commission expires the 31 day of July, 2017.

7563376
Registration Number

Notary Public

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, which shall include provisions for granting and terminating user access.

2. Personnel allowed access to an automated dispensing device shall have a specific access code that 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. The delivery record 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 Schedules 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 ensuring reconciliation of the discrepancy or properly reporting of a loss.

<u>D. Distribution of drugs from a central warehouser or wholesale distributor</u>

<u>1. Notwithstanding subsection (C)(1), a central warehouser or wholesale distributor may distribute Schedule VI drugs to hospitals to be placed in specific automated dispensing devices under the following conditions:</u>

a. A pharmacist licensed in Virginia, employed by or otherwise working at the central warehouser or wholesale distributor, shall verify the accuracy of all Schedule VI drugs to be placed in specific automated dispensing devices within the hospital prior to delivery of the drugs directly to the hospital pharmacy;

b. A pharmacist at the hospital pharmacy shall not be required to:

(i) verify the accuracy of these drugs prior to leaving the hospital pharmacy for delivery to the hospital unit as floor stock as required in 18VAC110-20-460(A) or,

(ii) initial the delivery record as required in 18VAC110-20-490 C.

c. The central warehouser or wholesale distributor shall maintain a record of all Schedule VI drugs distributed to a hospital for placement in a specific automated dispensing device. The record shall include the date; drug name, dosage form, and strength; quantity; hospital name; hospital unit and a unique identifier for the specific automated dispensing device receiving the drug; and initials of the pharmacist employed by or working at the central warehouser or wholesale distributor who is responsible for verifying the drugs for accuracy;

d. The central warehouser or wholesale distributor shall provide an invoice to each hospital pharmacy indicating the drugs delivered to the hospital to be placed in a specific automated dispensing device;

c. A pharmacist or pharmacy technician at each hospital shall load the drugs into the specific automated dispensing device and the hospital pharmacy shall maintain a record which consists of the initials of the person loading the automated dispensing device.

f. A pharmacist licensed in Virginia, employed by or otherwise working at the warehouser or wholesale distributor, shall perform barcode linking of any drug to the related drug files in the hospital information system and automated dispensing device.

f. Each hospital receiving drugs from the central warehouser or wholesale distributor shall maintain at least a 90% bar code scanning rate for restocking automated dispensing devices. If the scanning rate for restocking the automated dispensing device is less than 90% for any quarter, the pharmacy at the hospital shall immediately reinstitute a 100% pharmacist verification process at the receiving pharmacy until a 90% scanning rate for a subsequent quarter is achieved and documented.

g. The hospital pharmacy receiving such services from a central warehouser or wholesale distributor shall maintain quarterly reports containing the hospital's restocking bar code scanning rate, bedside bar code scanning rate, and any errors in drug product received from the central warehouser or wholesale distributor.

~~D~~E. Distribution of drugs from the device.

1. Automated dispensing devices in hospitals shall be capable of producing a hard-copy record of distribution that 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 or maintained electronically.

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~~F. Discrepancy reports. A discrepancy report for all Schedules II through V drugs and any drugs of concern, as defined in § 54.1-3456.1 of the Code of Virginia, shall be generated for each discrepancy in the count of a drug on hand in the device. Each such report shall be initiated or 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~~G. Reviews and audits.

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

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

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

b. If a pharmacy has an ongoing method for perpetually monitoring drugs in Schedules II through 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 the dispensing and administration records of Schedules II through V drugs from each automated dispensing device as follows:

a. The audit shall include a review of administration records for each device per month for possible diversion by fraudulent charting. The review shall include all Schedules 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 that 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 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~~H. 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:

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

2. 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;

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

4. 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~~I. Records.

1. All records required by this section shall be maintained for a period of not less than two years. Records required to be maintained by the pharmacy shall be maintained at the address of the pharmacy providing services to the hospital and records required to be maintained by the warehouser or wholesale distributor shall be maintained at the address of the applicable facility. ~~except~~ ~~m~~Manual Schedule VI distribution records, reports auditing for indications of suspicious activity, ~~and~~ focused audits, and records required to be maintained by the warehouser or wholesale distributor distributing Schedule VI drugs to specific automated dispensing devices ~~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. Schedules II through V distribution and delivery records may also be stored off site 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: Consideration of regulations to implement HB1324

Included in your agenda package are:

HB1324 (Chapter 628 of the 2022 Acts of Assembly)

Pages 4-5 of the minutes of the January 18, 2022 Workgroup regarding pharmacy working conditions.

Proposed Guidance document 110-26 (public comment period runs until May 11, 2022).

Action needed:

- Propose draft language for full Board to consider as emergency regulations at September 2022 meeting.

VIRGINIA ACTS OF ASSEMBLY — CHAPTER

An Act to direct the Board of Pharmacy to adopt regulations related to work environment requirements for pharmacy personnel; emergency.

[H 1324]

Approved

Be it enacted by the General Assembly of Virginia:

1. *§ 1. That the Board of Pharmacy shall adopt regulations related to work environment requirements for pharmacy personnel that protect the health, safety, and welfare of patients. Such regulations shall include provisions (i) addressing sufficient pharmacy staffing to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with competence and safety; (ii) stating standards for uninterrupted rest periods and meal breaks for pharmacy personnel; (iii) stating standards that ensure adequate time for pharmacists to complete professional duties and responsibilities, including drug utilization reviews, immunization administration, patient counseling, and verification of prescription accuracy; and (iv) limiting external factors such as productivity or production quotas to the extent that such factors interfere with the ability to provide appropriate professional services to the public.*

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.

staff with a budget that is as high as its ever been.

Bolyard commented that District Leaders do not have control over staffing and that it's based previous numbers and projections. Nothing is done with staffing suggestions.

St. Clair discussed limiting staffing collaboration to the Pharmacist-In-Charge (PIC). He recommended implementing a staffing request form similar to Oklahoma which was referenced in Warriner's handouts. He stated they could be maintained in the pharmacy for inspector review.

Ratliff reminded the group that current regulation requires the PIC or pharmacist on duty to control all aspects of the practice of pharmacy.

Richards-Spruill commented that the profession is going to start losing good pharmacists if something is not done. She recommended that a staffing form should be in an electronic format.

Warriner recommended the Board issue a Statement similar to Missouri's that was included her handouts.

MOTION:

The workgroup voted unanimously to recommend to the full board that it adopt a Notice of Intended Regulatory Action at the March board meeting that would include language for unprofessional conduct akin to:

- **Failure to provide a working environment for all pharmacy personnel that protects the health, safety, and welfare of a patient including:**
  - **Sufficient personnel to prevent fatigue, distraction or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety or creates an environment that jeopardizes patient care;**
  - **Appropriate opportunities for uninterrupted rest periods and meal breaks;**
  - **Adequate time for a pharmacist to complete professional duties and responsibility including:**
    - **Drug utilization review;**
    - **Immunization;**
    - **Testing;**
    - **Counseling;**
    - **Verification of the accuracy of a prescription;**
    - **All other duties required in Chapters 33 and 34 and Regulations Governing the Practice of Pharmacy**
  - **Introducing external factors such as productivity or**

production quotas or other programs to the extent that they interfere with the ability to provide appropriate professional services to the public.

- **Failure to take appropriate action regarding safety and welfare on issue escalated by staff practicing at this location. (motion by St.Clair, seconded by Richards-Spruill)**

MOTION:

The workgroup voted unanimously to recommend to the full Board that it amend 18VAC110-20-110(B) to change "six" to "eight" such that it would read "...and shall allow at least eight hours of off-time between consecutive shifts." (motion by Ratliff, seconded by Beckner)

MOTION:

The workgroup voted unanimously to recommend to the full Board to adopt regulation akin to Oklahoma Section 535:15-3-16:

- **In order to ensure adequate staffing levels a staffing form shall be available in each pharmacy. A copy of this form, when executed, shall be given to the immediate supervisor and a copy must remain in the pharmacy for Board inspection.**
- **Such form shall include the following:**
  - **Date and time the inadequate staffing occurred;**
  - **Number of prescriptions filled during this time frame;**
  - **Summary of events; and**
  - **Any comments or suggestions.**
- **Such forms are not to be sent to the Board.**
- **Pharmacy personnel shall complete the form when:**
  - **Personnel is concerned regarding staffing due to:**
    - **Inadequate number of support persons; or**
    - **Excessive workload.**
- **Completing the form may enable management to make a better decision concerning staffing.**
- **If the PIC believes the situation warrants earlier Board review, the PIC shall inform the Board.**
- **Each pharmacy shall review completed staffing reports and address any issues listed, documenting any corrective action taken or justification for inaction to assure continual self-improvement. If the issue is not staffing-related, measures taken to address the issue should be described.**
- **Each pharmacy shall retain completed staffing reports until reviewed and released by the Board. Such reports requiring further review may be held by the Board and may become part of an investigation.**
- **Pharmacy personnel shall not be subject to discipline by the employing pharmacy for completing a staffing report in good faith. (motion by Warriner, seconded by Beckner)**

MOTION:

The workgroup voted unanimously to recommend to the full Board that it develop a form similar to the Oklahoma staffing form that could be completed optionally by pharmacy personnel prior to a regulatory requirement mandating use of the form. (motion by

Virginia Board of Pharmacy
Pharmacy Working Conditions

Exacerbated by the COVID-19 pandemic and other public health crises, pharmacists, pharmacy technicians, and pharmacy interns have experienced increased demands on their skills and time to provide patient care.

Pharmacies holding permits to operate in Virginia are subject to the following requirements:

§ 54.1-3434, which states:

> The application for such permit shall be made on a form provided by the Board and signed by a pharmacist who will be in full and actual charge of the pharmacy…
>
> If the owner is other than the pharmacist making the application, the type of ownership shall be indicated and shall list any partner or partners, and, if a corporation, then the corporate officers and directors. Further, if the owner is not a pharmacist, he shall not abridge the authority of the pharmacist-in-charge to exercise professional judgment relating to the dispensing of drugs in accordance with this act and Board regulations.
>
> The permit shall be issued only to the pharmacist who signs the application as the pharmacist-in-charge and as such assumes the full responsibilities for the legal operation of the pharmacy. This permit and responsibilities shall not be construed to negate any responsibility of any pharmacist or other person.

18VAC110-20-110(C), which states:

> The PIC [pharmacist in charge] or the pharmacist on duty shall control all aspects of the practice of pharmacy. Any decision overriding such control of the PIC or other pharmacist on duty shall be deemed the practice of pharmacy and may be grounds for disciplinary action against the pharmacy permit.

Additionally, Virginia Code § 54.1-3316(13) states that the Board may discipline a pharmacy permit holder if that permit holder has:

> conducted his practice, or activity requiring a license, permit, certificate, or registration from the Board in such a manner as to be a danger to the health and welfare of the public[.]

Due to these requirements, pharmacy permit holders should consult with the PIC or pharmacist on duty and other pharmacy staff to ensure patient care services are safely provided in compliance with applicable standards of patient care. Permit holders should ensure their

decisions are not overriding the control of the PIC or other pharmacist on duty and, via consultation with pharmacy staff, that permit holders are providing a working environment for all pharmacy personnel that protects the health, safety, and welfare of patients. Ensuring a safe environment that does not jeopardize patient care includes, at a minimum:

- Ensuring sufficient personnel are scheduled to work at all times in order to prevent fatigue, distraction, or other conditions that interfere with a pharmacist's ability to practice with reasonable competency and safety;

- Avoiding the introduction of external factors, such as productivity or production quotas, or other programs to the extent that they interfere with the pharmacist's ability to provide appropriate professional services to the public;

- Ensuring staff are sufficiently trained to safely and adequately perform their assigned duties, and demonstrate competency;

- Providing appropriate opportunities for uninterrupted rest periods and meal breaks; and

- Providing adequate time for a pharmacist to complete professional duties and responsibilities, including:

    - drug utilization review;
    - immunization;
    - counseling;
    - verification of prescriptions;
    - patient testing; and
    - all other duties required by Virginia Code §§ 54.1-3300 *et seq.*, 54.1-3400 *et seq.*, and 18VAC20-10 *et seq.*

To ensure adequate staffing levels, a PIC is encouraged to develop and implement use of a staffing report form to address staffing requests or concerns. Pharmacy personnel should complete the form when concerned with staffing due to inadequate number of support persons or excessive workload. Completing the form may result in better decisions concerning staffing.
A copy of the form, when executed, should be given to the immediate supervisor and a copy should remain in the pharmacy. If the PIC believes the situation warrants earlier Board review, the PIC should inform the Board.

Such form should include the following:

- Date and time the inadequate staffing occurred;
- Number of prescriptions filled during this time frame;
- Summary of events; and
- Any comments or suggestions.

Each pharmacy should review completed staffing reports and address any issues listed, documenting any corrective action taken or justification for inaction to assure continual self-

improvement. If it is determined that the issue is not staffing-related, measures taken to address the issue should be described.

It is recommended that each pharmacy retain completed staffing reports for three years from date of execution. Pharmacy personnel should not be subject to discipline by the employing pharmacy for completing a staffing report in good faith.

Evidence of possible violations of law, to include § 54.1-3434 and Regulation 18VAC110-20-110 C, may be submitted online to the Virginia Department of Health Professions, Enforcement Division at http://www.dhp.virginia.gov/PractitionerResources/Enforcement/

Agenda Item: Consideration of final regulations for implementation legislation for registration of pharmacy technician trainees

Included in your agenda package are:

Regulatory Town Hall summary page.

Town Hall public comment.

Public comment received by the agency.

FAQs sent to board-approved training programs and licensees.

Final regulations implementing legislation for the registration of pharmacy technician trainees as required by Chapter 237of the 2020 Acts of Assembly. Final regulations will replace emergency regulations.

Action needed:

- Motion to recommend the Board adopt final regulations at the June 2022 meeting.

Virginia.gov Agencies | Governor

Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter **Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]**

Action: Implementation of legislation for registration of pharmacy technicians

Proposed Stage

Action 5603 / Stage 9243

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	4/12/2021 10:14 am	Sync Text with RIS
Agency Background Document	4/12/2021	Upload / Replace
Attorney General Certification	5/4/2021	
DPB Economic Impact Analysis	6/17/2021	
Agency Response to EIA	7/13/2021	Upload / Replace
Governor's Review Memo	12/2/2021	
Registrar Transmittal	12/6/2021	

Status	
Changes to Text	The proposed text has changed from that of the emergency stage.
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
Attorney General Review	Submitted to OAG: 4/12/2021 Review Completed: 5/4/2021 Result: Certified
DPB Review	Submitted on 5/4/2021 Economist: Jini Rao Policy Analyst: Jeannine Rose Review Completed: 6/17/2021
Secretary Review	Secretary of Health and Human Resources Review Completed: 11/4/2021
Governor's Review	Review Completed: 12/2/2021 Result: Approved
Virginia Registrar	Submitted on 12/6/2021 The Virginia Register of Regulations Publication Date: 1/3/2022 Volume: 38 Issue: 10
Public Hearings	02/07/2022 8:45 AM

Comment Period	**Ended 3/4/2022** **1 comments**

Contact Information	
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This person is the primary contact for this board.

This stage was created by Elaine J. Yeatts on 04/12/2021 at 10:14am
This stage was last edited by Elaine J. Yeatts on 04/12/2021 at 10:14am

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Agency **Department of Health Professions**

Board **Board of Pharmacy**

Chapter

Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians [18 VAC 110 - 21]

Action	**Implementation of legislation for registration of pharmacy technicians**
Stage	**Proposed**
Comment Period	Ends 3/4/2022

1 comments

All good comments for this forum **Show Only Flagged**

Back to List of Comments

Commenter: douglas schiffman, Rappahannock Center for Education
www.rappce.org

2/23/22 8:48 pm

Are you aware of the impact on Pharmacy Tech Training Programs?

The regulations, which follow up on legislation enacted in 2020, will drastically reduce the number of pharmacy tech training programs, thereby drastically reducing the pool of trained pharmacy technicians. Responsibility for regulating training programs moves from the Board of Pharmacy to the ASHP beginning in July 2022. After July, pharmacy tech training programs not accredited by ASHP will not be able to train students to become Virginia certified Pharmacy Technicians. Many if not most of the current Board of Nursing approved programs will not be able to attain ASHP certification, due to the costs ($720 plus $2900 PER YEAR annual assessment fee), the length of the program (400 hours!) and the time and expense needed to assemble the required information. The current fee to apply to the Board of Pharmacy is $200.

As of today (Feb 23, 2022), there are just 2 programs accredited by ASHP. There are over one hundred programs approved by the Board of Pharmacy, and a number of applications pending. After July, pharmacy tech students will still need to take and pass either the ExCPT or the PTCB exam, but unless their training program is ASHP accredited, they will not be eligible to become state certified.

If Virginia wonders why there are so few new pharmacy tech students, look no further than the impact of the law and the new regulations. Is anyone on the Board of Pharmacy thinking about this?

CommentID: **120133**

March 1, 2022

Dear Ms. Yeatts:

I'd like to make a few comments regarding the Proposed Regulations for Pharmacy Technician Training Programs. By way of background, I own The Compounding Center in Leesburg, Virginia and have practiced pharmacy since 1990. We employ 16 registered technicians and have had at least 12 technicians take and pass our Board approved technician training program.

I have some concerns regarding the requirement that training programs be ASHP/ACPE accredited. The shortage of technicians is the worst I've seen in my entire career. This change may throw up additional barriers to this career path which will make the staffing situation worse.

I do not agree with the following statement in the summary:

> *Small Businesses[5] Affected. The proposed amendments are unlikely to adversely affect any small businesses. Pharmacies in Virginia that are independently operated small businesses would benefit from standardized education requirements for pharmacy technicians to the extent that it results in a better-trained pool of potential employees.*

It is not financially realistic for a small business (independent pharmacies) to obtain ASHP/ACPE accreditation for their technician training program. We currently have a Board approved training course and this was one advantage we had in recruiting. We could put a prospective technician through our course at no cost to the employee and minimal cost to the business.

I inquired at our local community college to ask about their technician program and was told they will be discontinuing it due to the accreditation requirements. "The change to the requirements will make the cost of the program triple (or more). We will be shutting it down as I'm not sure too many students want to borrow $8-$10k for a job that pays what Target pays."

www.compoundingcenter.com

36-C Catoctin Circle, SE
Leesburg, VA 20175
(703) 779-3301

It seems that passing the PTCB or NHA exam is the ultimate measure of successful training. I feel certain that our FREE on the job training, supplemented with course material is equal to or better than an online course for which they will have to pay. I'm certain the chains have programs in place because they can afford the fees of accreditation spread over many stores, but there are many other pharmacies across the Commonwealth that are not affiliated with a chain.

I also wanted to ask about the two year time limit to finish the course and pass the exam. Is the Technician Trainee registration specific to the training program? What would happen if the Technician changed jobs during their Trainee period? Would they re-register with the Board or notify the Board of a change in their program enrollment/employment, and would their two year time frame start over?

Thank you for your time in reviewing my concerns. I look forward to seeing you at our next Board of Pharmacy meeting.

Sincerely,

Cheri Garvin, RPh

VIRGINIA BOARD OF PHARMACY

PHARMACY TECHNICIAN TRAINING PROGRAM AND REGISTRATION

FREQUENTLY ASKED QUESTIONS

BACKGROUND:

Refer to §54.1-3321 of the Code of Virginia and emergency regulations

Except as noted below, effective July 1, 2022, to be registered with the Board as a pharmacy technician, an applicant who enrolls in a pharmacy technician training program shall provide:

1) Evidence of completion of a pharmacy technician training program that is:

a. A program jointly accredited by the American Society of Health-System Pharmacists (ASHP) and the Accreditation Council for Pharmacy Education (ACPE),

b. An accredited training program operated through the Department of Education's (DOE) Career and Technical Education program,

c. A program operated through a federal agency or branch of the military, or

d. A program accredited by an accreditation body approved by the board.

2) Evidence that they successfully passed a national certification examination administered by PTCB or NHA.

NOTED EXCEPTIONS:

1. A person who successfully completed or was enrolled in a Board-approved pharmacy technician training program but did not successfully pass a national examination **prior to July 1, 2022** may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a Board-approved pharmacy technician training program and passing examination score.
2. A person who passed a national certification examination administered by PTCB or NHA but did not complete a Board-approved pharmacy technician training program **prior to July 1, 2022** may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination.
3. A pharmacy technician who has previously practiced in another U. S. jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.

GENERAL FAQs:

1. **Q: I operate a Board-approved pharmacy technician training program. We will not pursue ASHP/ACPE accreditation, but currently have a pharmacy technician trainee enrolled in our program who may not have sufficient time to complete the program prior to 7/1/22. Is this trainee eligible for obtaining a pharmacy technician registration from the Board of Pharmacy?**

A: Yes, if the pharmacy technician trainee was enrolled in the Board-approved training program prior to July 1, 2022, he or she must simply pass a national certification examination administered by PTCB or NHA and submit to the board documentation of enrollment in the Board-approved pharmacy technician training program and passing examination score. As of July 1, 2022, this trainee is no longer required to complete the Board-approved pharmacy technician training program prior to sitting for the national exam, however, timely completion of the program may assist the trainee in successfully passing the exam. At no time may a trainee perform the duties restricted to a pharmacy technician without holding a current active pharmacy technician registration.

2. **Q: I operate a Board-approved pharmacy technician training program. We will not pursue ASHP/ACPE accreditation, but currently have a pharmacy technician trainee enrolled in our program who may not have sufficient time to complete the program prior to 7/1/22. May we continue to teach this trainee after 7/1/22?**

   A: Yes, you may continue to teach trainees who enrolled prior to 7/1/22 and have a current active pharmacy technician trainee registration to prepare them for taking the national PTCB or NHA examination, however, the trainee is legally not required to complete the training program. Effective 7/1/22, any person enrolled in a Board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022 may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a Board-approved pharmacy technician training program and passing examination score.

3. **Q: I operate a Board-approved pharmacy technician training program. Must I continue to renew this approval with the Board after 7/1/22?**

   A: No. The authority for the Board to approve pharmacy technician training programs ceases as of 7/1/22. A program could elect to obtain accreditation from ASHP/ACPE if it wishes to continue to offer a pharmacy technician training program.

4. **Q: I operate a pharmacy technician training program and intend to obtain accreditation from ASHP/ACPE. Do I also need to obtain approval from the Board of Pharmacy?**

   A: No, simply maintaining accreditation from ASHP/ACPE is sufficient.

5. **Q: What if a registered pharmacy technician trainee is enrolled in a Board-approved distance learning program prior to 7/1/2022 that will not pursue ASHP/ACPE accreditation? Will the pharmacy technician trainee still be allowed to complete their externship training experience in a pharmacy that is not an approved site by an ASHP/ACPE accredited pharmacy technician training program after 7/1/2022 in order to complete/graduate from the program?**

   A: Yes, if the pharmacy technician trainee was enrolled in the Board-approved training program prior to July 1, 2022, he or she may choose to complete the externship training experience in a pharmacy in order to complete/graduate from the program. However, as of July 1, 2022, completion of the Board-approved training program is no longer required. The trainee must simply pass a national certification examination administered by PTCB or NHA and submit to the board documentation of enrollment in the Board-approved pharmacy technician training program and passing examination score.

6. **Q: I received my PTCB or NHA national certification in a different state, and I'm moving to Virginia. I did not complete/graduate from an ASHP/ACPE-accredited program. Am I eligible to apply for registration as a pharmacy technician in Virginia?**

   A: A pharmacy technician who has previously practiced in another U.S. jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.

7. **Q: I operate an independent pharmacy that does not have an ASHP/ACPE-accredited training program. As of July 1, 2022, am I able to hire a pharmacy technician trainee to work in my pharmacy?**

   A: Yes, as long as the pharmacy technician trainee is registered by the Board and enrolled in a training program accredited by ASHP/ACPE, accredited and operated though the Department of Education's (DOE) Career and Technical Education program, or through a federal agency or branch of the military, you may hire the trainee to perform the duties of a pharmacy technician under the supervision of a pharmacist.

   If the pharmacy is an approved site of the training program for obtaining the required hours of practical experience AND the trainee has completed the didactic and simulation components of the program, the paid hours will be evaluated against the key elements and standards which may satisfy the externship rotation. Paid hours worked prior to completing the didactic and simulation components of the program cannot be used to satisfy the externship rotation.

   If the pharmacy is NOT an approved site of the training program for obtaining the required hours of practical experience, the trainee may be paid for performing duties restricted to a pharmacy technician under the supervision of a pharmacist but the hours will not satisfy the externship rotation which may be required by the training program. Such pharmacy technician is responsible for ensuring successful completion of an eligible pharmacy technician training program and passing the required exam prior to the expiration of the pharmacy technician trainee registration.

8. **Q: Once I complete/graduate from an ASHP/ACPE-accredited pharmacy technician training program, how long can I continue to work as a registered pharmacy technician trainee before I take and/or pass the PTCB or NHA national certification exam?**

   A: A registered pharmacy technician trainee that completes/graduates from a training program accredited by ASHP/ACPE, accredited and operated though the Department of Education's (DOE) Career and Technical Education program, or through a federal agency or branch of the military is strongly encouraged to sit for the PTCB or NHA national certification exam as soon as practical. A trainee's registration shall be assigned a registration with an expiration date, not to exceed two years, to cover the estimated time period for the trainee to complete the training required for completion of the program and pass the required examination.

9. **Q: Are the pharmacy technicians who were registered with the Virginia Board of Pharmacy prior to the 7/1/2022 grandfathered in or are they required to meet current requirements?**

A: A pharmacy technician that has obtained registration with the Board prior to 7/1/2022 shall not be required to meet the increased educational standards in Regulation 18VAC110-21-141(B) and may simply renew the registration after obtaining the required 5 hours of continuing education annually. If a pharmacy technician allows the registration to expire and fails to reinstate the expired pharmacy technician registration within five years of expiration, the technician must satisfy the increased educational requirements and re-testing. (Refer to FAQ #3)

10. **Q: I was not enrolled in a Board-approved pharmacy technician training program prior to July 1, 2022, nor did I pass the PTCB or NHA exam prior to July 1, 2022. May I simply complete a self-study and take the PTCB or NHA exam?**

    A: No. Only a person who was enrolled in a Board-approved pharmacy technician training program prior to July 1, 2022 but who did not complete the program is eligible to simply pass the PTCB or NHA national examination. Proof of enrollment and successful passing of the exam must be submitted to the Board with the application for a pharmacy technician registration.

11. **Q: If I operate an independent pharmacy, and I'm approved to serve as a site for externship training experience by an ASHP/ACPE-accredited distance learning pharmacy technician training program, am I automatically eligible to serve as an externship training experience site for all ASHP/ACPE-accredited distance learning training programs or do I have to be approved by each program I work with?**

    A: Each training program reviews the sites for externship training experience, therefore, your pharmacy will need to be approved by each program that you work with for externship training.

12. **Q: My pharmacy technician training program applied for ASHP/ACPE accreditation and obtained a "candidate status" upon submission of an application. Will the Virginia Board of Pharmacy accept graduates of an ASHP/ACPE training program in "candidate" status?**

    A: Yes. Assuming no other reasons exist for denial, graduates of an ASHP/ACPE training program in "candidate status" are eligible to obtain Board registration as a pharmacy technician if the applicant has also successfully passed the PTCB or NHA national examination.

FAQs RELATED TO ASHP/ACPE ACCREDITATION PROCESS (Prepared by ASHP):

13. **Q: Where can I find information regarding ASHP/ACPE accreditation of pharmacy technician education and training programs?**

    A: Refer to the ASHP website for the accreditation standards, regulations, application fees, directory of accredited programs, and videos on how to start a program.

    https://www.ashp.org/professional-development/technician-program-accreditation?loginreturnUrl=SSOCheckOnly

Once on that page, hit the "Learn More" button in the box on the far right on the top line of boxes. Within this box is information that someone interested in starting a program or is seeking accreditation MUST review:

- **Accreditation Standards, Regulations, and Other Tools**
  The following documents and webinars are found under this section:
  - **Accreditation Standards**
    - Accreditation Standards for Pharmacy Tech Education and Training
  - **Accreditation Regulations**
    - Regulations on Accreditation for Pharmacy Tech Education/Training
  - **Accreditation Tools**
    - Guidance Document - provides what surveyors are looking at against the Accreditation Standard when surveying the program
    - Model Curriculum - provides example activities for each key element of the Standard to modify or develop a program

    Informational Videos - designed to answer questions in concert with reviewing the Accreditation Standards
    - Advisory Committees for Pharmacy Technician Programs - how to put together an advisory committee for your program
    - Developing a Strategic Plan for your Program
    - 10 Key Steps to ASHP/ACPE to Pharmacy Technician Education and Training Programs - a must watch

14. Q: What are some of the key factors within the ASHP/ACPE accreditation standards that I MUST have to apply for accreditation?

A: It is essential to review the Standards prior to considering applying for accreditation. The program must be constructed to meet the Standards and include the key elements within the Standards. Not all Standards and Key Elements will necessarily be in place when you apply for accreditation since this is a continuous quality process. BUT, with that said, there are a few areas that MUST be in place prior to applying for accreditation:

A) Must have at least one student in the program-you can apply for accreditation the first day of the program, as long as there is one student in the program.

B) The program director must meet the elements of the Standard:
(a) is a licensed pharmacist or a nationally certified pharmacy technician; (b) has at least five years of experience as a pharmacist or pharmacy technician in pharmacy practice prior to entering the position; (c) adheres to the state's regulations for licensure or registration in the practice of pharmacy;
(b) if the program director is a pharmacy technician- has graduated from an ASHP/ACPE-accredited pharmacy technician training program; or (b) possesses or is actively pursuing, with a written plan for achieving, at least an Associate's Degree; or (c) has an appropriate state teaching credential.

C) Must have an active advisory committee that meets at least twice a year that consists of a broad base of pharmacists and pharmacy technicians-this group of individuals will be the group that assists in approving your curriculum, externship sites, strategic plan, criteria for admission and dismissal; criteria for

successful completion of the program. They can also help by serving as externship coordinators to place your students for rotation, ultimately hire your students, provide you with supplies/technology that they are no longer using at their pharmacies.

D) **Length of program-most will be applying for an Entry-level program, the following hours MUST be following within the program:**
The training schedule consists of a minimum of 400 hours total, of health-related education and training, extending over a period of at least 8 weeks. The period of training includes the following educational modalities: Didactic; Simulated; and Experiential. The minimum number of hours for each component is as follows: Didactic – 120 hours; Simulated – 50 hours; Experiential – 130 hours (total of 300 hours); plus 100 additional hours, to obtain the minimum of 400 hours of training total. The additional 100 hours may be allocated to the three educational modalities listed above, based on the discretion of the program director and faculty.
Advanced level programs are 600 hours in duration-see the Standards for details on Advanced level programs.

15. **Q: Okay, I've read the standards, I'm a pharmacist that meets the criteria, I have put together an advisory committee (and even watched the video on the website), and I have 400 hours in the correct amounts for each component. I've watched the 10 Key Steps to ASHP/ACPE Pharmacy Technician Education and Training Accreditation. I also have a student enrolled for the fall, now what?**

A: As mentioned previously, you can apply for accreditation the first day of the class of the program. Once you apply, the program is in ASHP/ACPE Candidate Status. The Virginia Board of Pharmacy accepts programs in candidate status since they have started the ASHP/ACPE accreditation process. Once accredited, the accreditation is retroactive to the date of application. This is why it is essential that the application for accreditation occurs when a program is constructed against the Standards.

16. **Q: How much is it to apply or accreditation?**
A: It depends on how many sites you have within your organization. Most will have one site, therefore the fees will be $720 (in 2022) for the initial application fee and $2900 (in 2022) for the annual fee. The annual fee is prorated to the time of the year that you apply. If you apply in July, you would pay ½ of the annual fee, in February, you'd pay 10/12th of the fee. You will be invoiced for the fees, you do not need to send a check in for the fees. For more details of fees for other training environments see the following site:

https://www.ashp.org/professional-development/technician-program-accreditation/applying-for-accreditation?loginreturnUrl=SSOCheckOnly

The application for accreditation is located on this page of the website, too. Complete that form and include a completed academic and professional form (found in the link below) and a current CV:

https://www.ashp.org/professional-development/technician-program-accreditation/preparing-for-an-accreditation-survey?loginreturnUrl=SSOCheckOnly

17. **Q: I'm ready to apply for accreditation, what's next?**

A: Submit the materials (application, program director's academic and profressional form; program director's CV) to asd@ashp.org and copy llifshin@ashp.org
Your application, academic and professional form, and CV will be reviewed. The Senior Director for Technician Education and Training will contact you to confirm that all of the items are approved. She will ask you when you will have your first graduate. She will schedule your accreditation survey for a time close to when your first class has graduated. She will assign a lead surveyor (who will also have a practitioner educator surveyor) to review your program against the standards. This generally happens between 6-12 months after receipt of the application, if you have a graduate at that point. You will receive a copy via email of the pre-survey questionnaire that must be completed and submitted electronically back to ASHP 45 days prior to the survey. You will receive these directions for submission when the date for your survey is confirmed. You will also receive the pre-survey packet upon confirmation of the survey date. You can review the pre-survey questionnaire (which you should do prior to application) from the site below:
https://www.ashp.org/professional-development/technician-program-accreditation/preparing-for-an-accreditation-survey?loginreturnUrl=SSOCheckOnly

18. **Q: What happens when my site survey is scheduled?**

A: Your lead surveyor will be the main person that you will communicate questions to until the survey report is submitted for review for accreditation. The lead surveyor will help you with the agenda for the review, answer any questions that you may have in putting together your packet, and any other questions that you may have in getting ready. The main thing to remember is to prepare with the materials listed in FAQ #13. The Guidance Document found on the website under Accreditation Standards, Regulations and Other Tools will be very helpful to get ready for the survey.

19. **Q: What happens during the survey?**

A:

a. Surveyors conduct review onsite or virtually.
b. Surveyors meet with you, your instructors, current students, graduates, your advisory committee, and your college, hospital, or store administration.
c. Surveyors review site and discuss program against the standard and pre-survey questionnaire-you may feel like you had everything in the packet, but the surveyors want to make sure that they understand everything-they are your advocates for you to be successful in the process.
d. Areas of non- (the area is not happening), partial (1-99 percent fulfilled), and full compliance (100% done), as well as consultative recommendations are documented.
e. Draft report is presented to technician training program director and college, hospital, or store administration.

20. Q: **What happens after the survey, I'm nervous, I had a lot of citations?**

A: a) Technician Training Program Director and College, Hospital, or Store Administration receive report within 30 days of the survey.

b) Technician Training Program Director has 75 days from the survey to respond to the report.

Your Response is more important than the report that is written by the team during the survey and sent to you. Listen to all of the feedback that they provide to you at the site survey when they provide the report to you and your administration. They are also available to you when you are preparing your response if you have any questions. Make sure and provide evidence that you are remedying any areas that were cited. Provide completed forms, picture of equipment that are purchased, documentation of things that are in the works. The survey report and your response are reviewed by the lead surveyor and practitioner educator surveyor to make a recommendation (not accredit, one year, three years, full cycle accreditation) for accreditation for consideration by Pharmacy Technician Accreditation Commission (PTAC).

c) The survey team reviews both the response against the initial report to review progress since the survey.

21. Q: When do I find out if I am accredited?

A: Once the surveyors review the reports, they write up a summary on progress on each of the findings and make a recommendation for accreditation or to withold accreditation to the Pharmacy Technician Accreditation Commission (PTAC) and they will vote on accreditation. These actions must go to the ASHP and ACPE Board of Directors meetings for final voting. Once they vote, you will receive notification on your accreditation. Depending on when you're reviewed, that's when you'll find out your accreditation decision. If you are reviewed from July 16-February 14th, your report will go to the May PTAC meeting and the June ASHP and ACPE Board of Directors meetings and you will find out in early July. If you are reviewed from February 15th to July 15th, your report will go to the October PTAC meeting and the January ASHP and ACPE Board of Directors Meeting and you will find out in early February.

REMEMBER SUCCESSFUL ACCREDITATION IS RETROACTIVE TO THE DATE OF APPLICATION

22. Q: Will I get a letter and certificate to verify that my training program is accredited?

A: Yes, you will receive a certificate that you can hang on your wall, you can then put the ASHP/ACPE-accredited seal that you download from the website on all graduation certificates (prior to that, you add the ASHP/ACPE-candidate downloaded seal to the graduates' certificates).

23. Q: How long is my program accredited?

A: Successful programs are reviewed every six years. Surveys will occur every six years. Written reports are required at either 1 or 3 year points, depending on what still needs to be resolved. No program goes longer than 3 years reporting back to the PTAC.

24. Q: Can my graduates take the national exams if my program is in candidate status?

A: Yes. ASHP/ACPE candidate programs are recognized by the Board of Pharmacy. ASHP/ACPE candidate programs are also recognized by PTCB.

25. Q: How does the VA Board of Pharmacy (VABOP) know which programs are in candidate status and accredited status?

A: The ASHP Accreditation Services Office staff will notify the VABOP of the status of programs that have submitted applications for accreditation and when status changes.

26. Q: Where may I find a list of ASHP/ACPE technician training programs?

Visit: https://accreditation.ashp.org/directory/#/program/technician
To search for Distance Learning Pharmacy Technician Training Programs, choose "Distance Learning/Online Program" under "Select Organization Type". Then, select "Entry (400)" under "Select a Sub-Category". Any program listed here with an Accreditation Status of "Accredited" or "Candidate" will satisfy Virginia's requirements.

To search for a training program with a classroom located in Virginia, simply choose "Virginia" under "Select a State".

27. Q: So, tell me what candidate status is again?

A: ASHP/ACPE candidate status is the designation that programs are given when they have met the criteria to apply for accreditation and submit their application and it is approved by ASHP staff to be scheduled for review for accreditation. Please review #12-27 for the full accreditation process. Candidate status continues until the program is accredited. Be ready, read the standards, work towards fulfilling the key elements and standards and you will be ready to be accredited.

28. Q: What if I don't have the resources to have an accredited program, but I have to get my technicians trained?

A: There are many distance learning programs available that are ASHP/ACPE- accredited that you can use to support your employees to complete while working. They can even use your place as their externship experience. The distance learning programs will review your site for approval for externship experiences and then you can count the 130 hours that will be at the end of the program, while you're reviewing them as their preceptor, against the designated key elements established for the rotation by the program. In addition, there are several training and education programs in Virginia that are ASHP/ACPE accredited or in candidate status that you may be able to send your students.

29. Q: Any other questions?

A: For VABOP questions, send an email to: pharmbd@dhp.virginia.gov
For ASHP/ACPE accreditation questions, email: asd@ashp.org

Proposed Text

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Action: Implementation of legislation for registration of pharmacy ...
Stage: Proposed 4/12/21 10:14 AM

18VAC110-20-111 Pharmacy technicians

A. Every pharmacy that employs or uses pharmacy technicians shall maintain a site-specific training program and manual for training pharmacy technicians to work at that pharmacy. The program shall include training consistent with that specific pharmacy practice to include, but not be limited to, training in proper use of site-specific computer programs and equipment, proper use of other equipment used at the pharmacy in performing technician duties, and pharmacy calculations consistent with the duties at that pharmacy.

B. Every pharmacy shall maintain documentation of successful completion of the site specific training program for each pharmacy technician for the duration of the employment and for a period of two years from date of termination of employment. Documentation for currently employed pharmacy technicians shall be maintained on site or at another location where the records are readily retrievable upon request for inspection. After employment is terminated, such documentation may be maintained at an off-site location where it is retrievable upon request.

C. Every pharmacy that employs or uses a person enrolled in ~~an approved~~ a pharmacy technician training program pursuant to § 54.1-3321 ~~D~~ of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians ~~for no more than nine months without that person becoming registered as a pharmacy technician with the board as set forth in 18VAC110-20-101. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training~~ only if the person is currently registered as a pharmacy technician trainee.

18VAC110-21-10 Definitions

Part I General
Provisions

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

"ACPE" means the Accreditation Council for Pharmacy Education.

"ASHP" means the American Society of Health-System Pharmacists.

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

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

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

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

"NHA" means National Healthcareer Association.

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

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

18VAC110-21-20 Fees

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

B. Unless otherwise provided, any fees for taking required examinations shall be paid directly to the examination service as specified by the board.

C. Initial application fees.

1. Pharmacist license	$235
2. Pharmacy intern registration	$20
3. Pharmacy technician trainee registration	$20
~~3.~~ 4. Pharmacy technician registration	$35
~~4.~~ 5. Approval of a pharmacy technician training program	$200
~~5.~~ 6. Approval of a continuing education program	$130

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	$120

2. Pharmacist inactive license – due no later than December 31	$60
3. Pharmacy technician registration – due no later than December 31	$35
4. Pharmacy technician training program	$100 every two years

E. Late fees. The following late fees shall be paid in addition to the current renewal fee to renew an expired license or registration within one year of the expiration date or within two years in the case of a pharmacy technician training program. In addition, engaging in activities requiring a license or registration after the expiration date of such license or registration shall be grounds for disciplinary action by the board.

1. Pharmacist license	$40
2. Pharmacist inactive license	$20
3. Pharmacy technician registration	$15
4. Pharmacy technician training program	$20

F. Reinstatement fees. Any person or entity attempting to renew a license or registration more than one year after the expiration date, or more than two years after the expiration date in the case of a pharmacy technician training program, shall submit an application for reinstatement with any required fees. Reinstatement is at the discretion of the board and, except for reinstatement following revocation or suspension, may be granted by the executive director of the board upon completion of an application and payment of any required fees.

1. Pharmacist license	$275
2. Pharmacist license after revocation or suspension	$650
3. Pharmacy technician registration	$45
4. Pharmacy technician <u>or pharmacy technician trainee</u> registration after revocation or suspension	$165
5. A pharmacy technician training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of $75. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration.	

G. Miscellaneous fees.

1. Duplicate wall certificate	$50
2. Returned check	$35
3. Duplicate license or registration	$15
4. Verification of licensure or registration	$35

18VAC110-21-40 Unprofessional conduct

The following practices shall constitute unprofessional conduct within the meaning of § 54.1-3316 of the Code of Virginia:

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to providing patient records to another practitioner or to the patient or the patient's personal representative;

2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;

3. Failing to maintain the confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;

4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;

5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or the patient's family, including sexual misconduct with a patient or a member of the patient's family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against the diversion of controlled substances;

7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;

8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;

9. Failing by the pharmacist in charge to ensure that pharmacy interns ~~and~~, pharmacy technicians, and pharmacy technician traineees working in the pharmacy are registered and that such registration is current;

10. Failing to exercise professional judgment in determining whether a prescription meets the requirements of law before dispensing;

11. Obtaining money or property of a patient or client by fraud or misrepresentation;

12. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;

13. Violating any provision of this chapter, 18VAC110-20, or Chapter 33 (§ 54.1-3300 et seq.) or 34 (§ 54.1-3400 et seq.) of Title 54.1 of the Code of Virginia;

14. Performing any act likely to deceive, defraud, or harm the public; or

15. Having a restriction of a license to practice pharmacy or a registration as a pharmacy technician in another jurisdiction in the United States.

18VAC110-21-135 Registration as a pharmacy technician trainee

A. A person desiring to gain practical pharmacy experience toward completion of a pharmacy technician training program in Virginia shall first register with the board as a pharmacy technician trainee on a form provided by the board prior to engaging in the duties of a pharmacy technician pursuant to § 54.1-3321 of the Code of Virginia.

B. In order to be eligible to register as a pharmacy technician trainee, an applicant shall be enrolled in a pharmacy technician training program. An expiration date, not to exceed two years, shall be assigned to the registration to cover the estimated time period for the trainee to complete the practical pharmacy experience required for completion of the training program and pass the required examination. If the trainee is no longer enrolled in the training program, takes a voluntary break from the program, or is otherwise not actively progressing toward completion of such program, the registration is no longer valid and shall be returned to the board immediately.

C. A pharmacy technician trainee shall be directly monitored by a supervising pharmacist who holds a current active license and assumes full responsibility for the training and supervision of the trainee.

D. A pharmacy technician trainee shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-21-140 Application for registration as a pharmacy technician (Effective until July 1, 2022)

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Satisfactory completion of a board-approved training program; and

2. A passing score on a board-approved examination.

C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification or NHA certification.

~~D. A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to § 54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians for no more than nine consecutive months from the date the trainee begins performing duties restricted to a pharmacy technician without becoming registered as a pharmacy technician.~~

18VAC110-21-141 Requirements for pharmacy technician training (Effective July 1, 2022)

A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.

B. To be registered as a pharmacy technician, an applicant shall provide evidence of the following:

1. Completion of a pharmacy technician training program that is:

a. Jointly accredited by the ASHP and ACPE;

b. An accredited training program operated through the Department of Education's Career and Technical Education Program;

c. Operated through a federal agency or branch of the military; or

d. Accredited by an accreditation body approved by the board.

2. Successfully having passed a national certification examination administered by PTCB or NHA.

C. A pharmacy technician who has previously practiced in another United States jurisdiction may be eligible to obtain registration as a pharmacy technician upon documentation of previous practice and having passed a national certification examination administered by PTCB or NHA.

D. A person who successfully completed or was enrolled in a board-approved pharmacy technician training program but did not successfully pass a national examination prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician after successfully passing a national certification examination administered by PTCB or NHA and submitting to the board documentation of such completion or enrollment in a board-approved pharmacy technician training program and passing examination score.

E. A person who passed a national certification examination administered by PTCB or NHA but did not complete a board-approved pharmacy technician training program prior to July 1, 2022, may be eligible to obtain registration as a pharmacy technician upon documentation of having passed such examination.

18VAC110-21-150 Criteria for approval for training programs (Effective until July 1, 2022)

A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee, a sample certificate, and an application on a form approved by the board and meet the criteria established in this section.

B. The curriculum of a training program for pharmacy technicians shall include instruction in applicable current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:

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

2. The preparation of prescription labels or patient information;

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

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

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

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

7. The acceptance of refill authorization from a prescriber or the prescriber's authorized agent provided there is no change to the original prescription.

C. Each program shall have a program director who shall be either (i) a pharmacist with a current license in any jurisdiction and who is not currently suspended or revoked in any jurisdiction in the United States; (ii) a pharmacy technician with at least one year of experience performing technician tasks who holds a current registration in Virginia or current PTCB certification and who is not currently suspended or revoked as a pharmacy technician in any jurisdiction; or

(iii) other person approved and deemed qualified by the board to be a program director.

D. Instructors for the core components listed in subsection B of this section shall meet the requirements for the program director listed in subsection C of this section. The program director may serve as an instructor.

E. The length of the program shall be sufficient to prepare a program participant to sit for the board-approved examination and demonstrate entry-level competency.

F. The program shall maintain records of program participants either on site or at another location where the records are readily retrievable upon request for inspection. A program shall provide a certificate of completion, including the program approval number, to participants who successfully complete the program and provide verification of completion of the program for a participant upon request by the board. Records shall be maintained for two years from date of completion or termination of program.

G. The program shall report within 14 days any substantive change in the program to include a change in program name, program certificate, program director, instructors, name of institution or business if applicable, address, program content, length of program, or location of records.

H. A pharmacy technician training program approval expires after two years, after which the program may apply for renewal. For continued approval, the program shall submit the renewal application, renewal fee, and a self-evaluation report on a form provided by the board at the time of renewal notification. Renewal of a program's approval is at the discretion of the board, and the decision to renew shall be based on documentation of continued compliance with the criteria set forth in this section.

18VAC110-21-160 ~~Examination.~~ (Repealed.)

~~A. The board shall approve one or more examinations to test entry-level competency for pharmacy technicians. In order to be approved, a competency examination shall be developed in accordance with and meet the recognized acceptable test measurement standards of the Joint Technical Standards for Education and Psychological Testing (American Psychological Association, current edition), and shall be administered by an independent third party.~~

~~B. The board may contract with an examination service for the development and administration of a competency examination.~~

~~C. The board shall determine the minimum passing standard on the competency examination.~~

~~D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-21-80 F.~~

18VAC110-21-170 Renewal and reinstatement of registration

A. Pharmacy technician registrations expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and an e-profile number issued by NABP. A pharmacy technician newly registered on or after July 1 shall not be required to renew that registration until December 31 of the following year. Failure to receive the application for renewal shall not relieve the pharmacy technician of the responsibility for renewing the registration by the expiration date.

B. A pharmacy technician who fails to renew his registration by the expiration date may renew his registration at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and attestation of having met the continuing education requirements.

C. A pharmacy technician who fails to renew his registration for more than one year following expiration and who wishes to reinstate such registration shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement. Practicing as a pharmacy technician with a lapsed registration shall be illegal and may subject the registrant to disciplinary action by the board.

D. A person who fails to reinstate a pharmacy technician registration within five years of expiration shall ~~not be eligible for reinstatement and shall repeat an approved training program and repeat and pass the examination or hold current PTCB certification before applying to be reregistered~~:

1. Take and pass a national certification examination administered by PTCB or NHA, unless national certification is currently maintained;

2. Document completion of 20 hours of continuing education; and

3. Pay the current renewal fee and a reinstatement fee.

18VAC110-21-180 Requirements for continued competency

A. A pharmacy technician shall be required to have completed a minimum of 0.5 CEUs or five contact hours of approved continuing education for each annual renewal of registration. Hours in excess of the number required for renewal may not be transferred or credited to another year.

B. An approved continuing education program shall meet the requirements as set forth in 18VAC110-21-120 B or 18VAC110-21-130 B.

C. Upon written request of a pharmacy technician, the board may grant an extension of up to one year in order for the pharmacy technician to fulfill the continuing education requirements for the period of time in question. The granting of an extension shall not relieve the pharmacy technician from complying with current year requirements. Any subsequent extension shall be granted for good cause shown.

D. Up to one hour of the five hours required for annual renewal may be satisfied through delivery of pharmacy services as a pharmacy technician, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

E. ~~Original documentation~~ Documentation showing successful completion of continuing education programs shall be maintained by the pharmacy technician for a period of two years following the renewal of his registration. The pharmacy technician shall provide such documentation to the board upon request in a manner to be determined by the board.

Agenda Item: Consideration of final regulations for implementation of 2020 legislation regarding pharmacists initiating treatment

Included in your agenda package are:

Regulatory Town Hall summary page showing no comments.

Final regulations regarding pharmacists initiating treatment as required by Chapter 731 of the 2020 Acts of Assembly. Final regulations will replace emergency regulations.

Action needed:

- Motion to recommend the Board adopt final regulations at the June 2022 meeting.

Virginia.gov Agencies | Governor

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Action: Implementation of legislation for pharmacists initiating treatment

Proposed Stage

Action 5604 / Stage 9242

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Proposed Text	6/17/2021 2:49 pm	Sync Text with RIS
Agency Background Document	4/12/2021 (modified 6/17/2021)	Upload / Replace
Attorney General Certification	5/4/2021	
DPB Economic Impact Analysis	6/9/2021	
Agency Response to EIA	7/13/2021	Upload / Replace
Governor's Review Memo	12/2/2021	
Registrar Transmittal	12/6/2021	

Status	
Changes to Text	The proposed text for this stage is identical to the emergency regulation.
Incorporation by Reference	No
Exempt from APA	No, this stage/action is subject to Article 2 of the *Administrative Process Act*
Attorney General Review	Submitted to OAG: 4/12/2021 Review Completed: 5/4/2021 Result: Certified
DPB Review	Submitted on 5/4/2021 Economist: Larry Getzler Policy Analyst: Melanie West Review Completed: 6/17/2021
Secretary Review	Secretary of Health and Human Resources Review Completed: 11/4/2021
Governor's Review	Review Completed: 12/2/2021 Result: Approved
Virginia Registrar	Submitted on 12/6/2021 The Virginia Register of Regulations Publication Date: 1/3/2022 Volume: 38 Issue: 10
Public Hearings	02/07/2022 8:45 AM

Comment Period	Ended 3/4/2022 0 comments

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This person is the primary contact for this chapter.

This stage was created by Elaine J. Yeatts on 04/12/2021 at 10:10am
This stage was last edited by Elaine J. Yeatts on 07/13/2021 at 2:20pm

Proposed Text

highlight

Action: Implementation of legislation for pharmacists initiating ...
Stage: Proposed 6/17/21 2:49 PM [latest]

18VAC110-20-150 Physical standards for all pharmacies

A. The prescription department shall not be less than 240 square feet. The patient waiting area or the area used for counseling, devices, cosmetics, and proprietary medicines shall not be considered a part of the minimum 240 square feet. The total area shall be consistent with the size and scope of the services provided.

B. Access to stock rooms, rest rooms, and other areas other than an office that is exclusively used by the pharmacist shall not be through the prescription department. A rest room in the prescription department, used exclusively by pharmacists and personnel assisting with dispensing functions, may be allowed provided there is another rest room outside the prescription department available to other employees and the public. This subsection shall not apply to prescription departments in existence prior to November 4, 1993.

C. The pharmacy shall be constructed of permanent and secure materials. Trailers or other moveable facilities or temporary construction shall not be permitted.

D. The entire area of the location of the pharmacy practice, including all areas where drugs are stored, shall be well lighted and well ventilated; the proper storage temperature shall be maintained to meet USP-NF specifications for drug storage.

E. The prescription department counter work space shall be used only for the compounding and dispensing of drugs and necessary recordkeeping.

F. A sink with hot and cold running water shall be within the prescription department. A pharmacy issued a limited-use permit that does not stock prescription drugs as part of its operation is exempt from this requirement.

G. Adequate refrigeration facilities equipped with a monitoring thermometer for the storage of drugs requiring cold storage temperature shall be maintained within the prescription department if the pharmacy stocks such drugs.

H. A pharmacy stocking drugs requiring cold storage temperature shall record the temperature daily and adjust the thermostat as necessary to ensure an appropriate temperature range. The record shall be maintained manually or electronically for a period of two years.

I. The physical settings of a pharmacy in which a pharmacist initiates treatment with, dispenses, or administers drugs and devices pursuant to § 54.1-3303.1 of the Code of Virginia and 18VAC110-21-46 shall protect patient confidentiality and comply with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

18VAC110-21-46 Initiation of treatment by a pharmacist

A. Pursuant to § 54.1-3303.1 of the Code of Virginia, a pharmacist may initiate treatment with, dispense, or administer the following drugs and devices to persons

18 years of age or older:

1. Naloxone or other opioid antagonist, including such controlled paraphernalia as defined in § 54.1-3466 of the Code of Virginia as may be necessary to administer such naloxone or other opioid antagonist;

2. Epinephrine;

3. Injectable or self-administered hormonal contraceptives, provided the patient completes an assessment consistent with the United States Medical Eligibility Criteria for Contraceptive Use;

4. Prenatal vitamins for which a prescription is required;

5. Dietary fluoride supplements, in accordance with recommendations of the American Dental Association for prescribing of such supplements for persons whose drinking water has a fluoride content below the concentration recommended by the U.S. Department of Health and Human Services; and

6. Medications covered by the patient's health carrier when the patient's out-of-pocket cost is lower than the out-of-pocket cost to purchase an over-the-counter equivalent of the same drug.

B. Pharmacists who initiate treatment with, dispense, or administer a drug or device pursuant to subsection A of this section shall:

1. Follow the statewide protocol adopted by the board for each drug or device.

2. Notify the patient's primary health care provider that treatment has been initiated with such drug or device or that such drug or device has been dispensed or administered to the patient, provided that the patient consents to such notification. If the patient does not have a primary health care provider, the pharmacist shall counsel the patient regarding the benefits of establishing a relationship with a primary health care provider and, upon request, provide information regarding primary health care providers, including federally qualified health centers, free clinics, or local health departments serving the area in which the patient is located. If the pharmacist is initiating treatment with, dispensing, or administering injectable or self-administered hormonal contraceptives, the pharmacist shall counsel the patient regarding seeking preventative care, including (i) routine well-woman visits, (ii) testing for sexually transmitted infections, and (iii) pap smears.

3. Maintain a patient record for a minimum of six years following the last patient encounter with the following exceptions:

a. Records that have previously been transferred to another practitioner or health care provider or provided to the patient or the patient's personal representative; or

b. Records that are required by contractual obligation or federal law to be maintained for a longer period of time.

4. Perform the activities in a manner that protects patient confidentiality and complies with the Health Insurance Portability and Accountability Act, 42 USC § 1320d et seq.

18VAC110-21-9999 Documents Incorporated by Reference (18VAC110-21)

Virginia Routine Hormonal Contraceptive Self-Screening Questionnaire (eff. 01/2021)

Virginia Emergency Contraception Self-Screening Questionnaire (eff. 01/2021)

Virginia Algorithm for Pharmacists to Prescribe Routine Hormonal Contraceptives (eff. 01/2021)

Virginia Algorithm for Pharmacists to Prescribe & Administer Depot Medroxyprogesterone Acetate (eff. 01/2021)

Pharmacist Epinephrine Statewide Protocol (eff. 01/2021)

Pharmacist Emergency Contraception Statewide Protocol (eff. 01/2021)

Pharmacist Dietary Fluoride Supplement Statewide Protocol (eff. 01/2021)

Pharmacist Naloxone Statewide Protocol (eff. 01/2021)

Pharmacist Prenatal Vitamin Statewide Protocol (eff. 01/2021)

Pharmacist Hormonal Contraceptive Statewide Protocol (Excluding Emergency Contraception) (eff. 01/2021)

Pharmacist Statewide Protocol to Lower Out-of-Pocket Expense (eff. 01/2021)

Agenda Item: Consider Recommendations for Additional Duties for Pharmacy Technicians

Included in Agenda Packet:

- 2021 Report on Development of Recommendations of Additional Duties and Tasks that Pharmacy Technicians may Perform

Staff Note:

Additionally, the following subjects were previously discussed but were not included in the periodic review action.

- Clarifying that pharmacists and pharmacy technicians may administer CLIA-waived tests.

• Clarifying that pharmacy technicians may independently take medication histories including drug name, dose, and frequency.

• Allowing a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge.

Action to Take:

- Determine if adoption of a legislative proposal or regulatory action is recommended to address any of the recommendations in the report, including the subjects listed above.

Virginia Department of Health Professions

REPORT ON DEVELOPMENT OF RECOMMENDATIONS FOR ADDITIONAL DUTIES AND TASKS THAT PHARMACY TECHNICIANS MAY PERFORM: HB1304 AND SB830

OCTOBER 19, 2021

VIRGINIA BOARD OF PHARMACY

VIRGINIA DEPARTMENT OF HEALTH PROFESSIONS

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TABLE OF CONTENTS

I. EXECUTIVE SUMMARY

Pursuant to the third enactment clause of House Bill 1304 and Senate Bill 830 passed during the 2020 General Assembly Session, the Board of Pharmacy convened a work group on September 23, 2021 to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform.

Regarding the current pharmacist to pharmacy technician ratio, the work group voted 6:2 to decline a recommendation to eliminate the pharmacist to pharmacy technician ratio.

Regarding vaccine administration, the work group voted 7:1 to include a recommendation in this report to permanently authorize a pharmacy technician, who has obtained and maintains national certification, to administer vaccines consistent with the authority and training required under the Health and Human Services PREP Act; this would require legislative action.

Regarding product verification, the work group voted unanimously to recommend that the Board of Pharmacy further explore the subject of pharmacy technician product verification.

Regarding the ability to clarify prescriptions, the work group voted unanimously to include a recommendation in this report to allow a pharmacy technician to clarify the number of refills and drug quantity for Schedule VI new prescriptions or refill prescriptions; this would require legislative action.

Regarding the acceptance of new oral prescriptions, the work group voted 6:2 to not allow pharmacy technicians to accept new prescriptions.

Regarding the transfer of prescriptions, the work group voted unanimously to recommend that a nationally certified pharmacy technician be allowed to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge; this would require either legislative or regulatory action.

Regarding the ability to take medication histories from patients, the work group voted unanimously to recommend the Board of Pharmacy clarify regulations, if necessary, to clearly authorize pharmacy technicians to independently take medication histories to include drug name, dose, and frequency.

Work Group Members

Bill Lee, DPh
Workgroup Chairman, Board of Pharmacy Member

Cheryl Nelson, PharmD
Chairman, Board of Pharmacy

Glenn Bolyard, RPh
Board of Pharmacy Member

Patricia Richards-Spruill, RPh
Board of Pharmacy Member

Jermaine Smith, PharmD
President, Virginia Association of Chain Drug Stores (VACDS)

Tana Kaefer, PharmD
Virginia Pharmacists Association

Jessica Langley, MS
Executive Director of Education and Advocacy, National Healthcareer Association

Jamin Engle, PharmD
Virginia Society of Health-System Pharmacists (VSHP)

II. PHARMACIST TO PHARMACY TECHNICIAN RATIO

The Virginia Association of Chain Drug Stores (VACDS) and the National Association of Chain Drug Stores (NACDS) requested that the current 4:1 pharmacist to pharmacy technician ratio be eliminated. There was disagreement regarding this request from several members, including the representative from the Virginia Society of Hospital Pharmacists (VSHP) and the Virginia Pharmacy Association (VPhA). The work group voted 6:2 to decline the VACDS/NACDS recommendation to eliminate the pharmacist to pharmacy technician ratio. Motion was opposed by Smith and Langley.

III. VACCINE ADMINISTRATION

There was discussion regarding the minimum age requirement of the patient receiving a vaccine, benefits of the current allowances under the Health and Human Services PREP Act for pharmacy technicians to administer vaccines to persons 3 years of age and older, and minimum training requirements. The work group voted 7:1 to include a recommendation in the legislative report to permanently authorize a pharmacy

technician, who has obtained and maintains national certification, to administer vaccines consistent with the authority and training required under the Health and Human Services PREP Act. Motion was opposed by Richards-Spruill due to concern for requiring pharmacy technician to maintain national certification.

IV. COVID-19 TESTING

There was discussion regarding the ability for a pharmacy technician to perform COVID-19 tests. Because the Virginia Board of Pharmacy has a longstanding position that the performing of CLIA-waived tests is within the scope of practice of pharmacy and that pharmacy technicians under the supervision of a pharmacist may perform CLIA-waived tests, no action was taken by the work group on this issue.

V. PRODUCT VERIFICATION

Some members of the work group commented that responsibility for any verification errors should shift to the pharmacy technician and not fall back to the supervising pharmacist. There was discussion regarding successful use of board-approved innovative pilot programs in institutional settings for product verification by pharmacy technicians with assistance of technology, e.g., medication carousels, radio-frequency identification (RFID), and bar-coding, and bedside scanning by a licensed healthcare professional. No consensus was reached. The work group voted unanimously to recommend that the Board of Pharmacy further explore the subject of pharmacy technician product verification.

VI. CLARIFYING PRESCRIPTIONS

There was consensus that an ability for a pharmacy technician to clarify prescriptions with a prescriber's office should be limited to certain required elements of a prescription and restricted to prescriptions for Schedule VI drugs only. The work group voted unanimously to include a recommendation in this report to allow a pharmacy technician to clarify the number of refills and drug quantity for Schedule VI new prescriptions or refill prescriptions.

VII. ACCEPTING NEW PRESCRIPTIONS

Many members expressed concern for pharmacy technicians accepting new oral prescriptions based on minimal educational requirements for obtaining registration. Members commented that a pharmacist assesses the clinical appropriateness of the drug as it is being communicated by the prescriber or his agent and will ask clinically probing

questions as necessary. The work group voted 6:2 to not allow pharmacy technicians to accept new oral prescriptions. Motion was opposed by Smith and Langley.

VIII. TRANSFERRING PRESCRIPTIONS

Members debated the benefits and concerns of allowing pharmacy technicians to transfer prescriptions. There is a level of oversight that a pharmacist should have when authorizing a pharmacy technician to transfer a particular prescription to ensure that the correct prescription, including current dose and dosing schedule is transferred. Discussion focused on Schedule VI drugs only (not including on-hold prescriptions), and transferring electronically or by facsimile. There appeared to be consensus that the pharmacist-in-charge could document which pharmacy technicians were authorized (qualified) to transfer certain Schedule VI prescriptions and that the list should be readily available for inspector review. The work group voted unanimously to include a recommendation in this report to allow a nationally certified pharmacy technician to electronically transfer a Schedule VI refill prescription that is not an on-hold prescription when authorized by the pharmacist-in-charge.

IX. TAKING PATIENT MEDICATION HISTORIES

It was recommended that the work group consider an ability for pharmacy technicians to take medication histories from patients. There was discussion regarding how this would differ from medication reconciliations. Staff commented that the Board has a long-standing position that pharmacy technicians may perform medication reconciliations. Engle commented that there is confusion among licensees and that perhaps clarification is all that is needed. Board counsel agreed that § 54.1-3321 of the Code of Virginia appears to already authorize pharmacy technicians to perform this task if the Board views this duty as "the entry of prescription information and drug history into a data system or other record keeping system." The work group voted unanimously to recommend the Board of Pharmacy clarify regulations, if necessary, to clearly authorize pharmacy technicians to independently take medication histories to include drug name, dose, and frequency.

Agenda Item: Consideration of Legislative Proposal for Expanding Use of Technology for Storing and Dispensing Drugs in Certain Facilities

Included in Agenda Packet:

- Draft legislative proposal

Action to Be Taken:

- Recommend to full board in June to adopt legislative proposal as presented or as amended; OR
- Take no action.

Expanding Use of Technology for Storing and Dispensing Drugs in Certain Facilities
DRAFT 2023 Legislative Proposal

§ 54.1-3401

"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.

"Remote dispensing system" means a profile-driven automated drug dispensing system that performs operations or activities relative to the storage, packaging, labeling, or dispensing of medications employing bidirectional audio-visual technology to facilitate pharmacist communication with a patient, authorized agent of the patient, or person licensed to administer drugs, and collects, controls, and maintains all transaction information. Drugs intended to be administered by the patient or a person not licensed to administer drugs must fully comply with labeling requirements in § § 54.1-3410 and 54.1-3463 and Board regulation. Directions for use may only be abbreviated when drugs are administered exclusively by persons licensed to administer drugs.

18VAC110-20-10

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

§ 54.1-3434.02. Automated drug dispensing systems and remote dispensing systems.

A. Hospitals or nursing homes licensed pursuant to Title 32.1, a healthcare facility established pursuant to ~~or~~ Title 37.2 and wherein drug is administered only by persons licensed to administer drugs, or other facility authorized by the Board in regulation and where the pharmacist-in-charge can ensure the security and environmental integrity of the drugs and devices, may use automated drug dispensing systems and remote dispensing systems, as defined in § 54.1-3401, upon meeting the following conditions:

1. Drugs are placed in the automated drug dispensing system or remote dispensing system and are under the control of a pharmacy providing services to the ~~hospital~~ facility;

2. The pharmacist-in-charge of the pharmacy providing services to the ~~hospital~~ facility has established procedures for assuring the accurate stocking and proper storage of drugs in the

automated drug dispensing system or remote dispensing system and for ensuring accountability for and security of all drugs utilized in the ~~automated drug dispensing~~ system until the time such drugs are removed from the ~~automated drug dispensing~~ system for administration to the patients;

3. Removal of drugs from any automated drug dispensing system or remote dispensing system for administration to patients can only be made pursuant to a valid prescription or lawful order of a prescriber;

4. Adequate security for automated drug dispensing systems and remote dispensing systems is provided, as evidenced by written policies and procedures, for (i) preventing unauthorized access, (ii) complying with federal and state regulations on prescribing and dispensing controlled substances, (iii) maintaining patient confidentiality, and (iv) assuring compliance with the requirements of this section;

5. Accountability for drugs dispensed from automated drug dispensing systems or remote dispensing systems is vested in the pharmacist-in-charge of a pharmacy located within the ~~hospital~~ facility or the pharmacist-in-charge of ~~any~~ the outside pharmacy providing pharmacy services to the ~~hospital~~ facility;

6. Filling and stocking of all drugs in automated drug dispensing systems or remote dispensing systems shall be performed under the direction of the pharmacist-in-charge. The task of filling and stocking of drugs into ~~an automated drug dispensing~~ the system shall be performed by a pharmacist or a registered pharmacy technician, who shall be an employee of the provider pharmacy and shall be properly trained in accordance with established standards set forth in a policy and procedure manual maintained by the provider pharmacy. The pharmacist stocking and filling the automated drug dispensing system or the pharmacist-in-charge, if the automated drug dispensing system is stocked and filled by a registered pharmacy technician, shall be responsible for the proper and accurate stocking and filling of the automated drug dispensing system or remote dispensing system. However, nothing shall prohibit the Board from taking disciplinary action against a pharmacy technician who contributed to an error or violation of law or regulation.

7. Except when the automated drug dispensing system is used exclusively for administration of drug for emergencies, a pharmacy not located in the facility that provides services to the facility for use of an automated drug dispensing system or remote dispensing system shall first obtain a controlled substances registration issued in the name of the pharmacy at the address of the facility and a registration from the Drug Enforcement Administration, if required, prior to stocking drugs in Schedules II through VI.

B. Except as authorized in Board regulation, drugs placed into and removed from automated drug dispensing systems or remote dispensing system for administration to patients shall be in the manufacturer's or distributor's sealed original packaging or in unit-dose containers packaged by the pharmacy. Drugs in multi-dose liquid, injectable, or inhaled formulation, ~~packaging, other than those administered orally,~~ may be placed in such a device if approved by the pharmacist-in-charge in consultation with ~~a standing hospital committee comprised of pharmacy,~~ medical, ~~and~~ nursing staff of the facility.

C. The pharmacist-in-charge in a pharmacy located within ~~a hospital~~ the facility or the pharmacist-in-charge of any outside pharmacy providing pharmacy services to ~~a hospital~~ the facility shall be responsible for establishing procedures for (i) periodically inspecting and auditing automated drug dispensing systems to assure the proper storage, security, and accountability for all drugs placed in and removed from automated drug dispensing systems, and (ii) reviewing the operation and maintenance of automated drug dispensing systems. This monitoring shall be reviewed by a pharmacist while on the premises of the ~~hospital~~ facility and in accordance with the pharmacist-in-charge's procedures and the Board of Pharmacy's regulations.

D. The Board of Pharmacy shall promulgate regulations establishing minimum requirements for random periodic inspections and monthly audits of automated drug dispensing systems and remote dispensing systems to assure the proper storage, security, and accountability of all drugs placed in and removed from ~~automated drug dispensing~~ the systems, and for reviewing the operation and maintenance of ~~automated drug dispensing~~ the systems.

E. Notwithstanding this section, the Board shall promulgate regulations for the use of a remote dispensing system to store drugs previously dispensed and labeled by the provider pharmacy in compliance with current laws and regulations. Such regulations shall identify the location of where such system may be placed and requirements to ensure the security of the drug, confidentiality of protected health information, and appropriate recordkeeping.

Consider including enactment clauses to:

- Promulgate emergency regulations to implement provisions, e.g., regs that would define how AP Passport-like technology may be exempt from using drugs in manufacturing packaging and can use pharmacist-verified canisters of drugs that can be repackaged into patient-specific envelopes/containers;
- Promulgate emergency regulations to allow crisis stabilization units to stock drugs in Schedules II-VI. (Law currently permits it, but regulations restrict it to Schedule VI).