COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
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Tentative Agenda of Virtual Regulation Committee Meeting

November 12, 2020

9AM

*****Refer to the Second Page of Agenda for Meeting Access Information*****

TOPIC	PAGES
Call to Order: Cheryl Nelson, Committee Chair	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Update on Regulatory Actions	1-2
• Amendments to Guidance Documents	
○ 110-1, Categories of facility licensure	3-6
○ 110-13, Collaborative practice agreements	7-9
○ 110-29, Guidance on physician dispensing licenses	10-14
○ 110-44, Naloxone protocol	15-22
○ 110-41, Changes pharmacist may make to schedule II prescription	23
○ 110-39, Continuous hours worked by pharmacist and breaks	24-26
○ Draft guidance regarding contract employee access to pharmaceutical processor	27-28
• Consideration of remote order processing by a pharmacy technician outside of a pharmacy	29-40
• Consideration of amendments - medication carousels and RFID technology	41-49
• Adoption of NOIRA/Notice of Periodic Review	50-52
Adjourn	

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

Virginia Board of Pharmacy

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- **Access:** Perimeter Center building access is restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
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Agenda Item: **Regulatory Actions - Chart of Regulatory Actions**
As of October 26, 2020

Board	Board of Pharmacy	
Chapter		**Action / Stage Information**
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] NOIRA - *Register Date: 9/14/20* *Comment until 10/14/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Delivery of dispensed prescriptions; labeling [Action 5093] Proposed - *Register Date: 2/3/20* *Board to consider final regulations*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Handling fee [Action 5519] Fast-Track - *At Secretary's Office for 55 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 826 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Increase in fees [Action 4938] Final – *Register Date: 9/14/20* *Regulation effective: 10/14/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Final - *At Secretary's Office for 77 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Placement of chemicals in Schedule I [Action 5517] Final - *Register Date: 7/6/20* *Effective: 8/5/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	(E) Scheduling for conformity to DEA scheduling [Action 5518] Final - *Register Date: 7/6/20* *Effective: 8/5/20*
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	CE credit for volunteer hours [Action 5546] Fast-Track - *At Secretary's Office for 30 days*

[18 VAC 110 - 50]	Regulations Governing Wholesale Distributors, Manufacturers and Warehousers	Delivery of Schedule VI prescription devices [Action 5084] Final - *At Secretary's Office for 30 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452] Emergency/NOIRA - *Emergency effective 8/6/20* *Comment on NOIRA: 8/31/20 to 9/30/20*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Proposed - *At Secretary's Office for 44 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	(E) Conforming to 2020 legislation [Action 5545] Final - *Register Date: 8/31/20* *Effective: 9/30/20*

Agenda Item: Amendments to Guidance Documents

Staff Note:

1. Several guidance documents need to be amended for consistency with changes in the Code in 2020. They are:
    a. 110-01; Categories of facility licensure
    b. 110-13; Collaborative practice agreements
    c. 110-29; Guidance on physician dispensing licenses
    d. 110-44; Naloxone protocol
2. Provisions in Guidance Document 110-41 were incorporated into regulations during the last periodic regulatory review, so it can now be repealed.
3. There was a request to refer 110-39 – Continuous Hours Worked by a Pharmacist and Breaks to the Regulation Committee for possible revision.
4. There was a request to alleviate the need to obtain board permission for contract employees to access the premises of a pharmaceutical processor – draft document included in agenda.

Regulation Committee action:

To recommend adoption of the amendments, as presented or amended, to guidance documents listed in the first grouping (can be voted on in a block unless the Committee prefers to take each separately);

To repeal 110-41;

Discussion of 110-39 – may or may not result in action by the Committee;

Adopt draft guidance, as presented or amended, regarding contract employee access to a pharmaceutical processor.

VIRGINIA BOARD OF PHARMACY

CATEGORIES OF FACILITY LICENSURE

PHARMACY: This permit gives the permit holder the authority to conduct the practice of pharmacy which includes, but is not limited to, the dispensing of prescription drugs and devices directly to the ultimate user pursuant to the order of a prescriber. Federal law allows pharmacies, without being registered as a wholesale distributor, to distribute prescription drugs to other persons appropriately licensed to possess such drugs, such as another pharmacy or a physician, provided such distributions do not exceed 5% of gross annual prescription drug sales, or in the case of Schedule II-V drugs, do not exceed 5% of total number dosage units of Schedule II-V drugs dispensed annually.

NONRESIDENT PHARMACY: This registration is required of any pharmacy located in another state that ships, mails, or delivers, in any manner, Schedule II through VI drugs or devices pursuant to a prescription into the Commonwealth.

MEDICAL EQUIPMENT SUPPLIER: This permit gives the permit holder the authority to dispense, directly to the patient or ultimate user pursuant to an order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI* controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This permit will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

NONRESIDENT MEDICAL EQUIPMENT SUPPLIER: This registration authorizes a medical equipment supplier located in another state to ship, mail, or deliver to a consumer in the Commonwealth pursuant to a lawful order of a prescriber, **only** the following prescription items:

1. medical oxygen
2. hypodermic needles and syringes
3. Schedule VI controlled devices
4. Schedule VI controlled substances with no medicinal properties that are used for the operation and cleaning of medical equipment
5. sterile water and saline for irrigation
6. peritoneal dialysis solutions.

This registration will also allow distribution of **only** medical oxygen to entities other than the consumer, e.g., nursing homes or hospitals, if the quantity distributed is less than 5% of your gross annual sales of medical oxygen.

WHOLESALE DISTRIBUTOR: This license authorizes the license holder to distribute prescription drugs to other entities authorized to possess prescription drugs for their further or retail distribution.

NONRESIDENT WHOLESALE DISTRIBUTOR: This registration allows a wholesale distributor located in another state to distribute prescription drugs, Schedules II-VI to pharmacies, physicians, or other "retail" entities in Virginia. A separate Virginia controlled substances registration is not required of nonresident wholesale distributors.

WAREHOUSER: This permit is for those entities which distribute prescription drugs, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company

sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This permit may also be preferable for those entities that only distribute prescription devices, and no prescription drugs.

NONRESIDENT WAREHOUSER: This registration is for those entities located in another state which distribute prescription drugs into Virginia, but which are excepted from the legal definition of wholesale distribution in both federal and state law, such as persons conducting only "intra-company sales", only certain charitable donations, only distributions for emergency medical reasons, only distribution of drug samples, only distribution of medical gases, et. al. This registration may also be preferable for those entities that only distribute prescription devices, and no prescription drugs.

NON-RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of prescription drugs.

RESTRICTED MANUFACTURER: This permit authorizes the permit holder to engage in the manufacturing or production, to include the packaging and labeling or the repackaging or relabeling, of proprietary or non-prescription drugs. This permit also provides authority for the manufacture or transfilling of gases for medical use.

NONRESIDENT MANUFACTURER:
This registration authorizes any manufacturer located outside the Commonwealth to ship prescription drugs into the Commonwealth.

CONTROLLED SUBSTANCES REGISTRATION (CSR): This registration is similar to a federal DEA registration and is required of any manufacturer, wholesale distributor, warehouser, or humane society which possesses Schedule II-V controlled substances. This registration may also be required for other persons or entities who want to possess Schedule II-VI controlled substances for purposes of administering to patients, for research, for use within a teaching institution, or for locations serving as an alternate delivery site for prescriptions. Researchers, laboratories, government officials, teaching institutions who would otherwise not have authority to possess prescription drugs must obtain this registration prior to purchasing any prescription drug substances. Other entities such as EMS agencies which want to purchase drugs and not use a hospital kit exchange system, hospitals without in-house pharmacies, ambulatory surgery centers, and large group medical practices or clinics where practitioners share a common stock of drugs may elect to obtain this registration or may be required to obtain it under certain circumstances. A humane society or shelter, or government animal control officer with or without an animal shelter, may use this registration to possess drugs approved by the State Veterinarian for the purpose of restraint, capture, and euthanasia. A humane society or shelter may also use this to purchase drugs for the purpose of preventing, controlling, and treating certain communicable diseases that failure to control would result in transmission to the animal population in the shelter or pound. A person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of injectable naloxone with a hypodermic needle and syringe and who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may obtain this registration. An entity at which a patient is being treated by the use of instrumentation and diagnostic equipment through which images and medical records may be transmitted electronically for the purpose of establishing a bona fide practitioner-patient relationship and is being prescribed Schedule II through VI controlled substances may obtain this registration to assist in complying with federal requirements for the practice of telemedicine.

OUTSOURCING FACILITY: This permit authorizes the permit holder to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration. As a prerequisite, the permit holder shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the permit holder wishes to compound sterile drugs pursuant to patient specific prescriptions, a pharmacy permit

must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

NONRESIDENT OUTSOURCING FACILITY: This registration authorizes an outsourcing facility located in another state to engage in non-patient specific sterile compounding in compliance with all state and federal laws and regulations, including all applicable guidance documents and Current Good Manufacturing Practices published by the U.S. Food and Drug Administration and ship, mail, or deliver in any manner Schedule II through VI drugs or devices into the Commonwealth. As a prerequisite, the registrant shall be registered as an outsourcing facility with the U.S. Secretary of Health and Human Services. If the registrant wishes to compound sterile drugs pursuant to patient specific prescriptions, a non-resident pharmacy registration must also be obtained. Both non-patient specific and patient specific sterile compounding must be performed in compliance with Current Good Manufacturing Practices.

PRACTITIONER OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES FACILITY PERMIT: This permit authorizes a doctor of medicine, osteopathic medicine or podiatry who is licensed by the Board of Pharmacy to dispense patient-specific drugs in Schedules II-VI to his own patients from the permitted location.

LIMITED USE PRACTITIONER DISPENSING PERMIT: This permit authorizes a nurse practitioner or a physician assistant who is licensed by the Board of Pharmacy and practicing at a nonprofit facility, to dispense Schedule VI controlled substances (excluding the combination of misoprostol and methotrexate) and hypodermic syringes and needles for the administration of prescribed controlled substances. The nurse practitioner or physician assistant must also obtain a Limited Use Practitioner Dispensing License.

THIRD-PARTY LOGISTICS PROVIDER: This permit authorizes the permit holder, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device.

NONRESIDENT THIRD-PARTY LOGISTICS PROVIDER: This registration authorizes the registrant located in another state, that does not take ownership of the product or have responsibility for directing the sale or disposition of the product, to coordinate warehousing of or other logistics services for a drug or device in interstate commerce on behalf of a manufacturer, wholesale distributor, or dispenser of the drug or device.

* **§ 54.1-3455. Schedule VI.**

The following classes of drugs and devices shall be controlled by Schedule VI:

1. Any compound, mixture, or preparation containing any stimulant or depressant drug exempted from Schedules III, IV or V and designated by the Board as subject to this section.

2. Every drug, not included in Schedules I, II, III, IV or V, or device, which because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not generally recognized among experts qualified by scientific training and experience to evaluate its safety and efficacy as safe for use except by or under the supervision of a practitioner licensed to prescribe or administer such drug or device.

3. **Any drug, not included in Schedules I, II, III, IV or V, required by federal law to bear on its label prior to dispensing, at a minimum, the symbol "Rx only," or which bears the legend "Caution: Federal Law Prohibits Dispensing Without Prescription"** or "Caution: Federal Law Restricts This Drug To Use By Or On The Order Of A Veterinarian" **or any device which bears the legend "Caution: Federal Law Restricts This Device To Sales By Or On The Order Of A _____ ."** (The blank should be completed with the word "Physician," "Dentist," "Veterinarian," or with the professional designation of any other practitioner licensed to use or order such device.)

Adopted: December 10, 2020
Effective: February 5, 2021

VIRGINIA BOARD OF PHARMACY

Guidance Regarding Collaborative Practice Agreements

To clarify whether a collaborative practice agreement is required for each patient, the Board offers the following guidance.

1. A pharmacist and a practitioner or other authorized person as found in the definition of "collaborative agreement" in §54.1-3300 may enter into a collaborative practice agreement. Such agreement is not executed for each patient, but rather serves as a general agreement between the pharmacist and practitioner for how a pharmacist may implement, modify, continue, or discontinue drug therapy; order laboratory tests; or complete other patient care management measures related to monitoring or improving the outcomes of drug or device therapy.
2. The agreement may only be implemented for an individual patient pursuant to an order from the practitioner for that patient.
3. ~~Documented informed consent must then be obtained from the patient by the practitioner who authorizes the patient to participate in the agreement or by the pharmacist who is also a party to the agreement~~. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement but who chooses to not participate in a collaborative procedure must notify the prescriber of his/her refusal to participate in such collaborative procedure.

References:

Code of Virginia:

§ 54.1-3300. Definitions.

"Collaborative agreement" means a voluntary, written, or electronic arrangement between one pharmacist and his designated alternate pharmacists involved directly in patient care at a single physical location where patients receive services and (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working under the supervision of a person licensed to practice medicine, osteopathy, or podiatry; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care which authorizes cooperative procedures with respect to patients of such practitioners. Collaborative procedures shall be related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes. A collaborative agreement is not required for the management of patients of an inpatient facility.

Adopted: December 10, 2020
Effective: February 5, 2021

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

A. A pharmacist and his designated alternate pharmacists involved directly in patient care may participate with (i) any person licensed to practice medicine, osteopathy, or podiatry together with any person licensed, registered, or certified by a health regulatory board of the Department of Health Professions who provides health care services to patients of such person licensed to practice medicine, osteopathy, or podiatry; (ii) a physician's office as defined in § 32.1-276.3, provided that such collaborative agreement is signed by each physician participating in the collaborative agreement; (iii) any licensed physician assistant working in accordance with the provisions of § 54.1-2951.1; or (iv) any licensed nurse practitioner working in accordance with the provisions of § 54.1-2957, involved directly in patient care in collaborative agreements which authorize cooperative procedures related to treatment using drug therapy, laboratory tests, or medical devices, under defined conditions or limitations, for the purpose of improving patient outcomes for patients who meet the criteria set forth in the collaborative agreement. However, no person licensed to practice medicine, osteopathy, or podiatry, or licensed as a nurse practitioner or physician assistant, shall be required to participate in a collaborative agreement with a pharmacist and his designated alternate pharmacists, regardless of whether a professional business entity on behalf of which the person is authorized to act enters into a collaborative agreement with a pharmacist and his designated alternate pharmacists.

B. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of his refusal to participate in such collaborative procedure. A prescriber may elect to have a patient not participate in a collaborative procedure by contacting the pharmacist or his designated alternative pharmacists or by documenting the same on the patient's prescription.

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

D. Collaborative agreements may only be used for conditions which have protocols that are clinically accepted as the standard of care, or are approved by the Boards of Medicine and Pharmacy. The Boards of Medicine and Pharmacy shall jointly develop and promulgate regulations to implement the provisions of this section and to facilitate the development and implementation of safe and effective collaborative agreements between the appropriate practitioners and pharmacists. The regulations shall include guidelines concerning the use of protocols, and a procedure to allow for the approval or disapproval of specific protocols by the Boards of Medicine and Pharmacy if review is requested by a practitioner or pharmacist.

E. Nothing in this section shall be construed to supersede the provisions of § 54.1-3303.

Regulations of the Board:

Adopted: December 10, 2020
Effective: February 5, 2021

18VAC110-40-20. Signed authorization for an agreement.

A. The signatories to an agreement shall be a practitioner involved directly in patient care and a pharmacist involved directly in patient care. Within the agreement, the pharmacist may designate alternate pharmacists, provided the alternates are involved directly in patient care at a single physical location where patients receive services.

B. An agreement shall only be implemented for an individual patient pursuant to an order from the practitioner for that patient. A patient who meets the criteria for inclusion in the category of patients whose care is subject to a collaborative agreement and who chooses to not participate in a collaborative procedure shall notify the prescriber of the patient's refusal to participate in such collaborative procedure.

1. The patient may decline to participate or withdraw from participation at any time.

2. The patient shall be informed by the practitioner or the pharmacist of the collaborative procedures that will be used pursuant to an agreement, and such discussion shall be documented in the patient record.

3. The practitioner and the pharmacist shall provide written disclosure to the patient of any contractual arrangement with any other party or any financial incentive that may impact one of the party's decisions to participate in the agreement.

Revised: December 10, 2020
Effective: February 4, 2021

Virginia Board of Pharmacy

Physicians Dispensing Drugs

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

Permitted Physicians – Practice as a pharmacy

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

Physicians Selling Drugs

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

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

Within this category of licensure, it is possible to request a **limited-use license.** Pursuant to Regulation 18VAC110-30-20 and the delegation of authority to the Executive Director as set forth in Bylaws of the Board, a physician may apply for a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. Under a limited-use license, a waiver of the square footage requirement for the controlled substances selling and storage area may be provided. Additionally, a waiver of the security system may be provided when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

Limited-use license for a nurse practitioner or physician assistant
The Board may also issue a limited-use license for the purpose of dispensing Schedule VI controlled substances, excluding the combination of misoprostol and methotrexate, and hypodermic syringes and needles for the administration of prescribed controlled substances to a nurse practitioner or a physician assistant, provided that such limited-use licensee is practicing at a nonprofit facility. Such facility shall obtain a limited-use permit from the Board and comply with regulations for such a permit. The term "non-profit" is defined in the Virginia Tax Code, so those entities satisfying that definition would be recognized as non-profit for the purpose of issuing such a limited-use license.

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

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

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

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

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

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

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

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

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

7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in § 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary, providing manufacturers' samples of these drugs to his own patients, or dispensing, administering, or selling ophthalmic devices as authorized in § 54.1-3204;

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

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

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

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

12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other jurisdiction with the Board, (v) notifies the Board at least five business days prior to the voluntary provision of services of the dates and location of such service, and (vi) acknowledges, in writing, that such licensure exemption shall only be valid, in compliance with the Board's regulations, during the limited period that such free health care is made available through the volunteer, nonprofit organization on the dates and at the location filed with the Board. The Board may deny the right to practice in Virginia to any pharmacist whose license has been previously suspended or revoked, who has been convicted of a felony or who is otherwise found to be in violation of applicable laws or regulations. However, the Board shall allow a pharmacist who meets the above criteria to provide volunteer services without prior notice for a period of up to three days, provided the nonprofit organization verifies that the practitioner has a valid, unrestricted license in another state.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Revised: December 10, 2020
Effective: February 4, 2021

Virginia Board of Pharmacy

Naloxone Protocols

54.1-3408 (X) and (Y) authorize certain persons to dispense naloxone pursuant to an oral, written, or standing order and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. This document contains the protocols which must be followed when dispensing naloxone pursuant to these subsections of law. The protocols include information on the required elements of a standing order, instruction the recipient must receive, and labeling and recordkeeping requirements.

§54.1-3408

X. Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, a pharmacist, a health care provider providing services in a hospital emergency department, and emergency medical services personnel, as that term is defined in § 32.1-111.1, may dispense naloxone or other opioid antagonist used for overdose reversal and a person to whom naloxone or other opioid antagonist has been dispensed pursuant to this subsection may possess and administer naloxone or other opioid antagonist used for overdose reversal to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose. Law-enforcement officers as defined in § 9.1-101, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, employees of regional jails, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, other school board employees or individuals contracted by a school board to provide school health services, and firefighters who have completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal and may dispense naloxone or other opioid antagonist used for overdose reversal pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding the provisions of § 54.1-3303, pursuant to an oral, written, or standing order issued by a prescriber or a standing order issued by the Commissioner of Health or his designee authorizing the dispensing of naloxone or other opioid antagonist used for overdose reversal in the absence of an oral or written order for a specific patient issued by a prescriber, and in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health, an employee or other person acting on behalf of a public place who has completed a training program may also possess and administer naloxone or other opioid antagonist used for overdose reversal other than naloxone in an injectable formulation with a hypodermic needle or syringe in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

Notwithstanding any other law or regulation to the contrary, an employee or other person acting on behalf of a public place may possess and administer naloxone or other opioid antagonist, other than naloxone in an injectable formulation with a hypodermic needle or syringe, to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose if he has completed a training program on the administration of such naloxone and

15

administers naloxone in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health.

For the purposes of this subsection, "public place" means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

Y. Notwithstanding any other law or regulation to the contrary, a person who is acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal may dispense naloxone to a person who has received instruction on the administration of naloxone for opioid overdose reversal, provided that such dispensing is (i) pursuant to a standing order issued by a prescriber and (ii) in accordance with protocols developed by the Board of Pharmacy in consultation with the Board of Medicine and the Department of Health. If the person acting on behalf of an organization dispenses naloxone in an injectable formulation with a hypodermic needle or syringe, he shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe, and he shall obtain a controlled substance registration from the Board of Pharmacy. The Board of Pharmacy shall not charge a fee for the issuance of such controlled substance registration. The dispensing may occur at a site other than that of the controlled substance registration provided the entity possessing the controlled substances registration maintains records in accordance with regulations of the Board of Pharmacy. No person who dispenses naloxone on behalf of an organization pursuant to this subsection shall charge a fee for the dispensing of naloxone that is greater than the cost to the organization of obtaining the naloxone dispensed. A person to whom naloxone has been dispensed pursuant to this subsection may possess naloxone and may administer naloxone to a person who is believed to be experiencing or about to experience a life-threatening opioid overdose.

I. Protocol for the Prescribing and Dispensing of Naloxone by Persons Listed in 54.1-3408 (X)

a. Authorized Dispensers

The following individuals may dispense naloxone pursuant to an oral, written or standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection X of §54.1-3408:

- Pharmacists,
- Health care providers providing services in a hospital emergency department,
- Emergency medical services personnel as defined in § 32.1-111.1

And the following persons who have completed a training program:

- Law-enforcement officers as defined in § 9.1-101,
- Employees of the Department of Forensic Science,
- Employees of the Office of the Chief Medical Examiner,
- Employees of the Department of General Services Division of Consolidated Laboratory Services,
- Employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1,
- Employees of regional jails,
- School nurses,

- Local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board,
- Other school board employees or individuals contracted by a school board to provide school health services, ~~and~~
- Firefighters
- Employees or other persons acting on behalf of a "public place" which means any enclosed area that is used or held out for use by the public, whether owned or operated by a public or private interest.

b. Required Training

i. Those persons listed above who must first complete a training program prior to dispensing naloxone shall complete training in accordance with policies and procedures of their employer or governing entity. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.

c. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive an oral or written order issued by a prescriber for a specific person to receive naloxone or a standing order issued by an individual prescriber or the Health Commissioner that authorizes the dispenser to dispense naloxone. The prescriber may indicate on such orders that the order is valid and may be refilled for up to two years from the date of issuance. Except for pharmacists, persons authorized in 54.1-3408(X) shall only dispense formulations for intranasal administration or an autoinjector formulation.

ii. If the naloxone is dispensed pursuant to a standing order, the standing order must contain the following information at a minimum:

1. Name of entity or group of entities authorized to dispense naloxone pursuant to standing order;
2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
3. Prescriber's signature;
4. Date of issuance; and
5. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal
Naloxone 2mg/2ml prefilled syringe, # 2 syringes Directions: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.	Naloxone 2 mg #1 twin pack Directions: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Narcan Nasal Spray 4mg, #1 twin pack Directions: Administer a single spray intranasally into one nostril. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.

Must dispense with 2 prefilled syringes and 2 atomizers and instructions for administration.		

d. Required Labeling and Recordkeeping

i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the oral, written, or standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.

iii. The oral, written, or standing order must be maintained for two years from the last date of dispensing.

iv. Unless a waiver has been granted by the Prescription Monitoring Program, pharmacies and physicians licensed to dispense shall report the dispensing to the Prescription Monitoring Program.

e. Required Instruction

i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

II. Protocol for the Prescribing of Naloxone and Dispensing by Persons Listed in 54.1-3408 (Y)

a. Authorized Dispensers

The following individuals who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone, e.g., non-profit organization, community service board, or behavioral health authority, may dispense naloxone pursuant to a standing order to a person to administer to another person believed to be experiencing or about to experience a life-threatening opioid overdose and shall follow this protocol when dispensing naloxone as authorized in subsection Y of §54.1-3408:

- A person who is acting on behalf of such organization may dispense formulations for intranasal administration or an autoinjector formulation;

- A person who is authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe may dispense formulations for intranasal administration, autoinjector formulation, or an injectable naloxone formulation with a hypodermic needle or syringe, if the organization has obtained a controlled substances registration from the Board of Pharmacy at no charge.

b. Training

- While it is recommended that those persons acting on behalf of such organization and who are dispensing naloxone formulations for intranasal administration or autoinjectors complete training in accordance with policies and procedures of their employer or governing entity, it is not a requirement of law. Selection of or development of the training program is at the discretion of the employer or governing entity. The REVIVE! training program developed by the Department of Behavioral Health and Developmental Services is an available option.
- Those persons acting on behalf of such organization and who intend to dispense injectable naloxone formulation with a hypodermic needle or syringe, must first complete training developed by and be authorized by the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe

c. Required Order

i. Prior to dispensing naloxone, the dispenser shall receive a standing order issued by an individual prescriber that authorizes the dispenser to dispense naloxone. The standing order must contain the following information at a minimum:

1. Name of organization authorized to dispense naloxone pursuant to standing order;
2. Name of drug, strength, quantity to be dispensed, and directions for administration, as indicated in the chart below;
3. If hypodermic needles and syringes are to be dispensed by an authorized trainer for administering such naloxone, the standing order must also specify the kind and quantity of hypodermic needles and syringes to be dispensed as outlined in the chart below;
4. Prescriber's signature;
5. Date of issuance; and
6. Amount of time, up to two years from date of issuance, for which the order is valid.

Intranasal	Auto-Injector	Intranasal	Injection*
Naloxone 2mg/2ml prefilled syringe, # 2 syringes SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives. Mucosal Atomization Device (MAD) # 2	Naloxone 2 mg #1 twin pack SIG: Use one auto-injector upon signs of opioid overdose. Call 911. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.	Narcan Nasal Spray 4mg, #1 twin pack SIG: Administer a single spray intranasally into one nostril upon signs of opioid overdose. Administer additional doses using a new nasal spray with each dose, if patient does not respond or responds and then relapses into respiratory depression. Call 911. Additional doses may be given every 2 to 3 minutes until	Naloxone 0.4mg/ml #2 single-use 1ml vials SIG: Inject 1ml in shoulder or thigh upon signs of opioid overdose. Call 911. Repeat after 2-3 minutes if no or minimal response. #2 (3ml) syringe with 23-25 gauge 1-1.5 inch IM needles SIG: Use as directed for naloxone administration.

SIG: Use as directed for naloxone administration. Dispenser must dispense 2 prefilled syringes and 2 atomizers and instructions for administration.		emergency medical assistance arrives.	Dispenser must dispense 2 single-use 1ml vials, 2 (3ml) syringes and 2 (23-25 gauge) hypodermic needles for administration.

d. Registration

An organization that intends to dispense an injectable naloxone formulation with a hypodermic needle or syringe must first obtain a controlled substances registration from the Board of Pharmacy at no charge. The application may be downloaded at http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm The person authorized by the Department of Behavioral Health and Developmental Services to train individuals on the administration of naloxone and dispense naloxone for opioid overdose reversal must serve as the responsible party on the application. The prescriber issuing the standing order must serve as the supervising practitioner. An alarm system is not required for the controlled substances registration.

e. Required Labeling, Recordkeeping, and Storage

i. The dispenser shall affix a label to the naloxone container that bears the name and strength of the dispensed naloxone, directions as indicated on the standing order, name of prescriber, date of dispensing, and name and address or telephone of dispensing entity. The name of the recipient does not have to appear on the label. Optional items that may be dispensed that do not require labeling include rescue breathing masks and latex-free gloves.

ii. The dispenser shall maintain a record of dispensing indicating the name of the recipient, the name, strength, and quantity of naloxone dispensed, date of dispensing, and name or initials of dispenser. Such record shall be maintained for two years from the date of dispensing.

iii. The standing order must be maintained for two years from the last date of dispensing.

iv. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall comply with the requirements of Board of Pharmacy Regulation 18VAC110-20-735, in lieu of the requirements listed above in section (i) and (ii).

v. The naloxone, hypodermic needles, and syringes shall be stored and transported under appropriate storage conditions in accordance with the manufacturer's directions to protect from adulteration and unlawful use.

f. Required Instruction

i. The dispenser shall provide instruction to the recipient on opioid overdose prevention, overdose recognition, proper administration and dosing of naloxone, effectiveness and response following administration, adverse effects, safety, storage conditions, and expiration date. If the recipient refuses instruction, the instruction may be accomplished by providing the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services

website at http://www.dhp.virginia.gov/Pharmacy/docs/osas-revive-pharmacy-dispensing-brochure.pdf If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, information or referrals to appropriate resources may be provided.

ii. If the dispenser is dispensing an injectable naloxone formulation with a hypodermic needle or syringe, the dispenser shall also train the individual on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

III. Protocol for Pharmacies to Distribute Naloxone to Entities Authorized to Possess, Administer, and Dispense Naloxone

a. In addition to a wholesale distributor, third party logistics provider, or manufacturer, a pharmacy may distribute naloxone via invoice to:

i. Designated health care providers providing services in a hospital emergency department and emergency medical services personnel, as that term is defined in § 32.1-111.1;

ii. Designated law enforcement officers, firefighters, employees of the Department of Corrections designated as probation and parole officers or as correctional officers as defined in § 53.1-1, and employees of regional jails, employees of the Department of Forensic Science, employees of the Office of the Chief Medical Examiner, employees of the Department of General Services Division of Consolidated Laboratory Services, school nurses, local health department employees that are assigned to a public school pursuant to an agreement between the local health department and the school board, and other school board employees or individuals contracted by a school board to provide school health services who have successfully completed a training program; or

iii. Persons who are acting on behalf of an organization that provides services to individuals at risk of experiencing an opioid overdose or training in the administration of naloxone for overdose reversal and who are authorized to dispense naloxone pursuant to §54.1-3408 (Y). Examples of such an organization may include non-profit entities, a community service board, or behavioral health authority. Such organization is not required to obtain a controlled substances registration (CSR) from the Board of Pharmacy if only dispensing intranasal or autoinjector formulations. If dispensing injectable formulations, along with hypodermic needles and syringes, then the organization must first obtain a CSR and the person dispensing such items shall first obtain authorization from the Department of Behavioral Health and Developmental Services to train individuals on the proper administration of naloxone by and proper disposal of a hypodermic needle or syringe.

It is recommended that the wholesale distributor, third party logistics provider, manufacturer, or pharmacy distributing naloxone first obtain confirmation from the entity that designated persons have completed any required training and that the entity has obtained a standing order, if necessary.

IV. Resources

a. REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum "Understanding and Responding to Opioid Overdose Emergencies Using Naloxone", available at http://www.dhp.virginia.gov/pharmacy/docs/osas-revive-training-curriculum.pdf

b. Substance Abuse Mental Health Services Administration's "Opioid Prevention Toolkit" (2014), available at http://store.samhsa.gov/product/Opioid-Overdose-Prevention-Toolkit-Updated-2014/SMA14-4742
c. Prescribe to Prevent, http://prescribetoprevent.org/pharmacists
d. Harm Reduction Coalition, http://harmreduction.org/issues/overdose-prevention/tools-best-practices/od-kit-materials
e. Dispensers may obtain kits to have on-hand for dispensing naloxone from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

Virginia Board of Pharmacy

Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance

On November 19, 2007, the DEA published in the Federal Register the Final Rule entitled *Issuance of Multiple Prescriptions for Schedule II Controlled Substances* (72 FR 64921). In the preamble to that Rule, DEA stated that "the essential elements of the [schedule II] prescription written by the practitioner (such as the name of the controlled substance, strength, dosage form, and quantity prescribed)...may not be modified orally." This, however, is in opposition to DEA's previous policy which permitted the pharmacist to make limited changes to a prescription written for a Schedule II controlled substance after oral consultation with the prescriber. DEA plans to resolve this confusion through future rulemaking and instructs pharmacists to adhere to state regulations or policy regarding changes that a pharmacist may make to a schedule II prescription. Therefore, through policy, the Board will allow a pharmacist to make limited changes to a schedule II prescription as stated below.

When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist is never permitted to make changes to the controlled substance prescribed (except for generic substitution permitted by law) or the prescriber's signature.

- 110-22: referenced language for 18VAC110-20-270 needs to be replaced with current language;
- 110-27: new requirements for at least one hard-wired communication method in security system and notification of PIC or pharmacist working at pharmacy of security breach needs to be added, along with new requirement for at least two-years of experience for serving as PIC; clarification needed to use License Lookup to determine if pharmacy technician held registration within past 5 years which would require submission of a reinstatement application, not a new application;
- 110-35: similar amendments needed for nurse practitioners and physician assistants as indicated in 110-8.

MOTION:

The board voted unanimously to adopt Guidance Documents 110-8, 110-9, 110-16, 110-20, 110-22, 110-27, and 110-35 as presented in the agenda package. (motion by Jenkins, seconded by Boone)

Repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40

Ms. Juran recommended the board repeal these guidance documents based on the most recent periodic regulatory review resulting in regulatory amendments effective December 11, 2019 and indicated the following:

- 110-14: sample size was addressed in SB 1045 and SB 976 during the 2020 General Assembly Session and is now found in 54.1-3442.6 of the Code;
- 110-19: transferring of orders between medical equipment suppliers is now addressed in 18VAC110-20-680;
- 110-32: use of drop box for the collection of prescriptions is now addressed in 18VAC110-20-270;
- 110-40: storage of Schedule II drugs is now addressed in 18VAC110-20-200.

MOTION:

The Board voted unanimously to repeal Guidance Documents 110-14, 110-19, 110-32, and 110-40 as presented. (motion by Richards-Spruill, seconded by Logan)

Request to Amend Guidance Document 110-39 *Guidance for Continuous Hours Worked by Pharmacists and Breaks*

Ms. Juran commented that a pharmacist wanting to stay anonymous expressed concern about the current guidance which does not require a pharmacy to close during a pharmacist's break. The pharmacist told Ms. Juran that the guidance allows employers to require the pharmacy to remain open which does not provide an uninterrupted break for the pharmacist on-duty. After some discussion, the Board concluded that this topic should be discussed at the Regulation Committee meeting where more time could be devoted to consider the matter.

MOTION:

The Board voted unanimously to refer the request to amend Guidance Document 110-39 *Guidance for Continuous Hours Worked by*

Pharmacists and Breaks **to the Regulation Committee which is scheduled to meet in November 2020. (motion by Lee, seconded by Ratliff)**

Request for Guidance for Granting Exception to Minimum Two Years' Experience for PIC Eligibility

The Board had some discussion on possible exceptions to the two year pharmacist eligibility requirement for serving as PIC such as in a rural area. Mr. Ratliff recommended looking at past experience, consider if denial would harm the underserved, and consider if person completed PIC training. Mr. Bolyard stated it should be evaluated on a case-by-case basis and to consider if an emerging leader program has been completed. It was discussed that the Board's Bylaws currently have several delegated authorities for allowing consideration of certain matters in a timely manner. The current timeframe for changing a PIC is 14 days and often requests come in at the last minute.

MOTION:

The board voted unanimously to amend the Bylaws, Guidance Document 110-12, to delegate to the Executive Director, in consultation with the Board Chairman, the ability to approve or deny a request for an exception to the two-year pharmacist eligibility requirement to serve as the PIC, with the ability for the applicant to request an Informal Conference if denied. (motion by Lee, seconded by Nelson)

Request to Amend Regulation to Extend Change of PIC Timeframe from 14 to 30 Days

Mr. Bolyard indicated that he is requesting the Board extend the change of PIC timeframe from 14 days to 30 days. He stated it is too short and creates difficulties; don't always know if need a new PIC; inventories can take 6 hours and Sunday evenings are often the best time to perform the inventory; a temporarily assigned PIC may not always be the best candidate; on-duty pharmacists are also responsible for drug security; can be hard to find good candidates in rural areas; 8 states currently allow 30 days and Maryland has no PIC requirement. Mr. Lee recommended possibly extending to 21 days. Mr. Logan recommended possibly requiring inventory to be performed after 15 days during a 30-day window. Ms. Thornbury supported a longer timeframe based on challenges in rural areas. Ms. Yeatts questioned what information NABP may have on this subject.

MOTION:

The Board voted unanimously to refer the request to amend 18VAC110-20-110 to extend the change of PIC timeframe from 14 to 30 days to the Regulation Committee which is scheduled to meet in November 2020. (motion by Logan, seconded by Bolyard)

OLD BUSINESS:

Consideration for Requiring CE on a Specific Topic in 2021

Ms. Warriner reminded the Board that this was an action item from the December 2019 board meeting. After some discussion regarding various possible CE topics and past mandated topics, it was stated that the new requirement for pharmacists to obtain 3 hours of live or real-time interactive

Virginia Board of Pharmacy

Guidance for Continuous Hours Worked by Pharmacists and Breaks

Regulations Governing the Practice of Pharmacy

18VAC110-20-110. Pharmacy permits generally.

B. Except in an emergency, a permit holder shall not require a pharmacist to work longer than 12 continuous hours in any work day and shall allow at least six hours of off-time between consecutive shifts. A pharmacist working longer than six continuous hours shall be allowed to take a 30-minute break.

The Board provides the following guidance regarding subsection B of Regulation 18VAC110-20-110 which addresses continuous hours worked by pharmacists and 30-minute breaks:

- While a permit holder cannot require a pharmacist to work longer than 12 continuous hours in any work day, except in an emergency, a pharmacist may volunteer to work longer than 12 continuous hours;
- A pharmacy may, but is not required to, close when a pharmacist is on break;
- If a pharmacy does not close, the pharmacist must ensure adequate security of the drugs by taking his break within the prescription department or on the premises;
- The pharmacist on-duty must determine if pharmacy technicians or pharmacy interns may continue to perform duties and if he is able to provide adequate supervision. Pharmacy technicians shall never perform duties otherwise restricted to a pharmacist;
- If the pharmacy remains open, only prescriptions verified by a pharmacist pursuant to Regulation 18VAC110-20-270 may be dispensed when the pharmacist is on break. An offer to counsel must be extended pursuant to § 54.1-3319. Persons requesting to speak with the pharmacist should be told that the pharmacist is on break, that they may wait to speak with the pharmacist upon return, or provide a telephone number for the pharmacist to contact them as soon as he or she returns from break. Pharmacists returning from break should immediately attempt to contact persons requesting counseling and document when counseling is provided.

Virginia Board of Pharmacy

Contracted Employee Access to Pharmaceutical Processor

In addition to the persons allowed on the premises of a pharmaceutical processor as identified in 18VAC110-60-220(F), the Board of Pharmacy authorizes an employee of a business that is contracted by a pharmaceutical processor who needs to be allowed on the premises of the pharmaceutical processor to perform his duties. The contract may be with an individual or with a service company such as security, cleaning, electrical, HVAC, plumbing, etc. A request for the Board to authorize these contracted employees to be allowed on the premises of the processor is not required. To mitigate security risks, the pharmaceutical processor should apply the requirements for visitor access in 18VA110-60-220(G) to the contracted employee.

Excerpt from 18VAC110-60-220

18VAC110-60-220. Pharmaceutical processor prohibitions.

F. No person except a pharmaceutical processor employee or a registered patient, parent, or legal guardian shall be allowed on the premises of a processor with the following exceptions: laboratory staff may enter a processor for the sole purpose of identifying and collecting Cannabis or cannabis oil samples for purposes of conducting laboratory tests; the board or the board's authorized representative may waive the prohibition upon prior written request.

G. All persons who have been authorized in writing to enter the facility by the board or the board's authorized representative shall obtain a visitor identification badge from a pharmaceutical processor employee prior to entering the pharmaceutical processor.

1. An employee shall escort and monitor an authorized visitor at all times the visitor is in the pharmaceutical processor.

2. A visitor shall visibly display the visitor identification badge at all times the visitor is in the pharmaceutical processor and shall return the visitor identification badge to a pharmaceutical processor employee upon exiting the pharmaceutical processor.

3. All visitors shall log in and out. The pharmaceutical processor shall maintain the visitor log that shall include the date, time, and purpose of the visit and that shall be available to the board.

4. If an emergency requires the presence of a visitor and makes it impractical for the pharmaceutical processor to obtain a waiver from the board, the processor shall provide written notice to the board as soon as practicable after the onset of the emergency. Such notice shall include the name and company affiliation of the visitor, the purpose of the visit, and the date and

time of the visit. A pharmaceutical processor shall monitor the visitor and maintain a log of such visit as required by this subsection.

Agenda Item: Consideration of remote order processing by a pharmacy technician outside of a pharmacy

Staff note:

This was the subject of a petition for rulemaking from Bioscript. At its meeting on June 16, 2020, the Board voted not to initiate rulemaking but to refer the issue to the Regulation Committee for further consideration.

Included in your agenda package are:

A copy of the petition request
Excerpt from the June 16th minutes
Excerpt from 10/5/20 minutes of Special Conference Committee on request for Pilot

Committee options:

1) Report to the Board that the Committee considered the issue and does not recommend further regulatory action; or
2) Recommend to the Board the issuance of a Notice of Intended Regulatory Action.

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,)
HomeChoice Partners, Inc. dba Bioscrip Infusion Services

Street Address
5365 Robin Hood Road, Suite 200

Area Code and Telephone Number
757-855-4255 (Pharmacy)
312-715-5139 (Counsel)

City
Norfolk

State
Virginia

Zip Code
23513-2416

Email Address (optional)
James.vermaak@bioscrip.com (James Vermaak, PIC)
Edward.rickert@quarles.com (counsel for Bioscrip Infusion Services)

Fax (optional)

Respond to the following questions:

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

   18 VAC 110-20-276. Central or Remote Processing.

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.

   The legal authority is found in VA Code § 54.1-2400.

Signature: Edward Rickert

Date: 4-01-2020

Counsel for Petitioner

Substance of Proposed Change to 18 VAC 110-20-276

Petitioner is seeking an amendment to 18 VAC 110-20-276 to allow remote order entry by technicians to occur from outside the licensed pharmacy space. Petitioner operates a sterile compounding pharmacy in Norfolk, VA. There is no need from a patient safety or security standpoint for pharmacy personnel that perform order entry activities to be physically located in the licensed space. Virginia's Central or Remote Processing regulation presently allows pharmacists to access the pharmacy's database from a remote location for the purpose of performing certain prescription processing functions. Petitioner is seeking to expand this regulation to allow a technician under the supervision of a pharmacist to perform those functions from outside the licensed pharmacy, in a space that is located on the same premises as the licensed pharmacy.

The following is a proposed amendment to address this issue. The proposed language is identified by <u>double underscoring.</u>

18 VAC 110-20-276. Central or Remote Processing.

Centralized or remote processing of a prescription does not include the dispensing of a drug, but does include any of the following activities related to the dispensing process:

1. Receiving, interpreting, analyzing, or clarifying prescriptions;
2. Entering prescription and patient data into a data processing system;
3. Transferring prescription information;
4. Performing a prospective drug review as set forth in § 54.1-3319 of the Code of Virginia;
5. Obtaining refill or substitution authorizations, or otherwise communicating with the prescriber concerning a patient's prescription;
6. Interpreting clinical data for prior authorization for dispensing;
7. Performing therapeutic interventions; or
8. Providing drug information or counseling concerning a patient's prescription to the patient or patient's agent.

B. A pharmacy may outsource certain prescription processing functions as described in subsection A of this section to another pharmacy in Virginia or a registered nonresident pharmacy under the following conditions:

1. The pharmacies shall either have the same owner or have a written contract describing the scope of services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with all federal and state laws and regulations related to the practice of pharmacy;
2. Any central or remote pharmacy shall comply with Virginia law and regulation with respect to requirements for supervision of pharmacy technicians and the duties that are restricted to pharmacists and pharmacy technicians. Pharmacy technicians at the remote pharmacy shall either be registered in Virginia or possess credentials substantially equivalent to those required for a technician registered in Virginia;
3. A pharmacist licensed in Virginia, whether at the remote pharmacy or the dispensing pharmacy, shall perform a check for accuracy on all processing done by the remote processor; and
4. The pharmacies shall share a common electronic file or have technology that allows sufficient information necessary to process a nondispensing function.

C. Any pharmacy that outsources prescription processing to another pharmacy shall provide notification of such to patients. A one-time written notification or a sign posted in the pharmacy in a location that is readily visible to the public will satisfy this notification requirement. The notice shall state the name of any contract pharmacy providing central or remote prescription processing. If the pharmacy uses a network of pharmacies under common ownership, this fact shall be disclosed in the notice.

D. A policy and procedure manual that relates to central or remote processing shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

1. The responsibilities of each pharmacy;
2. A list of the name, address, telephone numbers, and permit/registration numbers of all pharmacies involved in central or remote processing;
~~3. Procedures for protecting the confidentiality and integrity of patient information;~~

4. Procedures for ensuring that pharmacists performing prospective drug reviews have access to appropriate drug information resources;
5. Procedures for maintaining required records;
6. Procedures for complying with all applicable laws and regulations to include counseling;
7. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
8. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

E. In addition to any other required records, pharmacies engaged in central or remote processing shall maintain retrievable records that show, for each prescription processed, each individual processing function and identity of the pharmacist or pharmacy technician who performs a processing function and the pharmacist who checked the processing function, if applicable.

1. The records may be maintained separately by each pharmacy, or in a common electronic file shared by both pharmacies provided the system can produce a record showing each processing task, the identity of the person performing each task, and the location where each task was performed.
2. The record shall be readily retrievable for at least the past two years through the primary dispensing pharmacy, and shall be available for inspection by the board.

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist or pharmacy technician in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section, provided the pharmacy establishes controls to protect the privacy and security of confidential records. A pharmacy technician is permitted to access the pharmacy's database only under the following conditions:

1. The remote location must be a location that is on the same premises as the licensed pharmacy;
2. The technician is performing only prescription processing functions, patient care documentation, patient and prescriber communications, activities falling within the scope of VA ST § 54.1-3321 that do not require the handling of or access to prescription drug inventory; and activities that do not fall within the scope of the practice of pharmacy;
3. The prescription processing functions performed by the pharmacy technician shall be limited to the entry of prescription information and drug history into the database: and
4. A policy and procedure manual that relates to remote processing functions performed by a pharmacy technician shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:

a. Procedures for protecting the confidentiality and integrity of patient information;
b. Procedures for ensuring that original prescriptions received by the pharmacy as an original hard copy or verbally and reduced to writing do not leave the licensed space, and that technicians performing processing functions have access to an exact, unalterable image of such prescriptions to perform prescription order entry;
c. Procedures for ensuring adequate pharmacist supervision of pharmacy technicians that perform prescription processing functions;
d. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and
e. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.

Rationale or Purpose for the Amended Rule

Petitioner believes that it is important that a licensed pharmacy have sufficient space to allow for drug storage and fulfillment activities. Pharmacies that perform compounding, including sterile compounding, require even more space. Pharmacy personnel that are not directly performing activities related to the physical preparation of drug products should be allowed to perform those functions from outside the licensed space.

The proposed amendment will ensure adequate supervision and security in connection with the performance of prescription processing functions. Amending the existing regulation will not have a negative impact on patient safety, and could potentially result in improved patient safety. Allowing processing functions to be moved outside the licensed space will

decrease noise and other distractions that are present in a busy pharmacy, and could improve accuracy associated with this important pharmacy activity.

Petitioner believes that a rule amendment is preferable to a pilot project, because the technology required to perform processing from outside of a licensed space is already in common use throughout the state, and there is no need to validate that technology. Petitioner further believes that other licensed pharmacies in the state would benefit from a rule amendment.

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

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

Back to List of Comments

Commenter: Lauren Paul

5/5/20 10:28 am

CVS Health's comments on petition for rule-making of 18VAC110-20-276. Central or Remote Processing

Dear Executive Director Juran:

I am writing to you in my capacity as Sr Director of Regulatory Affairs for CVS Health and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Virginia through our integrated offerings across the spectrum of pharmacy care. CVS Health appreciates the opportunity to submit comments on the petition for rule-making of 18 VAC 110-20-276 to allow technicians to practice remote order entry from outside the licensed pharmacy space. We would also like to thank the Board for their vigilance to continuously improve the laws and regulations that guide pharmacists, pharmacy interns and pharmacy technicians serving Virginia patients.

While CVS Health appreciates the petitioners sentiment to amend 18 VAC 110-20-276 allowing technicians to perform remote order entry from outside the licensed pharmacy space, we feel the petitioner places undue restrictions on the allowance by proposing additional requirements outlined in subsection (F)(1-4), which are mostly duplicative of requirements already in regulation through policy and procedure. We support the allowance for technicians to perform prescription processing functions without specific additional restrictions. The NABP Model Rules address individual practice of not only a pharmacist, but also a pharmacy intern and pharmacy technician in the Practice of Pharmacy, within Section 8, Shared Pharmacy Services. The model rules provide an avenue for these individuals to access the pharmacy's electronic database from inside or outside the pharmacy to perform prescription drug order processing functions if there are established controls to protect confidentiality and integrity of protected health information and if no part of the database is duplicated, downloaded or removed. This is similar to language in Virginia regulations allowing pharmacists to perform certain prescription processing functions. Currently 11 states allow technicians to work remotely performing prescription processing functions, with 4 of those states using language from the model act to permit the practice. In light of the COVID-19 pandemic, an additional 34 states, including Virginia, either through guidance, waivers, emergency regulations or suspension of laws and/or regulations have allowed technicians to practice remotely. Therefore, we support the allowance of technicians to perform remote order entry and prescription processing functions remotely. Please see below our recommended language based on the petitioner's proposal along with NABP Model Rules for your reference.

Suggested Language:

18VAC 110-20-276 Central or Remote Processing

F. Nothing in this section shall prohibit an individual employee licensed as a pharmacist, pharmacy intern or pharmacy technician in Virginia from accessing the employer pharmacy's database from a remote location for the purpose of performing certain prescription processing functions as described in subsection A of this section, provided the pharmacy establishes controls to protect the privacy and security of confidential records. No part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database. ~~A pharmacy technician is permitted to access the pharmacy's database only under the following conditions:~~

~~1. The remote location must be a location that is on the same premises as the licensed pharmacy;~~

~~2. The technician is performing only prescription processing functions, patient care documentation, patient and~~

~~prescriber communications, activities falling within the scope of VA ST § 54.1-3321 that do not require the handling of~~
~~or access to prescription drug inventory; and activities that do not fall within the scope of the practice of pharmacy;~~
~~3. The prescription processing functions performed by the pharmacy technician shall be limited to the entry of prescription information and drug history into the database; and~~
~~4. A policy and procedure manual that relates to remote processing functions performed by a pharmacy technician shall be maintained at each pharmacy involved in the processing of a prescription and available for inspection. The manual shall at a minimum include the following:~~
~~a. Procedures for protecting the confidentiality and integrity of patient information;~~
~~b. Procedures for ensuring that original prescriptions received by the pharmacy as an original hard copy or verbally and reduced to writing do not leave the licensed space, and that technicians performing processing functions have access to an exact, unalterable image of such prescriptions to perform prescription order entry;~~
~~c. Procedures for ensuring adequate pharmacist supervision of pharmacy technicians that perform prescription processing functions;~~
~~d. Procedures for objectively and systematically monitoring and evaluating the quality of the program to resolve problems and improve services; and~~
~~e. Procedures for annually reviewing the written policies and procedures for needed modifications and documenting such review.~~

NABP Model Rules Section 8. Shared Pharmacy Services

(e) Individual Practice

(1) Nothing in this Section shall prohibit an individual Pharmacist licensed in the state, who is an employee of or under contract with a Pharmacy, or a licensed Certified Pharmacy Technician, Certified Pharmacy Technician Candidate, or Pharmacy Intern, working under the supervision of the Pharmacy, from accessing that Pharmacy's electronic database from inside or outside the Pharmacy and performing the Prescription Drug Order processing functions permitted by the Pharmacy Act, if both of the following conditions are met:

(i) the Pharmacy establishes controls to protect the confidentiality and integrity of Protected Health Information; and

(ii) no part of the database is duplicated, downloaded, or removed from the Pharmacy's electronic database.

CVS Health appreciates the opportunity to submit comments on this petition for rule-making.

CommentID: 80133

35

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

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

Previous Comment Back to List of Comments

Commenter: Natalie Nguyen, Virginia Society of Health-System Pharmacists (VSHP) 5/27/20 2:05 pm

VSHP's Comments on Remote Order Processing By Technicians

We ask the Board to consider amending Section 276 at the conclusion of the emergency provisions within the context of a Board of Pharmacy workgroup, that can carefully distinguish tasks more administrative in nature (appropriate for well-educated, well-trained pharmacy technicians) versus those more clinical in nature (reserved for pharmacists). As well, to include discussion of the specifics and practicality of pharmacist oversight of such.

Thank you for your time and consideration.

CommentID: 80169

KAISER PERMANENTE

Mid-Atlantic Permanente Medical Group, P.C.
Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc

Caroline Juran, RPh
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive, Suite 300
Richmond, VA 23233-1463

May 27, 2020

Re: 18VAC110-20-276. Central or Remote Processing

Dear Ms. Juran,

Thank you for the opportunity to provide comment on proposed new regulations 18VAC110-20-276. Established in 1980, Kaiser Permanente is the trade name for the total health organization comprised of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., the Mid-Atlantic Permanente Medical Group, P.C., an independent medical group that features approximately 1,600 physicians who provide or arrange care for patients throughout the area, and Kaiser Foundation Hospitals, which contracts with community hospitals for the provision of hospital services to our myriad patients. We provide and coordinate comprehensive health care services for approximately 780,000 members throughout the metropolitan area. Our organization operates thirteen pharmacies across ten medical facilities in the Commonwealth of Virginia, with several more planned in the near future.

We commend the Board for acknowledging the significant role pharmacy technicians play to support the profession and considering their contributions to operational efficiencies that extend the reach of pharmacy care. Kaiser Permanente is very interested in exploring opportunities that enhance value by allowing pharmacy technicians to process orders remotely beyond the physical location of a licensed pharmacy. Additionally, we encourage the Board to consider the inclusion of registered pharmacy interns in the proposed rule to enhance the ability of organizations to take full advantage of its capabilities.

Kaiser Permanente pharmacies use a shared common database. Our electronic pharmacy software encompasses HIPAA-compliant databases that integrate with patients' virtual medical records. Aided by multiple levels of quality assurance, patient safety and security – including the use of Virtual Private Network (VPN) technology when feasible – we have in place secure connectivity for remote order processing accessible from countless locations.

Under the proposed regulation, our pharmacy technicians would continue to be supervised by licensed pharmacists to review actions taken as well as manage all appropriate prescription evaluation, accuracy verification and patient counseling responsibilities. Over many years, evidence demonstrates that remote processing adds value by increasing the capacity to offer

expanded pharmacy coverage and allows organizations to redeploy pharmacists into direct patient care functions.[1] Remote processing, with proper checks and balances, provides the opportunity to augment creative and safe ways to provide care to our patients as the profession continues to evolve.

With a growing population in the Commonwealth of Virginia, an invigorated healthcare workforce practicing at the top of their profession is necessary to ensure adequate capacity and provision of health care services. Kaiser Permanente strongly supports the proposed petition for 18VAC110-20-276 – Central or Remote Processing.

Feel free to contact me at monet.stanford@kp.org or (301)552-5571, should any further inquiries arise. Thank you for your time and consideration.

Sincerely,

Monet M. Stanford

Monet Stanford, PharmD
Pharmacy Government Relations and Regulatory Affairs
Kaiser Foundation Health Plan of Mid-Atlantic States, Inc.
4000 Garden City Drive
New Carrollton, MD 20785

[1] Alicia Thorne, Pharm.D., Sarah Williamson, Pharm.D., Tara Jellison, Pharm.D., Chris Jellison, Pharm.D., Implementation of home-based medication order entry at a community hospital, American Journal of Health-System Pharmacy, Volume 66, Issue 21, 1 November 2009, Pages 1939–1942, https://doi.org/10.2146/ajhp080545

ACTION ITEM:

The Board requested staff to reach out to Governor's office regarding the status of the regulations prohibiting against incentives to transfer prescriptions.

Adopt Exempt Regulations for Pharmaceutical Processors

Ms. Yeatts provided an overview of the proposed exempt regulations in the agenda package. The proposed amendments reflect changes in the law which are eligible for exempt action since they are anticipated to be non-controversial.

MOTION:

The board voted unanimously to adopt the exempt regulations for pharmaceutical processors as presented. (motion by Ratliff, seconded by Jenkins)

Consider Petition for Rulemaking to Amend 18VAC110-20-276 to Allow Remote Order Processing by Pharmacy Technicians Outside a Pharmacy

Ms. Christian shared electronically through the WebEx platform the comments received from the National Association of Chain Drug Stores that were not included in the agenda packet and allow board members a few minutes to review the information. The board then discussed the petition and the comments received. It expressed some concern for oversight of pharmacy technicians working remotely from a location other than the pharmacy. It was stated that this is currently allowed under the emergency waivered provisions associated with COVID-19. Comments regarding ensuring proper safeguards are in place, as well as preserving the pharmacist to pharmacy technician ratio were expressed.

MOTION:

The Board voted unanimously to decline the petition for rulemaking, but refer the issue to the Regulation Committee in November for further consideration. (motion by Richards-Spruill, seconded by Bolyard)

Consider Adoption of Fast-track Regulation to Allow Volunteer CE to Satisfy Live CE Requirement

Ms. Yeatts shared that currently a pharmacist may obtain one hour of continuing education (CE) credit for volunteering for three hours to provide pharmacy services as a pharmacist, without compensation, to low-income individuals at a local health department or free clinic, but that counsel has indicated the CE does not satisfy the live or real-time interactive CE requirement. However, the Board could adopt a fast-track regulatory amendment of 18VAC110-21-120 to allow the volunteer CE to satisfy the live or real-time CE requirement.

MOTION:

The board voted unanimously to amend 18VAC110-21-120 through a fast-track action by inserting a new number 3 within subsection C indicating that a maximum of 2 hours for voluntary services in accordance with subsection D may be included in the 3 hours of live or real-time interactive CE. (motion by Logan, seconded by Richards-Spruill)

(DRAFT/UNAPPROVED)

VIRGINIA BOARD OF PHARMACY
MINUTES OF INFORMAL CONFERENCE COMMITTEE

October 5, 2020
Second Floor
Board Room 4

Department of Health Professions
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233

CALL TO ORDER: A meeting of an informal conference committee of the Board of Pharmacy was called to order at 9:09 AM.

PRESIDING: Kris Ratliff, Committee Chairman

MEMBER PRESENT: William Lee, Committee Member

STAFF PRESENT: Caroline D. Juran, Executive Director
Ellen Shinaberry, Deputy Executive Director
Mykl Egan, Discipline Case Manager
Jess Kelley, DHP Adjudication Specialist

Free Clinic of Franklin County
Tech Pre-dispensing Preparation

Kimberly Florio, Pharmacist in charge of the Free Clinic of Franklin County was present to discuss the application for approval of an Innovative (Pilot) Program from the Free Clinic of Franklin.

The Free Clinic of Franklin is seeking permission to allow pharmacy technicians to perform prescription data entry and printing of prescription label and patient information leaflet outside of the pharmacy when a pharmacist is not on duty and is seeking a waiver of § 54.1-3320 dealing with Acts Restricted to Pharmacist and 18VAC110-20-112 Supervision of Pharmacy Technicians.

DISCUSSION: Ms. Florio presented information related to the process of preparing the prescription label and leaflet by the technician in a room adjacent to the pharmacy and answered questions regarding the functionality of the computer software.

DECISION: After consideration of the application and statements concerning the proposed Innovative (Pilot) program the committee denied the request.

Johnston Memorial Hospital
Tech-Check-Tech

Carmen Meadows, Clinical Coordinator and Christina Shelton, Pharmacist in Charge of Johnston Memorial Hospital were present to discuss the application for approval of an Innovative (Pilot) Program from Johnston Memorial Hospital.
Johnston Memorial Hospital is seeking permission to allow

Agenda Item: Consideration of amendments to incorporate changes currently in approved as pilots – medication carousels and RFID technology

Included in your agenda package are:

DRAFT amendments to 18VAC110-20-425 and NEW section 18VAC110-20-505 as posted with the Notice of Intended Regulatory Action (NOIRA)

Copy of notice of comment page posted on the Townhall

Copy of comments on the NOIRA

Staff note:

Amendments would incorporate allowances for medication carousels with robotic systems and for use of RFID technology in provision of floor stock.

Committee action:

1) The Committee can recommend that the Board adopt the amendments as drafted and posted with the NOIRA; OR

2) The Committee can recommend adopt the proposed language with amendments.

Preliminary Draft Text

highlight

Action: Use of medication carousels and RFID technology
Stage: NOIRA 2/7/20 1:23 PM

18VAC110-20-425. Robotic pharmacy systems.

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

1. Pharmacists shall review for accuracy and appropriateness of therapy all data entry of prescription orders into the computer operating the system.

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

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

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

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

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

c. Removing expired drugs;

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

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

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

g. Accurate recording of any scheduled or unanticipated downtime with an explanation of the problem to include the time span of the downtime and the resolution;

42

h. Appropriately performing an analysis to investigate, identify, and correct sources of discrepancies or errors associated with the robotic pharmacy system; and

i. Maintaining quality assurance reports.

5. All manual picks shall be checked by pharmacists.

6. If it is identified that the robot selected an incorrect medication, the pharmacy shall identify and correct the source of discrepancy or error in compliance with the pharmacy's policies and procedures prior to resuming full operations of the robot. An investigation of the cause of the event shall be completed, and the outcome of the corrective action plan shall be summarized and documented in a readily retrievable format.

7. Quarterly quality assurance reports demonstrating the accuracy of the robot shall be maintained. At a minimum, these reports shall include a summary indicating the date and description of all discrepancies that include discrepancies involving the packaging, repackaging, and dispensing of drugs via the robotic pharmacy system found during that quarter plus a cumulative summary since initiation of the robotic pharmacy system.

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

B. Intravenous admixture robotics may be utilized to compound drugs in compliance with § 54.1-3410.2 of the Code of Virginia and 18VAC110-20-321; however, a pharmacist shall verify the accuracy of all compounded drugs pursuant to 18VAVC110-20-270 B.

C. Medication carousels that are a component of a robotic pharmacy system in a hospital may be utilized to store and guide the selection of drugs to be dispensed or removed from the pharmacy under the following conditions:

1. The entry of drug information into the barcode database for assignment of a barcode to an individual drug shall be performed by a pharmacist who shall verify the accuracy of the barcode assignment.

2. A pharmacist is not required to verify the accuracy of a patient-specific drug removed from a medication carousel if:

a. The entry of the order for a patient-specific drug into the pharmacy's dispensing software is verified by a pharmacist for accuracy and is electronically transmitted to the medication carousel; and

b. The patient-specific drug removed from the medication carousel by a pharmacy technician is verified for accuracy by the pharmacy technician who shall scan each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug removed from the medication carousel prior to dispensing, and a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient.

3. A pharmacist is not required to verify the accuracy of drug removed from the medication carousel by a pharmacy technician that is intended to be placed into an automated drug dispensing system as defined in § 54.1-3401 of the Code of Virginia if:

43

a. The list of drugs to be removed from the medication carousel for loading or replenishing an individual automated dispensing system is electronically transmitted to the medication carousel; and

b. The drug removed from the medication carousel is verified for accuracy by the pharmacy technician by scanning each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug removed from the medication carousel prior to leaving the pharmacy and delivering the drug to the automated drug dispensing system, and a nurse or other person authorized to administer drug scans each drug unit using barcode technology to verify the accuracy of the drug prior to administration of the drug to the patient. If the drug is placed into an automated drug dispensing system wherein a nurse or other person authorized to administer drug will not be able to scan each drug unit using barcode technology to verify the accuracy of the drug prior to patient administration, then a second verification for accuracy shall be performed by a pharmacy technician by scanning each drug unit, each intact blister card of each unit dose drug, or each unopened manufacturer's container of each unit dose drug at the time of placing the drugs into the automated dispensing system.

3. A pharmacist shall verify the accuracy of all drugs prior to dispensing or leaving the pharmacy that are manually removed from the medication carousel by a pharmacy technician without the use of the robotic pharmacy system to guide the selection of the drug product.

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

A. The pharmacy may prepare a kit for a licensed EMS agency provided:

1. The PIC of the hospital pharmacy shall be responsible for all prescription drugs and Schedule VI controlled devices contained in this kit. A Except as authorized in 18VAC110-20-505, a pharmacist shall check each kit after filling and initial the filling record certifying the accuracy and integrity of the contents of the kit.

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

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

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

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

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

4. When the drug kit has been opened, the kit shall be returned to the pharmacy and exchanged for an unopened kit. The record of the drugs administered shall accompany the opened kit when exchanged. An accurate record shall be

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

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

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

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

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

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

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

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

10. In lieu of exchange by the hospital pharmacy, the PIC of the hospital pharmacy may authorize the exchange of the kit by the emergency department. Exchange of the kit in the emergency department shall only be performed by a pharmacist, nurse, or prescriber if the kit contents include Schedule II, III, IV, or V drugs.

B. A licensed EMS agency may obtain a controlled substances registration pursuant to § 54.1-3423 D of the Code of Virginia for the purpose of performing a one-to-one exchange of Schedule VI drugs or devices.

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

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

3. Pursuant to § 54.1-3434.02 of the Code of Virginia, the EMS provider may directly obtain Schedule VI drugs and devices from an automated drug dispensing device.

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

45

5. If an EMS agency is performing a one-to-one exchange of Schedule VI drugs or devices, Schedule II, III, IV, or V drugs shall remain in a separate, sealed container and shall only be exchanged in accordance with provisions of subsection A of this section.

18VAC110-20-505. Use of radio-frequency identification.

A. A hospital pharmacy may use radio-frequency identification (RFID) to verify the accuracy of drugs placed into a kit for licensed emergency medical services pursuant to 18VAC110-20-500 or other kits used as floor stock throughout the hospital under the following conditions:

1. A pharmacist shall be responsible for performing and verifying the accuracy of the following tasks:

a. The addition, modification, or deletion of drug information into the RFID database for assignment of a RFID tag to an individual drug; and

b. The development of the contents of the kit in the RFID database and the associated drug-specific RFID tags.

2. A pharmacy technician may place the RFID tag on the drugs and a pharmacist shall verify that all drugs have been accurately tagged prior to storing the drugs in the pharmacy's inventory.

3. A pharmacy technician may remove RFID-tagged drugs from the pharmacy's inventory whose RFID tags have been previously verified for accuracy by a pharmacist, and place the drugs into the kit's container. A pharmacy technician may then place the container into the pharmacy's device that reads the RFID tags to verify if the correct drugs have been placed into the container as compared to the list of the kit's contents in the RFID database.

4. A pharmacist shall perform a daily random check for verification of the accuracy of 5% of all kits prepared that day utilizing the RFID technology. A manual or electronic record from which information can be readily retrieved, shall be maintained that includes:

a. The date of verification;

b. A description of all discrepancies identified, if any; and

c. The initials of pharmacist verifying the accuracy of the process.

5. Pharmacies engaged in RFID tagging of drugs shall be exempt from the requirements in 18 VAC 110-20-490 (C), 18 VAC 110-20-460 (A) and 18 VAC 110-20-355 (A)

6. All records required by this subsection shall be maintained for a period of one year from the date of verification by the pharmacist.

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Agency Department of Health Professions

Board Board of Pharmacy

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

Action: Use of medication carousels and RFID technology

Notice of Intended Regulatory Action (NOIRA)

Action 5480 / Stage 8892

Edit Stage | Withdraw Stage | Go to RIS Project

Documents		
Preliminary Draft Text	2/7/2020 1:23 pm	Sync Text with RIS
Agency Background Document	2/7/2020	Upload / Replace
Governor's Review Memo	8/12/2020	
Registrar Transmittal	8/12/2020	

Status	
Public Hearing	Will be held at the **proposed** stage
Exempt from APA	No, this stage/action is subject to article 2 of the *Administrative Process Act* and the standard executive branch review process.
DPB Review	Submitted on 2/7/2020 Policy Analyst: Jerry Gentile Review Completed: 2/21/2020 *DPB's policy memo is "Governor's Confidential Working Papers"*
Secretary Review	Secretary of Health and Human Resources Review Completed: 5/31/2020
Governor's Review	Review Completed: 8/12/2020 Result: Approved
Virginia Registrar	Submitted on 8/12/2020 The Virginia Register of Regulations Publication Date: 9/14/2020 Volume: 37 Issue: 2
Comment Period	Ended 10/14/2020 2 comments

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Agency Department of Health Professions

Board Board of Pharmacy

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

Action	Use of medication carousels and RFID technology
Stage	NOIRA
Comment Period	Ends 10/14/2020

2 comments

All good comments for this forum Show Only Flagged

Back to List of Comments

Commenter: Clinton Atwater, Carilion Clinic 10/13/20 5:16 pm

18VAC110-20-425 Robotic pharmacy systems (carousel subsection)

Section C of article 425 references the use of carousel technology and puts into place the necessary safeguards for technicians to safely and accurately dispense unit dose medications using barcode technology inherent in carousels technology. The article properly identifies the steps to be followed for dispensing of patient specific medications as well as replenishment stock for automated dispensing systems. The article does not specify dispensing of products that will be utilized in a satellite pharmacy or another hospital in the case of a hub and spoke distribution model. I encourage the addition of language that allows for dispensing to another pharmacy location following the same safeguards as outlined for patient specific medications and automated dispensing systems.

Note there are two sections labeled section 3 in the carousel portion of the article. It appears that this is a typo and perhaps the second section 3 should be section 4. *"3. A pharmacist shall verify the accuracy of all drugs prior to dispensing or leaving the pharmacy that are manually removed from the medication carousel by a pharmacy technician without the use of the robotic pharmacy system to guide the selection of the drug product. "* Carousel technology relies on barcode technology and not robotic technology for safety. I believe the intent of this section is to specify that any medication that is removed from a carousel without following the required steps for section 3 (electronically transmitted order and barcode scanning each item) requires a pharmacist verification prior to dispensing.

Changes to this regulation is long overdue and I am pleased that VA is recognizing the value of automation and technology in the inpatient hospital system.

CommentID: 87361

Commenter: Mark Hickman and Natalie Nguyen, VSHP 10/14/20 5:39 pm

VSHP Comment on Use of medication carousels and RFID technology

The Virginia Society of Health-System Pharmacists (VSHP) appreciates the Board of Pharmacy's considerations for promulgating regulations on two areas of pharmacy practices that have become

48

well incorporated into health-system pharmacy practice. We support the intent of the language proposed in this NOIRA. We would like to offer clarifying considerations and questions for the proposed language.

MEDICATION CAROUSELS
Section C, subsections 2b and 3b: VSHP requests that the Board revisit the language as written requiring the scanning of each unit dose / intact blister / unopened manufacturer. The current proposed language requires validation of the barcode based on type of product packaging, which is currently not a customizable option within medication carousel technology. The system cannot differentiate between when to require scanning a single unit dose vs. intact blister vs. unopened box. Instead, the system requires the scanning of a barcode of the product in order to proceed, regardless of it is a single unit or still attached to a whole box or blister. VSHP recommends adding language requiring the visual inspection by the pharmacy technician for all unit doses filled to a patient-specific dose or automated dispensing cabinet.

Another consideration is the requirement for scanning every single unit dose item to fill the order for a patient or automated dispense cabinet pocket. Although this is an option that can be implemented in the medication carousel technology, this counteracts the intent of this pharmacy automation technology to improve efficiency in addition to the added safety level of barcode validation.

RFID TECHNOLOGY
Section A, subsection 4: VSHP asks the Board to clarify expectations if errors are identified during the 5% pharmacist check, actions to be taken, and documentation. For example, does the pharmacist then expand to 10% check for validation?

Thank you for your attention and consideration.
CommentID: 87369

49

Agenda Item: Adoption of a NOIRA/Notice of Periodic Review

Staff note:

Regulations are required to be reviewed every four years. Therefore, staff is recommending initiation of a periodic review of the following chapters:

18 VAC 110-20 Regulations Governing the Practice of Pharmacy
18 VAC 110-21 Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians
18 VAC 110-30 Regulations for Practitioners of the Healing Arts to Sell Controlled Substances
18 VAC 110-40 Regulations Governing Collaborative Practice Agreements
18 VAC 110-50 Regulations Governing Wholesale Distributors, Manufacturers and Warehousers

The Board can announce the reviews as part of a Notice of Intended Regulatory Action that set out some of the issues that the Board will address in the context of a periodic review and invite the public to comment on other amendments that should be considered.

Included in your agenda package:

Listing of issues/recommended amendments that: 1) were made during the previous review and deferred; or 2) have been identified in the past few months.

Committee Action:

The Committee can recommend to the Board that it adopt a Notice of Intended Regulatory Action and a notice of periodic review for the chapters identified. The Committee can recommend inclusion of all or some of the issues/amendments identified in its agenda package.

Issues to be considered for a Periodic Review

Board of Pharmacy

The following are comments on proposed regulations that were received when the Board amended regulations pursuant to its last periodic review (concluded in 2019). The comments were either: 1) not included in the proposed regulations or the Notice of Intended Regulatory Action; or 2) not on sections being amended. The Board decided at the time of adoption of final regulations to defer consideration of these comments.

In section 10, amend the definition of personal supervision to allow a pharmacist to not be physically present in the pharmacy but to supervise through the use of "real-time, two-way technology communication" between the pharmacist and the technician.

In section 10, delete the definition of "personal supervision" to allow audio-visual technology *supervision of compounding in retail pharmacies*.

In section 112, eliminate the current ratio of four pharmacy technicians to one pharmacist. Possibly allow the "prescription department manager" or "consultant pharmacist" to determine the number of technicians.

In section 150, delete the square footage requirement and allow pharmacies to decide the amount of space "adequate to perform the practice of pharmacy." Allow for trailers or other moveable facilities in a declared emergency.

In section 270, except for electronic prescriptions, only require written prescriptions for "controlled substances" to have a signature.

In section 270, allow a pharmacist to use his professional judgment to alter or adapt a prescription, to change dosage, dosage form or directions, to complete missing information, or to extend a maintenance drug.

In section 270, amend the rule to not require data entry verification and prospective drug utilization review by a pharmacist who is dispensing an on-hold prescription at a future date.

In section 355, amend to allow for using returns of dispensed drugs to be restocked for reuse in an automated counting device.

In section 360, amend the regulation to allow pharmacy technicians to be involved in prescription transfers; pharmacist on duty should be able to delegate that task.

In section 420, change the provision of a seven-day supply of a drug in a unit dose systems in hospitals or long-term care facilities to allow for dispensing of a 14-day supply.

In new chapter 21, section 10, strike the definition of PTCB and insert new definition for certification meaning any individual who has passed a certification exam administered by an organization accredited by the National Commission for Certifying Agencies.

In addition, the following issues have been raised:

- Consideration of including a requirement for an e-profile identification number for facilities
- Requirement for applicants to graduate from pharmacy school prior to taking examinations
- Change of timeframe for notification of a change in the PIC from 14 to 30 days

The Committee or the Board may add other specific issues/amendments to the Notice of Intended Regulatory Action (NOIRA). The purpose of the Notice of Periodic Review, combined with the NOIRA, is to allow opportunity for members of the public, members of the Board, or the staff to identify other issues/amendments that may be proposed.