

BOARD OF PHARMACY

Outsourcing facilities

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

18VAC110-20-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	\$180
2. Pharmacy intern registration	\$15
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Permitted physician licensed to dispense drugs	\$270
6. Medical equipment supplier permit	\$180
7. Humane society permit	\$20
8. <u>Outsourcing facility permit</u>	<u>\$270</u>
8-9. <u>Nonresident pharmacy registration</u>	\$270
10. <u>Nonresident outsourcing facility registration</u>	<u>\$270</u>
9-11. <u>Controlled substances registrations</u>	\$90
10-12. <u>Innovative program approval.</u>	\$250

If the board determines that a technical consultant is required in order to make a decision on approval, any consultant fee, not to exceed the actual cost, shall also be paid by the applicant in addition to the application fee.

11-13. <u>Approval of a pharmacy technician training program</u>	\$150
12-14. <u>Approval of a continuing education program</u>	\$100

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	\$90
2. Pharmacist inactive license – due no later than December 31	\$45
3. Pharmacy technician registration – due no later than December 31	\$25
4. Pharmacy permit – due no later than April 30	\$270
5. Physician permit to practice pharmacy – due no later than February 28	\$270
6. Medical equipment supplier permit – due no later than February 28	\$180
7. Humane society permit – due no later than February 28	\$20
8. <u>Outsourcing facility permit – due no later than April 30</u>	<u>\$270</u>
8.9. <u>Nonresident pharmacy registration</u> – due no later than the date of initial registration	\$270
<u>10. Nonresident outsourcing facility registration – due no later than the date of initial registration</u>	<u>\$270</u>
9.11. Controlled substances registrations –due no later than February 28	\$90
10.12. Innovative program continued approval based on board order not to exceed \$200 per approval period.	
11.13. Approval of a pharmacy technician training program	\$75 every two years

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

1. Pharmacist license	\$30
2. Pharmacist inactive license	\$15
3. Pharmacy technician registration	\$10
4. Pharmacy permit	\$90
5. Physician permit to practice pharmacy	\$90
6. Medical equipment supplier permit	\$60

7. Humane society permit	\$5
8. <u>Outsourcing facility permit</u>	<u>\$90</u>
8-9. <u>Nonresident pharmacy registration</u>	\$90
10. <u>Nonresident outsourcing facility registration</u>	<u>\$90</u>
9-11. <u>Controlled substances registrations</u>	\$30
10-12. <u>Approval of a pharmacy technician training program</u>	\$15

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

1. Pharmacist license	\$210
2. Pharmacist license after revocation or suspension	\$500
3. Pharmacy technician registration	\$35
4. Pharmacy technician registration after revocation or suspension	\$125
5. Facilities or entities that cease operation and wish to resume shall not be eligible for reinstatement but shall apply for a new permit or registration. Facilities or entities that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus the following reinstatement fees:	
a. Pharmacy permit	\$240
b. Physician permit to practice pharmacy	\$240
c. Medical equipment supplier permit	\$210
d. Humane society permit	\$30
e. Nonresident pharmacy	\$115
f. Controlled substances registration	\$180

g. Approval of a pharmacy technician training program	\$75
h. Approval of a repackaging training program	\$50
G. Application for change or inspection fees for facilities or other entities.	
1. Change of pharmacist-in-charge	\$50
2. Change of ownership for any facility	\$50
3. Inspection for remodeling or change of location for any facility	\$150
4. Reinspection of any facility	\$150
5. Board-required inspection for a robotic pharmacy system	\$150
6. Board-required inspection of an innovative program location	\$150
7. Change of pharmacist responsible for an approved innovative program	\$25
H. Miscellaneous fees.	
1. Duplicate wall certificate	\$25
2. Returned check	\$35
3. Duplicate license or registration	\$10
4. Verification of licensure or registration	\$25

18VAC110-20-215. Outsourcing facilities.

A. Any facility in the Commonwealth engaged in the sterile compounding of drugs or devices to be dispensed without a prescription for a specific patient shall obtain a permit as an outsourcing facility from the board in accordance with § 54.1-3434.05. Any outsourcing facility located outside of the Commonwealth that delivers in any manner Schedule II through VI drugs or devices into the Commonwealth without a prescription for a specific patient shall be registered with the board in accordance with § 54.1-3434.5.

B. An outsourcing facility shall comply with all provisions of this chapter relating to a pharmacy in Parts IV and VI, with the following exceptions:

1. Subsections D and E of 18VAC110-20-190, relating to dispensed prescriptions.
2. Subsection A of 18VAC110-20-200, relating to prescriptions awaiting delivery.
3. Subsections B and C of 18VAC110-20-240, relating to prescriptions and chart orders.
4. Section 18VAC110-20-250, relating to automated data processing prescription records.
5. Subsections C, D, E, and F of 18 VAC110-20-270, relating to preparation and dispensing of prescriptions.

C. In addition to applicable requirements for pharmacies, outsourcing facilities shall comply with the following:

1. Pharmacist supervision.

At all times, such facilities shall be under the supervision of a PIC who routinely practices at the location designated on the permit application. A pharmacist shall be present at all times when the facility is open for business.

2. Records.

a. All records, including the receipt and disposition of drugs or devices, shall be maintained by the facility for a period of five years and shall be available to the board upon request.

b. Compounding records shall include identification and strength of the drugs and shall provide the ingredients, expiration dates and the source of such ingredients. Records shall also include the national drug code number of the source drug or bulk active ingredient, if available; the strength of the active ingredient per unit; the dosage form and route of administration; the package description; the number of individuals units produced; the national drug code number of the final product, if

assigned, or lot number; and an appropriately assigned expiration date or beyond use date.

c. Outsourcing facilities shall maintain quality control records to include stability and sterility testing for determining beyond use dating.

3. Renewal.

a. Upon initial application and at each renewal, outsourcing facilities shall submit to the board documentation that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act.

b. Upon initial registration and at renewal, outsourcing facilities shall submit to the board a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5.

c. No outsourcing facility may distribute or dispense any drug to any person pursuant to a prescription unless it is also maintains a current active pharmacy permit. The pharmacy shall comply with all state and federal laws, regulations and requirements, except it shall compound in compliance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

d. Outsourcing facilities that fail to demonstrate that the facility is registered as an outsourcing facility under the Federal Food, Drug and Cosmetic Act or submit a copy of a current inspection report consistent with § 54.1-3434.05 or § 54.1-3434.5 shall not meet the requirements for renewal of registration.

Part VIII

Labeling and Packaging Standards for Prescriptions

18VAC110-20-321. Compounding.

A. The compounding of both sterile and non-sterile drug products by a pharmacy that does not share the same physical space with an outsourcing facility shall be performed in accordance with USP-NF compounding standards and §54.1-3410.2 of the Code of Virginia.

B. The compounding of sterile drug products by an outsourcing facility or by a pharmacy sharing the same physical space with an outsourcing facility shall be performed in accordance with current Good Manufacturing Practices published by the U. S. Food and Drug Administration.

Agenda Item: Adoption of Proposed Regulations for a Prohibition on Incentives to Transfer Prescriptions

Included in your agenda package are:

A copy of the Notice of Intended Regulatory Action

Copies of comment on the NOIRA

Draft proposed regulation based on language from other states

Board action:

Adoption of proposed regulations as drafted or as amended

Notice of Intended Regulatory Action

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

Promulgating Board: **Board of Pharmacy**

NOIRA Notice: Notice is hereby given in accordance with § 2.2-4007.01 of the Code of Virginia that the Board of Pharmacy intends to consider amending the following regulations

Chapters Affected:

18 vac 110 - 20: Virginia Board of Pharmacy Regulations

Action Title: Prohibition against incentives to transfer prescriptions

The purpose of the proposed action is summarized as follows:

Agency Summary: The new provision would prohibit advertising or soliciting in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing a patient to transfer a prescription absent professional rationale by use of coupons, rebates, etc. The action responds to a petition for rulemaking from a Virginia pharmacist who is concerned about medication safety and errors because of incomplete drug profiles and drug utilization reviews.

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

Is a public hearing planned for the proposed stage? Yes

Public comments may be submitted until 5:00 p.m. on 12/16/2015.

Link to Regulatory Action on Townhall:

<http://townhall.virginia.gov/L/viewstage.cfm?stageid=6973>

Caroline Juran, RPh
Executive Director

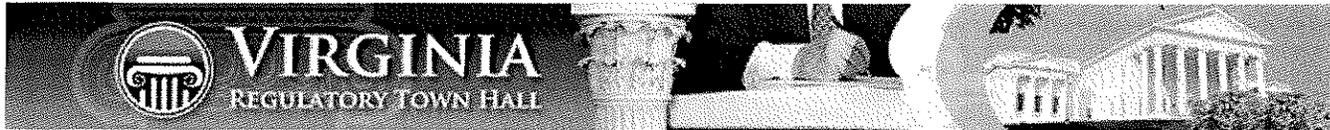
Agency Contact: (804)367-4416
(804)527-4472
caroline.juran@dhp.virginia.gov
Department of Health Professions

Contact Address: 9960 Mayland Drive

Suite 300
Richmond, VA 23233-1463

APA Compliance: This regulation has been adopted in accordance with the Administrative Process Act.

Virginia.gov Agencies | Governor



Agency Department of Health Professions

Board Board of Pharmacy

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

Action	Prohibition against incentives to transfer prescriptions
Stage	NOIRA
Comment Period	Ends 12/16/2015

All comments for this forum

[Back to List of Comments](#)

Commenter: Lauren Caldas *

11/20/15 11:22 pm

Against Transfer Incentives

To whom it may concern,

Please consider the banning of transfer incentives. This practice of incentivizing patients to change pharmacies multiple times solely based on coupon accumulation, is not only embarrassing for the profession but also opens us to unsafe medication practices. There is a potential for transcribing errors and also patients may accumulate unnecessary prescriptions solely based on financial outcome (ex. A patient buys unneeded \$4 prescription because can get \$25 coupon). The burden it places on pharmacies continues to create an unsafe working place. I cannot think of any other medical practice that give incentives for switching practices.

Please consider that this practice continues the public impression that pharmacies are equivalent to Cellular plans or Car insurance instead of as hospitals or medical practices. We should behave as professionals if we hope to be thought of as such in the public eye. Please end the gimmicks of transfer coupons.

Thank you.

Commenter: Katie Clasen *

11/21/15 12:11 am

Ban prescription transfer incentives

Patient safety is jeopardized by incentivizing prescription transfers. Patients end up with multiple pharmacies, each with a partial list of medications, and without a complete list, pharmacies can miss drug interactions and duplications of therapy. Although every attempt is made to ensure accurate transfer of information, each transfer does introduce an opportunity for

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transcription error. In addition, transfers done solely for the sake of a coupon add a significant and unnecessary burden to an already heavy workload.

We know that the best practice is to have coordinated care where all the players (doctors, pharmacists, nurses, patients, etc) have complete and accurate information, and the practice of encouraging prescription transfers through coupons and other incentives completely undermines this ideal.

Commenter: Brian Quigley R.PH. *

11/28/15 8:25 pm

PROHIBITION AGAINST INCENTIVES TO TRANSFER PRESCRIPTIONS

I am against incentives to transfer prescriptions. Pharmacist are here to help protect the public by looking for interactions of drugs and by knowing the patient and the medications they are taking. Every time you transfer a prescription you are adding another layer of chance that a interaction with some of the medicine they are already taking will be missed. Also, the prescription being transfered may be misinterpreted by the other pharmacy. To have people move prescriptions around from pharmacy to pharmacy because of a coupon offer is just adding another layer for mistakes to happen. Please consider that coupons put an added stress level on the Pharmacists, who are here to protect the public.

Commenter: Robert M. Rhodes, Pharmacist *

11/30/15 4:38 pm

Transfer coupons

This is one of the most dangerous things that are allowed and endorsed by the Virginia State Board of Pharmacy.

It has patients transferring prescriptions that they really do not need just to get a gift certificate and encourages patients to poly-pharmacy. Many of these prescriptions are not run on insurance because they are cheaper on the store plan so therefore no record of what the patient is taken is available to the pharmacy.

The duty of the Board is to protect the welfare and safety of the consumer. I believe that the NABP does not endorse coupons.

Coupons and gift cards also can not be used for prescriptions only on other store goods so no real benefit that outweighs the danger.

Coupons have no place in our profession and should have been addressed long ago.

Commenter: Robert M. Rhodes, Pharmacist *

11/30/15 5:20 pm

transfer coupons

Promotions end for consumers who transfer prescriptions



By Laura Gunderson | The Oregonian/OregonLive

Email the author | Follow on Twitter

on July 21, 2012 at 3:00 PM, updated July 21, 2012 at 3:22 PM

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Oregonian Pharmacies in Oregon can no longer offer deals to customers who transfer prescriptions. Such promotions, offering free gas, groceries and gift cards, gained popularity in recent years. However, local pharmacists said that when customers constantly switched prescriptions it became difficult for them to track what drugs they were taking and how they would interact.

In the past few years, many consumers have become expert pharmacy hoppers.

If Walgreens offered a \$25 gift card for transferring a prescription, off they'd trot to Walgreens. When Safeway made a similar deal a few months later, they'd switch their regular prescription to the grocer. The promotions were plentiful, offered by such big players as Fred Meyer, Target and Rite Aid -- each offering a range of extras, from free groceries to gasoline gift cards.

But in Oregon, such hopping has been halted.

The Oregon Board of Pharmacy voted last month to fine or revoke the licenses of pharmacies that offer promotions encouraging prescription-holders to switch. It also forbids retailers from guarantees on how quickly prescriptions will be ready -- programs that sometimes resulted in

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varying "punishments" for pharmacy employees when deadlines weren't met.

The changes were spurred by a survey the state board offered to its 5,700 licensed pharmacists last summer. The board was surprised when 1,300 responded online and another 500 sent in written responses, all sharing their concerns about unsafe working conditions that they felt put patients at risk.

"Every time a pharmacist dispenses a prescription, they review the patient's list of drugs to be sure there are no inconsistencies and that the new drug won't interact with another," said Gary Schnabel, executive director of the Oregon Pharmacy Board and past president of the National Association of Boards of Pharmacy.

"Every time a consumer switches pharmacies it breaks that chain," he said. "And every time you break that chain, a patient is more at risk."

Transfer offers became common and quite popular over the past few years, although Schnabel said he's not seen any data outlining the number of consumers who participated in them locally.

As with other deals through the recession, cash-strapped consumers welcomed ways to offset prescription costs with the variety of bonuses. So-called "mommy bloggers," who often share money-saving tips, regularly highlighted prescription-switching deals. One site that collects information geared for women readers recently included this "tip":

"Whenever Target runs their prescription promotion, my mom gets extra coupons from her friends and family. She has their prescriptions filled using the coupon, which gives her a \$10 gift card for each prescription... The promotions are a great way to help your dollars go further."

Schnabel said that during hearings on the issue he heard of a consumer who kept filling a prescription that was no longer needed to take advantage of the promotions.

In general the programs were offered at larger retail pharmacies. Independents, which make up about 200 of the 750 retail pharmacies statewide, didn't typically offer the transfer deals, Schnabel said.

Signs went up recently at Walgreens warning pharmacy customers that it could no longer honor its \$25 transfer coupons. Other retailers such as Fred Meyer, which offered such deals a few times a year, will simply stop the promotions.

Fred Meyer spokeswoman Melinda Merrill said the grocer will continue its practice of rewarding loyalty-card holders with points toward gas discounts each time they fill prescriptions.

"These retailers are creative and they can still do all kinds of marketing around rewarding those who stick around," Schnabel said. "The point of this rule is not to rein in what businesses are doing, we want them to be healthy, too -- just not at the expense of the public interest."

* Nonregistered public user

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VIRGINIA PHARMACISTS ASSOCIATION

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December 9, 2015

Caroline Juran, R.Ph.
Executive Director
Virginia Board of Pharmacy
9960 Mayland Drive
Henrico, VA 23233
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Comments on NOIRA: "Prohibition against incentives to transfer prescriptions"

Dear Ms. Juran,

The Virginia Pharmacists Association (VPhA) is pleased to provide comments in support of the NOIRA: "Prohibition against incentives to transfer prescriptions". These comments echo the comments we provided to the Board in January 2014 in response to the original petition for rulemaking.

The Virginia Pharmacists Association has the following policy concerning the use of pharmacy coupons and transfer incentives:

12-B01 Use of Pharmacy Coupons and Transfer Incentives

The Virginia Pharmacists Association recognizes the use of pharmacy competitor prescription coupons and other transfer incentives may encourage poly pharmacy. The use of these incentives does not facilitate the goal of a concise medical home or complete medication record for review by the pharmacist(s). Whereas the use of prescription coupons in the form of manufacturer coupons can assist patients with compliance to their medication regimen, VPhA discourages the use of transfer coupons and transfer incentives among pharmacies. Transfer coupons and other transfer incentives fragment the medication record of patients which leads to inaccuracies in the medication records and is detrimental to patient care. VPhA advocates for the use of a single pharmacy for pharmaceutical services and promotes the prescriber-pharmacist-patient relationship.

We encourage the Board to develop strong regulations that will eliminate these dangerous incentives from being offered in the Commonwealth.

Sincerely,



Timothy S. Musselman, Pharm.D.
Executive Director

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DRAFT Proposed Regulation

Prohibition on Incentives to Transfer Prescriptions

18VAC110-20-25. Unprofessional conduct.

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

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;
2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;
3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;
4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;
5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;
6. Failing to maintain adequate safeguards against diversion of controlled substances;
7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;
8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;
9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~
10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing; or

11. Advertising or soliciting in a manner that may jeopardize the health, safety and welfare of a patient, including incentivizing or inducing the transfer a prescription absent professional rationale by use of coupons, rebates, or similar offerings.

DRAFT

Agenda Item: Adoption of Final Regulations on setting certain conditions on work hours for pharmacists

Included in your agenda package are:

A copy of the Notice of Comment on Proposed Regulations

Copies of comments

Proposed regulation as published

Board action:

Adoption of final regulations as proposed or as amended

Notice of Public Comment: Proposed Action on Regulations

Elaine J. Yeatts
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Promulgating Board: **Board of Pharmacy**

Chapters Affected		Action Type
18VAC110 - 20:	Virginia Board of Pharmacy Regulations	Amend

Action Title: Addressing hours of continuous work by pharmacists

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

Is a public hearing planned for the proposed stage? Yes

Public Hearing Dates: 12/1/2015: 09:00 am
Perimeter Center, 9960 Mayland Drive, Suite 201, Board Room 2,
Richmond, VA 23233

Public comment deadline: 1/29/2016.

Previously Published: The NOIRA was previously published on 9/10/2012
Register Issue: Volume: 29 1

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Department of Health Professions

Contact Address: 9960 Mayland Drive
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APA Compliance: This regulation has been adopted in accordance with the Administrative Process Act.

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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	<u>Addressing hours of continuous work by pharmacists</u>
Stage	<u>Proposed</u>
Comment Period	Ends 1/29/2016

All comments for this forum

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Commenter: Robert Rhodes, Pharmacist *

12/1/15 8:58 pm

Continuous hours worked

First let me say , I have worked 10-12 hours shifts in my career. I was fortunate to have partners and staff that allowed us to take lunch breaks and dinner breaks away from the counter.

With that said, I think that breaks should be at least 15 minutes long and lunch or dinner breaks should be a minimum 30 minutes away from the pharmacy . To insure public safety is the duty of the Board of Pharmacy.

It is a proven fact that long hours and reduced help can contribute to errors and cause harm to patients.

I also feel that if you work a 10 or 12 hour shift having only a 6 hour rest between turn around. It should be at least 8 hours at a minimum

Commenter: T Barksdale *

12/3/15 12:45 pm

Pharmacy Hours

As a 2016 graduate who has worked for a major retail chain as a pharmacy technician, intern, and signed as a future staff pharmacist. I have seen pharmacists pull thirteen hour days with no overlap or extra pharmacist help. I have seen it done successfully and done not so successfully. I think the main issue isn't necessarily telling pharmacist that they get a 30minute break evry 6 hours... because most companies "tell" them that and to utilize their breaks, but these pharmacist sacrifice those "breaks" because they have goals, times, and script deadlines etc. imposed by their companies and non-patient customers to meet. I feel that in order to protect all pharmacists. Pharmacy's should be required to have a 2 thirty minute windows in which no prescriptions will be filled so a pharmacist can have a true break. It's hard to sit down for your lunch, when you can't stop patient from dropping off prescriptions. Once they drop them off and are filled by technicians, someone has to check them. So the pharmacist who is on "break" still has to get up, run over to the counter, verify the prescriptions, and check it. But then, another patient spots the pharmacist and asks a question, needs a recommendation, the phone rings, and basically that break is over.

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Pharmacies should be required to shut down at least 30 minutes to 1 full hour a day for a lunch. This would give everyone a time to PAUSE and regroup. I don't believe it's the long 13 hour days that are the issue. It's pharmacist feeling that if they take that 30minute to 1 hr break that they will be so behind and can't recover for the day. It's patients and consumers not understanding that retail pharmacy is not a McDonald's restaurant we can NOT premake all their orders an just hand it to them. It's medicine and can be deadly if mixed up incorrectly or wrong drug is given to the wrong patient.

All retail chain stores with pharmacies operating more than 12 hours a day should be closed to the public for atleast 30 minutes to 1 hour. A lot of docotors offices have a 30 minute to 1 hour break for lunch, so the medication centers for a community should do.

Monday through Friday most retail stores are open from 8am to 9pm, these shifts are doable and if the company was required to pause for 30 minutes, what a difference that would make for the whole team. Now on weekends, there are normally sortened hours and I don't think that a mandatory shut down would be needed. But, yes, lunch breaks should be required for all pharmacists and in order to protect these pharmacist from abusing themselves while trying to meet employer goals, the companies should be held to a mandatory 30 minute or 1 hour (they can choose) lunch shutdown. This could count to their employees lunch breaks as well, so if everyone took lunch at same time it would save them from having dips in production etc. when people have to keep switching out for breaks. Everyone would win and pharmacists can still keep their flexible shifts and have a day or two off for the week if they are completing longer shifts each day.

Commenter: anonymous, former Pharmacy Tech, Current Intern & PharmD. 12/3/15 2:39 pm
Candidate *

Pharmacist Hours

The hours in healthcare are not easy by any means and requires a certain type of individual with passion and precision for their field. This seems to be aimed more towards retail pharmacy, which I am glad to see. I do approve of the message being sent by this regulation, however it is flawed. A previous commenter made a solid point in which yes many corporations give or even require pharmacists to have an adequate break. However, those that have actually worked in retail know that customers that are regulars, or impatiently waiting for a medication, in a critical state etc can see the pharmacist during their break and ask for the service. A pharmacist is rarely going to say " I'm currently on my break, can you come back later." I believe that there needs to be a separate/ floater/ oncall pharmacist to cover for the pharmacist on break (I've worked for places where there is only one for the 12 hr day) or that the pharmacy shuts down for the 30 min break (less patient friendly option and more prone to robbery/ diversion) and that the pharmacist needs to vacate the premises during break with the white coat OFF. I also believe that if a pharmacist wants to work, or is basically forced to work more than 12 hours due to unforeseen causes etc, that the break should be 30 mins every 4 hours and be paid time and a half for those not on salary and some type of equivalent for those on salary.

Commenter: Wendy Klein, MD * 12/3/15 4:16 pm

Common sense

I am writing in staunch support of 18 VAC110-20-110, which would limit continuous work hours for pharmacists to not more than 12 continuous hours in a a work day and which would offer a 30 minute break after 6 hours. It is unconscionable that this even needs to mandated. Decent

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standards such as these are simple common sense, and will increase productivity by reducing fatigue and improving concentration. These rules should apply to all, but especially to those in a field such as this that demands intense attention to detail.

Commenter: anonymous, pharm.D. candidate *

12/5/15 12:24 am

how to implement this?

This law has no meaning unless pharmacists are 'required' to leave their stores for that 30 minutes. As a pharmacy technician, I often don't get to take the 30 minutes break although there is a law that mandates it and my company does not provide any compensation for that 30 minutes of my work. Many companies are cutting technician hours and do not provide enough tech helps for pharmacists. Knowing how busy my pharmacist is, often times I cannot just leave the pharmacy to get my lunch break alone. It is shocking how many pharmacists are not eating anything and standing on feet for whole 12 hour shift, but this is reality. This should be changed.

Commenter: Ifeanyi Ogbonna, Shenandoah University School of Pharmacy *

12/5/15 12:32 pm

Pharmacists 30 Minutes Break

As a student pharmacist and pharmacy intern at CVS pharmacy, I have seen what it is with pharmacists not allowed to take a 30 minutes break in a 13 hours shift. In my opinion, this is not the best way to go about the profession because the body as we all know needs some rest at some point. Working for 12 hours without break may affect the pharmacist performance with can indirectly affect the treatment/services patients get from pharmacists.

Commenter: 2016 Pharm D candidate *

12/24/15 2:43 pm

Pharmacist 12 hour/d restriction

I do not think that limiting a pharmacist to a 12 hour day will fix the issue that they are not taking breaks. Pharmacies should be allowed to break/shut down for at least 30 minute a day and not be obligated to take waiters, or fill prescriptions during this time unless there was an emergency situation to arise. However, most emergencies would land the patient in the ER and not their local retail chain store. Pharmacists whether working 8,10,or 13 hours a day shouldn't be limited.The hours worked isn't the problem, it's pharamcist not being allowed in "real life" to take a 30 minute break although their cooperations, etc. tell them to. Many community pharmacists (unless completely caught up or are priviledged to work in a store with overlap) feel too burdened to actually take the time and this is the problem. The problem is the community pharmacy system and the catering to unnecessary customer complaints due to their "fast food" concept of pharmacy drive-thru and dispencing services. Pharmacists need the Board to back them up and legally profess that all pharmacies must halt production for at least 30 minutes each day if the work day is 12 hours or more to insure that a pharmacist can truly rest and restore in order to increase patient safety.

Commenter: Tiffany Johnson, pharmacist *

1/1/16 4:52 pm

Mandatory break after 6 hours

Thank you for bringing the topic of 12-hour+ work days to our attention. As a pharmacist that works 12-hour shifts In a community setting, I would truly appreciate the break to reduce mental and

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physical fatigue. I feel that with a break I would be more confident in keeping public safety at the forefront of my profession. Knowing that I am the final check during the 12-hour shift leaves an immense burden that could safely be minimized through mandatory breaks. Thank you again for your consideration. Please favorably find the proposed regulation for increasing public safety.

Commenter: Drug Topics *

1/4/16 12:40 pm

How Pharmacy Metrics Affect Our Profession

Anonymous Jan 2, 2016

All that I know was that where I live the 2 CVS pharmacy managers with > 20 years each with the company were fired on the same day rumored to be due to "metrics". A recent graduate I know had an interview with CVS and was told "they are slowly weeding out the old guys". After double-digit years of above average reviews with my company I was given a poor rating by a new supervisor (no longer with the company) and demoted from my position to fast-track another employee to a supervisor position (that didn't happen). A pharmacist locally in a third company spoke his mind to a supervisor (no such thing as an open door policy) and was subsequently transferred to a more remote location from where he lives. All levels of management live on metrics only. Work hard, do your job, take care of your patients but don't completely trust your management at any level.

Commenter: Drug Topics *

1/4/16 12:41 pm

How Pharmacy Metrics Affect Our Profession

Anonymous May 6, 2015

I worked for Walgreens for 12 years in San Diego and 2 years at CVS between 2010 and 2014. CVS in San Diego create an extremely hostile working environment for ALL store and pharmacy employees especially pharmacists. I have been a floater pharmacist for CVS since 2008 and I have seen it all. In 2008, they hired a 30 year old Pharmacy District Supervisor who came in and fired and harassed numerous of older pharmacists INSIDE the pharmacy, using derogatory term regarding their age and performance based on CVS metrics. Terms like you are too old to work or too slow. They wrote up numerous counselings on pharmacists, pharmacist techs daily, weekly and fired them at their wish. They keep moving pharmacists around against their will to other stores and keep replacing with new pharmacy graduates and FORCED them to be pharmacist managers or get fired. They took advantage of the 2007 economic crisis and the abundance of pharmacists to keep threaten pharmacists to comply with their metrics or else face the ultimate penalty of getting fired. I have personally seen numerous of firings of pharmacists, techs on the job without any justifications. The average lifespan of a pharmacy manager is 6 months. Pharmacists are leaving CVS at an alarming rate. The 'don't care" and "it's me or the "highway" attitude display CVS' arrogance and disrespect for human dignity is beyond imagination.

Commenter: Drug Topics *

1/4/16 12:44 pm

Age Discrimination and the Use of Pharmacy Metrics

Anonymous Apr 3, 2015

I am 68 years old and after 6 months working at a CVS pharmacy that had been open for 10 months I was given a choice of having my hours cut from 30 hours/week to 5-10 hours/week. This store has never met it's metric goals. This was part of their solution!? I was told that my job

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performance was fine. Also at a earlier date we were told that we could only take at most a 15 minute break to eat something or eat while working or not at all. This is when working 10-14 hour shifts. The possibility for med errors increase under these conditions. It is my opinion that CVS does not care about employee or patient health. I do not understand how stopping the sale of tobacco but continue to sell alcohol shows real concern over a persons health.

Commenter: Drug Topics *

1/4/16 12:45 pm

Metrics equal Corporate Bullying

AnonymousApr 1, 2015

Oh yeah? And I can present to the clown DeAngelis the write ups that led to the termination of my partner(who was about 60)and me(nearly 40). The write ups specifically say, and I quote"on performance warning for failing to exhibit the ability to deliver and drive various business results. Some of which include" PCI(AO, NSPU) KPM and Service targets" This write up was copied and pasted by my DM 3 times. I was explicitly told to my face that they have a big line of new grads willing to take my job. More, according to my DM running a store dispensing 400-500 prescriptions per day with 1 pharmacist and 1-2 techs is perfectly fine, as long as you can manage your techs.

Commenter: Drug Topics *

1/4/16 12:47 pm

Metrics are More Important than Patient Health

AnonymousMar 31, 2015

...the same unfair criminal practice happened to me back in Las Vegas 2010,the vice president of operations for the whole District made up a special metric system just for me because I questioned in a big meeting when he he announced all pharmacist are expected to, on their days off, to go out, no reimbursement ,procure and work to generate flu shot clinics saying it was part of the job description when we got hired. He then forced me to sign a special document, that no other R.Ph had to sign, saying I had to meet metrics of 95% across the board, and that I was going to be reevaluated every two weeks and if I did not meet those metrics, I would than be rated as "not meeting expectations". I than got ahold of HR who got the document dismissed, but I was forced to quit because superiors started coming in once a week 'writing' me up, for example a dirty sink, due to a few smudges. Doing more than 600 rx's a day as well as immunizing,no overlap coverage, they than cut my tech grid weekly from 325 hr to 175,20% reduction every week. Unfair labor practices permeate this whole organization.

Commenter: Concerned Pharmacist *

1/4/16 1:03 pm

Pharmacy Metrics Define the Future of Pharmacy Not Patient Health

What other health care profession can you go into that will guarantee you work long hours, without a formal break, and expected to fulfill dispensing quotas and a failure to do so WILL cost you your job-----PHARMACY. The state of retail pharmacy has changed for the worse. Due to all time low 3rd party reimbursement practices and an inability to compete with mail order pricing guidelines. The current retail pharmacy outlet faces EXTINCTION. Your conventional drug stores like CVS, Walgreens, and Rite Aid have employed Pharmaceutical Metrics to "justify" eliminating older pharmacist in exchange for lower paid pharmacists, right out of school, so they can pay them less money and overall inject Millions if not Billions of dollars into an industry to satisfy financial goals of the company while putting more veteran/skilled pharmacists out of work. They set up dispensing metrics which directly contradict what they say they want us to do, which is spend more time

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counseling and managing patients health care challenges and less time dispensing YET many of the company metrics are time sensitive in reference to completing the dispensing process, which endangers public safety and health. Pharmacist's today have to choose between taking care of patients needs or satisfying company metrics. If the company metrics aren't satisfied the company will surely seek retribution including no raises, working on days off without pay, or ultimately TERMINATION! The time is now for the governing board of our great profession to stand up and put a STOP to this corporate bullying and greed!

Commenter: Concerned Pharmacist *

1/9/16 3:59 pm

In support of mandatory breaks for pharmacists...

As pharmacists have moved from being employers to being employees, we have not been able to take some of the "luxuries" like bathroom breaks and lunch breaks with us. The pharmacy metric driven corporate philosophy has removed much of the pharmacists ability to be able to sit down for 30 minutes to refresh themselves. I have worked for an employer before that shut the phones off for 30 minutes each day so that the pharmacist could have a break and that was a great time to step away and gather yourself for the rest of the day. Patients got used to the lunch concept and were for the most part respectful of it. People could still drop off and pick up during this time but nothing would be checked during this time. We need the board to step in and require this for patient safety because without board support the corporations will never implement it.

* Nonregistered public user

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BOARD OF PHARMACY

Addressing hours of continuous work by pharmacists

Part IV

Pharmacies

18VAC110-20-110. Pharmacy permits generally.

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

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

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

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

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

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

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

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

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

Agenda Item: Adoption of Amendment by a Fast-track Action

Staff Note:

This recommended regulatory action arises from the following request:

Omnicare, a CVS Health Company, provides Long Term Care pharmacy services to a diverse population of skilled nursing patients in Virginia to include sub-acute care for children. Specifically, the children in these facilities suffer from complex physical and neurological diseases and experience frequent seizures. As a result, nurses assigned to these pediatric units need immediate access to Diastat Rectal gel in their stat boxes. Limiting the access to this critical medication will most certainly threaten a successful patient outcome up to and including the survival of the patient(s). Unfortunately, current pharmacy regulation 18VAC110-20-550 does not allow a CIV rectal gel to be included in the contents allowed in the stat box. We respectfully request 18VAC110-20-550.5.b be amended to include this dosage form (gel) to allow our pharmacists and others to meet the needs of this fragile population.

The recommendation is for an amendment to 18VAC110-20-540 for the emergency drug kit to include diazepamrectal gel.

Included in your agenda package are:

Information about diazepamrectal gel

A draft amendment to section 540

Board action:

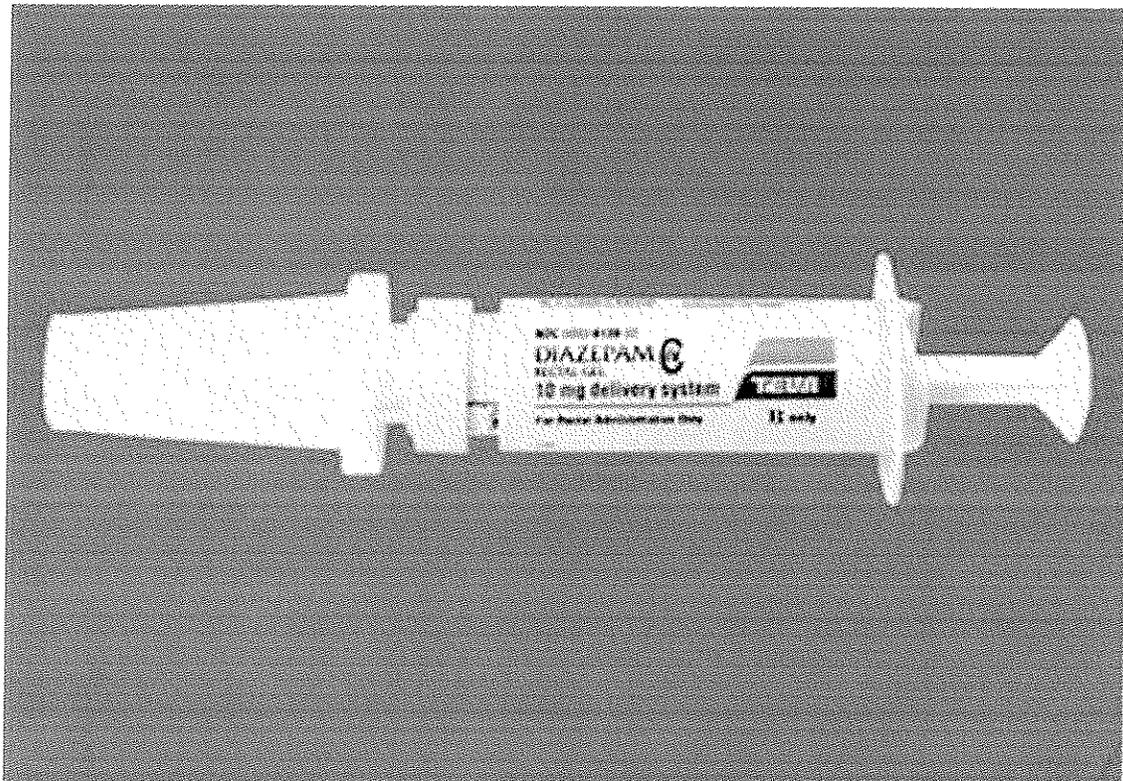
To amend section 540 by a fast-track action or to deny such an amendment.

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Yeatts, Elaine J. (DHP)

From: Lincoln, Michelle <Michelle.Lincoln@omnicare.com>
Sent: Wednesday, March 09, 2016 9:28 AM
To: Juran, Caroline (DHP); Irvin, William
Cc: Yeatts, Elaine J. (DHP)
Subject: RE: VA Board of Pharmacy - Request for Regulatory Review meeting on 3/24/16
Attachments: Diastat Rectal gel #2.JPG

Caroline,



Diastat AcuDial is available in varying mg delivery systems . The pharmacist dials the dose and locks it using the ring shown on the delivery system. The manufacturer actually supplies these in a twin pack in order to give a subsequent dose within 4 hours as needed (picture attached). Below are the delivery system units available and the doses that are available from each system.

Please let me know if you need more clarification.

Michelle

Diastat AcuDial is available in the following delivery system units: 2.5 mg, 10 mg, and 20 mg. The available doses from the 20 mg delivery system are 10 mg, 12.5 mg, 15 mg, 17.5 mg, and 20 mg. The available doses from 10 mg delivery system are 5 mg, 7.5 mg, and 10 mg. The 2.5 mg dose may also be used as a partial replacement dose for patients who may expel a portion of the first dose.

Proposed Amendment by Fast-track Action

18VAC110-20-540. Emergency drug kit.

The pharmacist providing services may prepare an emergency kit for a long-term care facility in which access to the kit is restricted to a licensed nurse, pharmacist, or prescriber and only these licensed individuals may administer a drug taken from the kit and only under the following conditions:

1. The contents of the emergency kit shall be of such a nature that the absence of the drugs would threaten the survival of the patients.
2. The contents of the kit shall be determined by the provider pharmacist in consultation with the medical and nursing staff of the institutions and shall be limited to drugs for administration by injection or inhalation only, except that Nitroglycerin SL and diazepam rectal gel may be included.
3. The kit is sealed in such a manner that it will preclude any possible loss of the drug.
 - a. The dispensing pharmacy must have a method of sealing such kits so 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 and/or resealing. The pharmacy shall maintain a record of the seal identifiers when placed on a box or kit and maintain the record until such time as the seal is replaced.
 - c. In lieu of seals, a kit with a built-in mechanism preventing resealing or relocking once opened except by the provider pharmacy is also acceptable.
4. The kit shall have a form to be filled out upon opening the kit and removing contents to write the name of the person opening the kit, the date, time and name and quantity of item(s) removed. The opened kit is maintained under secure conditions and returned to the pharmacy within 72 hours for replenishing.
5. Any drug used from the kit shall be covered by a prescription, signed by the prescriber, when legally required, within 72 hours.

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18VAC110-20-120. Special or limited-use pharmacy permits.

A. For good cause shown, the board may issue a special or limited-use pharmacy permit, when the scope, degree or type of pharmacy practice or service to be provided is of a special, limited or unusual nature as compared to a regular pharmacy service. The permit to be issued shall be based on special conditions of use requested by the applicant and imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:

1. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice.
2. A policy and procedure manual detailing the type and method of operation, hours of operation, schedules of drugs to be maintained by the pharmacy, and method of documentation of continuing pharmacist control must accompany the application.
3. The issuance and continuation of such permits shall be subject to continuing compliance with the conditions set forth by the board.

B. For a special-use pharmacy located in or providing services to a free clinic that uses volunteer pharmacists on a part-time basis with pharmacy business hours less than 20 hours a week, the board may grant a waiver to the restricted access provisions of 18VAC110-20-190 under the following conditions:

1. The access is only for the purpose of repairing or upgrading essential equipment or for the purpose of securing a delivered drug order in the pharmacy.
2. The PIC shall be notified prior to each entry and give permission for the designated, specific individuals to enter.
3. If entry is by a nonpharmacist, two persons must enter together, one of whom must be an employee or volunteer of the free clinic who holds a license as a nurse, physician, or a physician assistant. Both persons must remain in the pharmacy the entire time that access is required.
4. The key or other means of unlocking the pharmacy and the alarm access code shall be maintained in a secure location within the facility in a sealed envelope or other container with the name of the "sealing" pharmacist written across the seal. If a nonpharmacist accesses the pharmacy, this means of access may be used, and the licensed health professional, as set forth in subdivision 3 of this subsection, is responsible for resealing the means of access and writing his name across the seal. The PIC shall ensure that the alarm access code is changed within 48 hours. In lieu of the pharmacist's signature across a seal, the executive director for the board may approve other methods of securing the emergency access to the prescription department.
5. A log must be maintained of each nonpharmacist entry showing date and time of entry, names of the two persons entering, purpose for entry, and notation that permission was granted by the pharmacist-in-charge and the date it was granted. Such log shall be maintained on premises for one year.

§ 54.1-3320. Acts restricted to pharmacists.

A. Within the practice of pharmacy as defined in § 54.1-3300, the following acts shall be performed by pharmacists, except as provided in subsection B:

1. The review of a prescription, in conformance with this chapter and Chapter 34 (§ 54.1-3400 et seq.) of this title and with current practices in pharmacy, for its completeness, validity, safety, and drug-therapy appropriateness, including, but not limited to, interactions, contraindications, adverse effects, incorrect dosage or duration of treatment, clinical misuse or abuse, and noncompliance and duplication of therapy;
2. The receipt of an oral prescription from a practitioner or his authorized agent;
3. The conduct of a prospective drug review and counseling as required by § 54.1-3319 prior to the dispensing or refilling of any prescription;
4. The provision of information to the public or to a practitioner concerning the therapeutic value and use of drugs in the treatment and prevention of disease;
5. The communication with the prescriber, or the prescriber's agent, involving any modification other than refill authorization of a prescription or of any drug therapy, resolution of any drug therapy problem, or the substitution of any drug prescribed;
6. The verification of the accuracy of a completed prescription prior to dispensing the prescription;
7. The supervision of pharmacy interns and pharmacy technicians; and
8. Any other activity required by regulation to be performed by a pharmacist.

B. A pharmacy intern may engage in the acts to be performed by a pharmacist as set forth in subsection A or the Drug Control Act (§ 54.1-3400 et seq.) for the purpose of obtaining practical experience required for licensure as a pharmacist, if the supervising pharmacist is directly monitoring these activities.

C. A registered pharmacy technician, working under the direct supervision of a qualified nuclear pharmacist, as defined by regulations of the Board, may accept oral prescriptions for diagnostic, nonpatient specific radiopharmaceuticals in accordance with subsection C of § 54.1-3410.1.

D. Consistent with patient safety, a pharmacist shall exercise sole authority in determining the maximum number of pharmacy technicians that he shall supervise; however, no pharmacist shall supervise more pharmacy technicians than allowed by Board regulations.

(2001, c. 317; 2005, c. 403; 2006, c. 626; 2010, c. 90.)

§ 54.1-3321. Registration of pharmacy technicians.

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

1. The entry of prescription information and drug history into a data system or other record keeping system;
2. The preparation of prescription labels or patient information;
3. The removal of the drug to be dispensed from inventory;
4. The counting, measuring, or compounding of the drug to be dispensed;
5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;
6. The stocking or loading of automated dispensing devices or other devices used in the dispensing process;
7. The acceptance of refill authorization from a prescriber or his authorized agency, so long as there is no change to the original prescription; and
8. The performance of any other task restricted to pharmacy technicians by the Board's regulations.

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

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

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

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

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

From: CHAD W TOUSSANT [<mailto:>]
Sent: Tuesday, December 22, 2015 7:08 AM
To: Board of Pharmacy
Subject: Informatics as practice specialty

To whom it may concern:

When recently renewing my license, I was disappointed to find that Informatics is completely absent from the PGY2 residency and current pharmacy practice choices. We should certainly be represented as a practice specialty.

Please consider adding Informatics as a practice choice. Currently at Sentara Healthcare, we have 5 full time pharmacists in Informatics (up to the director level) and 1 pharmacy (PGY2) resident. With electronic medical records, this is a growing field and I'm sure the other health systems also have informatics pharmacists as well.

Thank you,
Chad Toussant, RPh
Sentara Healthcare

What Types of Residencies are Available?

Postgraduate Year 1—or **PGY1**—residencies provide training for “generalists” in health systems, managed care, or community settings.

Postgraduate Year 2—or **PGY2**—residencies provide advanced training in a focused area of patient care, including:

- Ambulatory care,
- Cardiology,
- Critical care,
- Drug information,
- Emergency medicine,
- Geriatrics,
- Immunology,
- Infectious diseases,
- Informatics,
- Internal medicine,
- Managed care pharmacy systems,
- Nuclear pharmacy,
- Nutrition support,
- Oncology,
- Pediatrics,
- Pharmacotherapy,
- Practice management or administration,
- Psychiatry, or
- Transplantation.

Note: You must complete a PGY1 (general practice) residency before going on to a PGY2 (specialized) residency.

For more information on the types of residencies available in programs across the U.S., check www.ashp.org.



American Society of
Health-System Pharmacists

7272 Wisconsin Ave. • Bethesda, MD 20814 • 301-657-3000 • www.ashp.org

Pharmacist Survey

Instructions:

The following survey will assist policymakers at the state, federal and local levels assess the adequacy of the current pharmacist workforce and project future workforce trends in relation to Virginia's changing population and health needs. It will help us advance the practice of pharmacy and to improve the health of all Virginians. By law, information collected as part of this survey is confidential. License numbers and other individually identifying information are removed from Healthcare Workforce Data Center data sets. The Healthcare Workforce Data Center only releases information in the aggregate or to qualified research organizations who meet our strict confidentiality standards. You may exit the survey at any time by scrolling to the bottom and pushing the "Submit" button or by clicking on the "Finish" button at the bottom of the left sidebar. Note: Clicking "Finish" will finalize your renewal application.

The survey questions are designed to allow comparisons across professions, and among state and federal data collection efforts. Some of the questions, particularly demographic questions, match Federal data collection standards.

Education and Background	
1) Year of Birth:	Dropdown: 2000 to 1920 (reverse order)
2) Sex:	Dropdown: Male/Female
Please select the items that best describe your race/ethnicity. Please answer both question 3a about Hispanic origin and 3b about race/ethnicity.	
3a) Select one:	Check one Hispanic, Latino or Spanish Origin Not Hispanic, Latino or Spanish Origin
3b) Select all that apply:	Check all that apply White Black or African American American Indian or Alaska Native Asian Native Hawaiian or Pacific Islander Some other race
3c) If some other race, please specify:	Fill in the blank
4) Where did you graduate from high school (Secondary School)?	
	Dropdown Outside of the US or Canada Canada 57 US States and Territories

5)	Was your childhood spent mostly in rural, urban or suburban areas?	Dropdown: urban, rural, suburban
6)	Where did you obtain your undergraduate degree?	Dropdown Did not obtain an undergraduate degree Outside of the US or Canada Canada 57 US States and Territories
7)	Where did you obtain the degree that initially qualified you to practice pharmacy?	Dropdown Outside of the US or Canada Canada 57 US States and Territories
8)	Please indicate the highest level of pharmacist education you have completed as of today:	Dropdown BS Pharm PharmD
9)	Do you hold an active license to practice pharmacy in any other jurisdiction?	Check all that apply District of Columbia Kentucky Maryland North Carolina Tennessee West Virginia One or more other US states
10a)	Please indicate any residencies you have completed as of today: Note: The list here is structured to match the current ASHP residency structure. General and clinical residencies were consolidated in 1993 into "pharmacy practice". The current PGY1/PGY2 structure was adopted in 2005. For those who completed residencies prior to these dates, please select the residency from either PGY1 or PGY2 that best matches your residency.	Dropdown Community Pharmacy Managed Care Pharmacy Pharmacy Practice (Post 1993) Pharmacy Practice (Pre-1993--Health Systems, Ambulatory Care, Clinical, etc.)

		Other
10b)	PGY2:	Dropdown
		Ambulatory Care
		Cardiology
		Critical Care
		Drug Information
		Emergency Medicine
		Geriatrics
		Health-system Pharmacy Administration
		Infectious Disease
		Informatics
		Internal Medicine
		Managed Care Pharmacy Systems
		Medication Safety
		Nuclear
		Nutrition Support
		Oncology
		Palliative Care
		Pediatrics
		Pharmacogenetics
		Pharmacotherapy
		Psychiatry
		Solid Organ Transplant
		Other
10c)	If you selected "other" for either residency, please provide a brief description and indicate whether the residency was PGY1 or PGY2:	Open-ended
11a)	Please indicate any Board Certifications for pharmacists you hold that are current as of today:	Check all that apply
		ABAT-Applied Toxicology
		BPS- Pharmacotherapy
		BPS-Ambulatory Care
		BPS-Nuclear Pharmacy
		BPS-Nutrition
		BPS-Oncology
		BPS-Psychiatric
		CCGP-Geriatrics
		Other



11b)	Please choose any self-designated specialty areas in which you practice and have advanced education, training, certification or experience:	Check all that apply:
		Ambulatory Care
		Anticoagulation
		Applied Toxicology
		Community Pharmacy
		Compounding
		Diabetic Educator
		Geriatrics
		Health Systems-Pharmacy Administration
		Immunization
		Managed Care
		Nuclear Pharmacy
		Nutrition
		Oncology
		Pharmacotherapy
		Psychiatric
		Other
11c)	If you have any other specialty areas or credentials, please provide short description:	open ended
Current Employment Status		
12)	Which choice best describes your current employment or work situation?	<p><i>Dropdown</i></p> <p>Employed in a pharmacy related capacity.</p> <p>Employed, NOT in a pharmacy related capacity.</p> <p>I am retired.</p> <p>Voluntarily unemployed (including for medical reasons).</p> <p>Involuntarily unemployed.</p>
13)	Overall, and taking into account all positions you fill, how satisfied are you with your current employment or work situation?	<p><i>Dropdown</i></p> <p>Very satisfied</p> <p>Somewhat satisfied</p> <p>Somewhat dissatisfied</p>

		Very dissatisfied
14)	How many positions do you currently hold? <i>Note: There is no legal standard for part-time work, and each employer defines part-time work differently. Part-time work generally refers to workweeks of 35-hours per week or less. Per diem, temporary, contract, self-employed and seasonal workers, and workers subject to annual limits on hours should consider average hours spent working over the term of employment.</i>	Dropdown One part-time position One full-time position Two part-time positions position Two full-time positions More than two positions
15)	Considering all positions you currently fill, how long is your average workweek?	Dropdown I am not currently working 1 to 4 hours 5 to 9 hours 10 to 14 hours 15 to 19 hours 20 to 24 hours 25 to 29 hours 30 to 34 hours 35 to 39 hours 40 to 44 hours 45 to 49 hours 50 to 54 hours 55 to 59 hours 60 to 64 hours 65 to 69 hours 70 to 74 hours 75 to 79 hours 80 or more hours
<p><i>Unless otherwise noted, the rest of the questions draws on your experiences over the past 12 months. If you did not work in the past 12 months in a capacity that drew on your pharmacy background, please skip to question 39.</i></p>		
<p>Primary Work Location</p>		

Questions 16 to 22 refer to your primary place of employment, work or practice (volunteer or paid) over the past 12 months. This is the location where you spend the most work hours during an average workweek or where you spent the most weeks working in the past 12 months. You do not need to currently work at this location. These questions refer to a location, not an employer. Persons who consistently work in multiple locations (e.g. temporary workers, home health, multi-facility rounds) should choose the location where they are based.

<p>16) Please select the Virginia County or Independent City, or other location, of your primary place of employment, work or practice:</p>	<p>Dropdown: Outside of US Virginia Border State/DC Other US State List of Virginia's Cities and Counties</p>
<p>17) How long have you worked at this particular location?</p>	<p>Dropdown I do not currently work at this location Less than 6 months 6 months to 1 year 1 to 2 years 3 to 5 years 6 to 10 years More than 10 years</p>
<p>18a) Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc.):</p>	<p>Dropdown: 1 week - 52 weeks</p>
<p>18b) How many hours do you (or did you) work in an average workweek at this location?</p>	<p>Dropdown 1 to 4 hours 5 to 9 hours 10 to 14 hours 15 to 19 hours 20 to 24 hours 25 to 29 hours 30 to 34 hours 35 to 39 hours 40 to 44 hours 45 to 49 hours 50 to 54 hours 55 to 59 hours 60 to 64 hours 65 to 69 hours</p>

	Home Health / Infusion
	Pharmacy Benefit Administration (e.g. PBM, n
	Academic Institution
	Wholesale Distributor
	Manufacturer
	Other
20c)	If you selected "other practice setting" please provide a brief description: Open-ended
21)	Please choose the option that best describes how you are (or were) personally compensated for activities at this location: Dropdown Business/Practice Income (including salary as owner/partner) Salary/Commission (excluding salary as owner/partner) Hourly wage By contract, per diem, traveling Volunteer, unreimbursed
22)	Do you provide any of the following services at this location? Check all that apply Telepharmacy: Off-site collaboration using telephone, video or other telecommunications devices. Central filling Collaborative Practice Agreement Compounding Medication Therapy Management Remote consulting/telepharmacy Remote order processing
If you only had one practice location in the past 12 months, please skip to question 33. If you had additional practice locations, please continue.	
Secondary Work Location	
Questions 23 to 30 refer to your secondary place of employment, work or practice (volunteer or paid) over the past 12 months. This is the location where you spend the second most work hours during an average workweek or where you spent the second most weeks working in the past 12 months. You do not need to currently work at this location. These questions refer to a location, not an employer. Persons who consistently work in multiple locations (e.g. temporary workers, home health, multi-facility rounds) should choose the location where they are based.	



<p>23) Is this location with the same employer or practice as your primary location, or a different employer/practice?</p>	<p>Dropdown Same employer or practice Different employer or practice</p>
<p>24) Please select the Virginia County or Independent City, or other location, of your secondary place of employment, work or practice:</p>	<p>Dropdown: Outside of US Virginia Border State/DC Other US State List of Virginia's Cities and Counties</p>
<p>25) How long have you worked at this particular location?</p>	<p>Dropdown I do not currently work at this location Less than 6 months 6 months to 1 year 1 to 2 years 3 to 5 years 6 to 10 years More than 10 years</p>
<p>26a) Approximate number of weeks at which at least some time was spent at this work location within the past twelve months (exclude vacation, medical leave, etc):</p>	<p>Dropdown: 1 week - 52 weeks</p>
<p>26b) How many hours do you (or did you) work in an average workweek at this location?</p>	<p>Dropdown 1 to 4 hours 5 to 9 hours 10 to 14 hours 15 to 19 hours 20 to 24 hours 25 to 29 hours 30 to 34 hours 35 to 39 hours 40 to 44 hours 45 to 49 hours 50 to 54 hours 55 to 59 hours 60 to 64 hours 65 to 69 hours 70 to 74 hours</p>

		75 to 79 hours
		80 or more hours
27)	In the average workweek at this location, roughly what percentage of your working hours were spent in the following roles: (Answers should roughly equate to 100%).	Dropdown: (for each sub-question)
27a)	Patient Care (including medication dispensing, direct patient care, patient education, reviewing charts, etc.)	1% to 9%
27b)	Administration (including recordkeeping, third-party billing, business management, wholesale distribution, manufacturing, etc)	20% to 29%
27c)	Formal Research (including practice-based research)	30% to 39%
27d)	Education (including preceptoring)	40% to 49%
27e)	Other	50% to 59%
		60% to 69%
		70% to 79%
		80% to 89%
		90% to 99%
		100%
28a)	Please select the choice that best describes this location's organizational sector:	Dropdown
		For-profit (e.g. private practice, corporate)
		Non-profit (including religious affiliated)
		State/local-government
		US military
		Veteran's Administration
		Other federal government
28b)	Please select the choice that best describes this practice setting:	Dropdown:
		Independent Community Pharmacy (1-4 store)
		Small Chain Community Pharmacy (5-10 store)
		Large Chain Community Pharmacy (11+ store)
		Mass Merchandiser (i.e. Big Box Store)
		Supermarket Pharmacy
		Clinic-Based Pharmacy
		Mail Service Pharmacy
		Hospital / Health System, Inpatient
		Hospital / Health System, Outpatient
		Nursing Home, Long Term Care
		Home Health / Infusion
		Pharmacy Benefit Administration (e.g. PBM, n
		Wholesale Distributor

Employment Information

The Healthcare Workforce Data Center collects compensation information to assess the balance of supply and demand in the state and in localities, and to assist students in planning health careers and choosing specialties. Information from these questions will only be presented in the aggregate. The confidentiality of information for these and all questions is protected by law. All questions are voluntary.

33) Within the past 12 months, have you experienced any of the following:	Check all that apply
	Voluntary unemployment (including for medical reasons)?
	Involuntary unemployment?
	Switched employers/practices?
	Worked part-time or temporary positions, but would have preferred a full-time or
	Worked two or more positions at the same time?
34) What is your estimated annual income (before taxes, net of business expenses) from pharmacy-related activities?	Dropdown:
	Volunteer work only
	Less than \$40,000
	\$40,000-\$49,999
	\$50,000-\$59,999
	\$60,000-\$69,999
	\$70,000-\$79,999
	\$80,000-\$89,999
	\$90,000-\$99,999
	\$100,000-\$109,999
	\$110,000-\$119,999
	\$120,000-\$129,999
	\$130,000-\$139,999
	\$140,000-\$149,999
	\$150,000-\$159,999
	\$160,000-\$169,999
	\$170,000 or more
35) Do you receive any of the following benefits from any current employer?	Check all that apply:
	Paid Vacation Leave
	Paid Sick Leave
	Health Insurance
	Dental Insurance

		Retirement (401k, Pension, etc.)
		Group Life Insurance
		Signing/retention bonus
36)	What is your estimated current educational debt?	<i>Dropdown:</i>
		None
		Less than \$10,000
		\$10,000-\$19,999
		\$20,000-\$29,999
		\$30,000-\$39,999
		\$40,000-\$49,999
		\$50,000-\$59,999
		\$60,000-\$69,999
		\$70,000-\$79,999
		\$80,000-\$89,999
		\$90,000-\$99,999
		\$100,000-\$109,999
		\$110,000-\$119,999
		\$120,000-\$129,999
		\$130,000-\$139,999
		\$140,000-\$149,999
		\$150,000-\$159,999
		\$160,000-\$169,999
		\$170,000-\$179,999
		\$180,000-\$189,999
		\$190,000-\$199,999
		\$200,000 or more
37)	At what age do you plan to retire from pharmacy?	<i>Dropdown</i>
		Under age 50
		50 to 54
		55 to 59
		60 to 64
		65 to 69
		70 to 74
		75 to 79
		80 or over
		I do not intend to retire
38)	Within the next two years do you plan to do any of the following:	<i>Check all that apply</i>

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		Retire
		Cease working in pharmacy
		Continue working in pharmacy, but cease working in Virginia
		Increase patient care hours
		Decrease patient care hours
		Increase time spent teaching pharmacy
		Decrease time spent teaching pharmacy
		Pursue additional pharmacy education
End of Questionnaire for active practitioners-Thank you!		
39)	If you did not practice, teach or otherwise work in pharmacy within the past twelve months, did/are you . . . ?	<p>Check all that apply:</p> <p>I am retired.</p> <p>Work occasionally for charity/consultation/special patients?</p> <p>Pursue pharmacy education or certifications?</p> <p>Pursue education not related to pharmacy?</p> <p>Work in another profession or field?</p> <p>Experience temporary voluntary unemployment (including for medical reasons)?</p> <p>Experience temporary involuntary unemployment?</p>
40)	Do you provide any pharmacy-related volunteer, mentoring or other services in Virginia? If so, approximately how many hours in the past year?	<p>Dropdown:</p> <p>None</p> <p>1-25 hours</p> <p>26-50 hours</p> <p>51-75 hours</p> <p>76-100 hours</p> <p>Over 100 Hours</p>
41)	Do you expect to begin working in Pharmacist in Virginia? If so, when?	<p>Dropdown:</p> <p>Not currently planning to practice/work in Virginia</p>

		Plan to practice/work in a volunteer capacity
		Yes, within the next year
		Yes, within 1-2 years
		Yes, within 3-5 years
		Yes, in more than 5 years
		Yes, do not know when
End of Questionnaire-Thank you!		

Protocol for the Prescribing and Dispensing of Naloxone

Pharmacists shall follow this protocol when dispensing 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 opiate overdose as authorized in §54.1-3408.

- 1) **Procedure:** When someone requests naloxone, or when a pharmacist in his or her professional judgment decides to advise of the availability and appropriateness of naloxone, the pharmacist shall:
 - a) Provide counseling in opioid overdose prevention, recognition, response, administration of naloxone, to include dosing, effectiveness, adverse effects, storage conditions, shelf-life, and safety. Recipient cannot waive receipt of this counseling, unless pharmacist is able to verify successful completion of REVIVE! training program.
 - b) The pharmacist shall provide the recipient with the current REVIVE! brochure available on the Department of Behavioral Health and Developmental Services website at <http://dbhds.virginia.gov/library/document-library/osas-revive-pharmacy-dispensing-brochure.pdf> If the recipient indicates interest in addiction treatment, recovery services, or medication disposal resources at this time, the pharmacist may provide information or referrals to appropriate resources.
- 2) **Product Selection:** The pharmacist who dispenses naloxone pursuant to an oral, written or standing order shall dispense the drug and other items for the kit as prescribed and in accordance with this protocol.
- 3) **Standing Order:** In addition to dispensing naloxone pursuant to an oral or written order, a pharmacist may dispense naloxone pursuant to a standing order. A standing order shall be valid for no more than two years from the date of issuance and shall contain the following information at a minimum:
 - a) Name of pharmacy authorized to dispense naloxone pursuant to standing order;
 - b) Contents of kit to be dispensed for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration, to include quantity of drug and directions for administration;
 - c) Prescriber's signature; and
 - d) Date of issuance.

4) Kit Contents for Intranasal or Auto-Injector Administration:

Intranasal	Auto-Injector	Intranasal
<p>Naloxone 2mg/2ml prefilled syringe, # 2 syringes</p> <p>SIG: Spray one-half of the syringe into each nostril upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p>Mucosal Atomization Device (MAD) # 2 SIG: Use as directed for naloxone administration.</p> <p>Kit must contain 2 prefilled syringes and 2 atomizers and instructions for administration.</p>	<p>Naloxone 0.4 mg/0.4 ml #1 twin pack</p> <p>SIG: Use one auto-injector upon signs of opioid overdose. Call 911. May repeat x 1.</p> <p><u>Kit is commercially available as a twin pack with directions for administration included. No kit is required. Product is commercially available.</u></p>	<p><u>Narcan Nasal Spray 4mg, #2</u></p> <p><u>SIG: 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. Additional doses may be given every 2 to 3 minutes until emergency medical assistance arrives.</u></p> <p><u>No kit is required. Product is commercially available.</u></p>

Optional items for the kits include rescue breathing masks, and latex-free gloves.

Pharmacies may obtain kits to have on-hand for dispensing naloxone 2mg/2ml prefilled syringes for intranasal administration from the REVIVE! program at the Department of Behavioral Health and Developmental Services. To request kits, contact REVIVE@dbhds.virginia.gov

5) Labeling and Records:

Each vial or syringe of naloxone shall be dispensed and labeled in accordance with §54.1-3410 with the exception that the name of the patient does not have to appear on the label. The pharmacist shall maintain a record of dispensing in accordance with recordkeeping requirements of law and regulation.

Protocol for Dispensing to Law-Enforcement Officers and Firefighters

Alternatively, a pharmacy, wholesale distributor, third party logistics provider, or manufacturer may distribute naloxone via invoice to designated law enforcement officers or firefighters who have successfully completed a training program developed by the Department of Behavioral Health and Developmental Services in consultation with the Department of Criminal Justice Services or Department of Fire Programs, respectively, at the address of the law enforcement agency or fire department. Training shall be conducted in accordance with policies and procedures of the law enforcement agency or fire department.

6) Resources:

- a) REVIVE! Opioid Overdose Reversal for Virginia Training Curriculum “Understanding and Responding to Opioid Overdose Emergencies Using Naloxone”, available at <http://www.dbhds.virginia.gov/library/document-library/osas-revive-02-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>

DRAFT

Virginia Board of Pharmacy Pharmacy Inspection Deficiency Monetary Penalty Guide

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
1. No Pharmacist-in-Charge or Pharmacist-in-Charge not fully engaged in practice at pharmacy location	54.1-3434 and 18VAC110-20-110	must have documentation	1000
2. Pharmacist-in-Charge in place, inventory taken, but application not filed with Board within the required timeframe	54.1-3434 and 18VAC110-20-110		100
3. Unregistered persons performing duties restricted to pharmacy technician when not enrolled in a Board-approved pharmacy technician training program or beyond 9 months from the initial enrollment date in a Board-approved pharmacy technician training program	54.1-3321 and 18VAC110-20-111	per individual	250
4. Pharmacists/pharmacy technicians/pharmacy interns performing duties on an expired license/registration	18VAC110-20-80, 18VAC110-20-40, and 18VAC110-20-105	per individual	100
5. Pharmacy technicians, pharmacy interns performing duties without monitoring by a pharmacist, or unlicensed persons engaging in acts restricted to pharmacists	54.1-3320	per each technician over the ratio First Offense – Minor Deficiency 143 deficiency Second Offense – Major Deficiency 6 deficiency	500
6. Exceeds pharmacist to pharmacy technician ratio	54.1-3320		100
7. Change of location or remodel of pharmacy without submitting application or Board approval	18VAC110-20-140	must submit an application and fee	250

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
<p>8. Refrigerator/freezer temperature out of range greater than +/- 4 degrees Fahrenheit.</p>	<p>18VAC110-20-150 and 18VAC110-20-10</p>	<p>determined using inspector's or pharmacy's calibrated thermometer</p>	<p>100 Drugs may be embargoed</p>
<p>9. The alarm is not operational. The enclosure is not locked at all times when a pharmacist is not on duty. The alarm is not set at all times when the pharmacist is not on duty.</p>	<p>18VAC110-20-180 and 18VAC110-20-190</p>	<p>Major Deficiency 9a if a drug loss occurred during the period of non-compliance. Minor Deficiency 144 if no drug loss.</p>	<p>1000</p>
<p>9a. Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.</p>	<p>18VAC110-20-180</p>	<p>Major Deficiency 11 if there is evidence that non-compliance contributed to a drug loss. Minor Deficiency 145 if no drug loss.</p>	<p>250</p>
<p>10. Unauthorized access to alarm or locking device to the prescription department</p>	<p>18VAC110-20-180 and 18VAC110-20-190</p>	<p>Major Deficiency</p>	<p>1000</p>
<p>11. Insufficient enclosures or locking devices</p>	<p>18VAC110-20-190</p>	<p>Major Deficiency 11 if there is evidence that non-compliance contributed to a drug loss. Minor Deficiency 145 if no drug loss.</p>	<p>500</p>
<p>12. Storage of prescription drugs not in the prescription department</p>	<p>18VAC110-20-190</p>	<p>Major Deficiency</p>	<p>500</p>

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
12a. Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.	18VAC110-20-200	Major Deficiency 12a if there is evidence that non-compliance contributed to a drug loss. Minor Deficiency 146 is no drug loss.	250
13. No biennial inventory, or over 30 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3404 and 18VAC110-20-240	Cite Minor Deficiency 113 if only expired drugs not included in inventory.	500
14. No incoming change of Pharmacist-in-Charge inventory, inventory taken or over 5 days late, or substantially incomplete, i.e., did not include all drugs in Schedules II-V.	54.1-3434 and 18VAC110-20-240	Cite Deficiency Minor 113 if only expired drugs not included in inventory.	500
15. Perpetual inventory not being maintained as required, to include not accurately indicating "physical count" on-hand at time of performing inventory or not noting explanation for any difference between "physical count" and "theoretical count"; perpetual inventory performed more than 7 days prior or more than 7 days after designated calendar month for which an inventory is required	18VAC110-20-240	Review 10 drugs for six consecutive months. Includes expired drugs. Deficiency if more than 5 drugs not compliant.	250
16. Theft/unusual loss of drugs not reported to the Board as required or report not maintained	54.1-3404 and 18VAC110-20-240	per report/theft-loss	250
17. Hard copy prescriptions not maintained or retrievable as required (i.e. hard copy of fax for Schedule II, III, IV & V drugs and refill authorizations)	54.1-3404 and 18VAC110-20-240		250

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
18. Records of dispensing not maintained as required	54.1-3404, 18VAC110-20-240, 18VAC110-20-250, 18VAC110-20-420, and 18VAC110-20-425		250
19. Pharmacists not verifying or failing to document verification of accuracy of dispensed prescriptions	18VAC110-20-270, 18VAC110-20-420 and 18VAC110-20-425	10% threshold for documentation	500
20. Pharmacist not checking and documenting repackaging or bulk packaging	54.1-3410.2, 18VAC110-20-355 and 18VAC110-20-425	Review all entries for 5 drugs for six consecutive months. Deficiency if 10% or more are not compliant.	250
20a. Pharmacist not documenting final verification of non-sterile compounding	54.1-3410.2, 18VAC110-20-355	10% threshold	500
20b. Pharmacist not documenting final verification of sterile compounding	54.1-3410.2, 18VAC110-20-355		5000
21. No clean room	54.1-3410.2	Compliant clean room present but not utilized for preparation of compounded sterile drug products.	10000
21a. Performing sterile compounding outside of a clean room.	54.1-3410.2		3000

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
<p>22. Certification of the direct compounding area (DCA) for compounded sterile preparations indicating ISO Class 5 not performed by a qualified individual no less than every 6 months and whenever the device or room is relocated, altered, or major service to the facility is performed.</p>	<p>54.1-3410.2</p>	<p>Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification</p>	<p>3000</p>
<p>23. Certification of the buffer or clean room and ante room indicating ISO Class 7 / ISO Class 8 or better not performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed.</p>	<p>54.1-3410.2</p>	<p>Review 2 most recent reports; certification must be performed no later than the last day of the sixth month from the previous certification</p>	<p>1000</p>
<p>24. Sterile compounding of hazardous drugs performed in an area not physically separated from other preparation areas.</p>	<p>54.1-3410.2</p>		<p>2000</p>
<p>25. No documentation of sterilization methods or endotoxin pyrogen testing for high-risk level compounded sterile preparations or high risk compounded sterile preparations assigned inappropriate beyond use date (BUD)</p>	<p>54.1-3410.2</p>		<p>5000</p>

Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
<p>25a. No documentation of initial and semi-annual (6 months) media-fill testing or gloved finger tip testing for persons performing high-risk level compounding of sterile preparations.</p>	54.1-3410.2	<p>Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the sixth month from the date the previous media-fill test was initiated.</p>	5000
<p>25b. High-risk compounded sterile preparations intended for use are improperly stored</p>	54.1-3410.2		5000
<p>25c. Documentation that a person who failed a media-fill test or gloved finger tip test has performed high-risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved finger tip test</p>	54.1-3410.2	<p>Review 2 most recent reports. Media-fill testing must be performed no later than the last day of the twelfth month from the date the previous media-fill test was initiated.</p>	5000
<p>26. No documentation of initial and annual (12 months) media-fill testing or gloved finger tip testing for persons performing low and medium-risk level compounding of sterile preparations.</p>	54.1-3410.2		500
<p>26a. Documentation that a person who failed a media-fill test or gloved finger tip test has performed low or medium risk level compounding of sterile preparations after receipt of the failed test result and prior to retraining and receipt of passing media-fill and gloved finger tip test</p>	54.1-3410.2		500

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Major Deficiency	Law/Reg Cite	Conditions	\$ Penalty
27. Compounding using ingredients in violation of 54.1-3410.2.	54.1-3410.2		1000
28. Compounding copies of commercially available products	54.1-3410.2	per Rx dispensed up to maximum of 100 RX or \$5000	50
29. Unlawful compounding for further distribution by other entities	54.1-3410.2		500
30. Security of after-hours stock not in compliance	18VAC110-20-450	Except for drugs that would be stocked in an emergency drug kit as allowed by 18VAC110-20-555 (3)(C)	500
31. Drugs removed and administered to a patient from an automated dispensing device in a nursing home prior to review of the order and authorization by a pharmacist.	18VAC110-20-555		250
32. Have clean room, but not all physical standards in compliance, e.g., flooring, ceiling	54.1-3410.2		2000
33. Low or medium-risk compounded sterile preparations assigned inappropriate beyond use date (BUD)	54.1-3410.2		1000
34. Combined with Minor Deficiency 142 – 12/2013.			
35. Schedule II through VI drugs are being purchased from a wholesale distributor or warehouse not licensed or registered by the board or from another pharmacy in a non-compliant manner	18VAC110-20-395		250

Minor Other Deficiencies

If five (5) or more minor deficiencies in this category are cited, a \$250 monetary penalty shall be imposed. Another \$100 monetary penalty will be added for each additional minor deficiency cited in this category, over the initial five.

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Minor Deficiency	Law/Regulation Cite	Conditions
General Requirements:		
101. Repealed 6/2011		
102. Special/limited-use scope being exceeded without approval	18VAC110-20-120	
103. Repealed 12/2013		
104. Sink with hot and cold running water not available within the prescription department.	18VAC110-20-150	
105. No thermometer or non-functioning thermometer in refrigerator/freezer, but temperature within range, +/-4 degrees Fahrenheit	18VAC110-20-150 and 18VAC110-20-10	determined using inspector's calibrated thermometer
106. Prescription department substantially not clean and sanitary and in good repair	18VAC110-20-160	must have picture documentation
107. Current dispensing reference not maintained	18VAC110-20-170	
108. Emergency access alarm code/key not maintained in compliance	18VAC110-20-190	
109. Expired drugs in working stock, dispensed drugs being returned to stock not in compliance, dispensed drugs returned to stock container or automated counting device not in compliance. (i.e. appropriate expiration date not placed on	54.1-3457 18VAC110-20-200 18VAC110-20-355	10% threshold

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Minor Deficiency	Law/Regulation Cite	Conditions
label of returned drug, mixing lot numbers in stock container)		
<u>110.</u> Storage of paraphernalia/Rx devices not in compliance	18VAC110-20-200	
<u>111.</u> Storage of prescriptions awaiting delivery outside of the prescription department not in compliance	18VAC110-20-200	
<u>112.</u> Biennial taken late but within 30 days	54.1-3404 and 18VAC110-20-240	
<u>113.</u> Inventories taken on time, but not in compliance, i.e., no signature, date, opening or close, Schedule II drugs not separate, failure to include expired drugs.	54.1-3404, 54.1-3434 and 18VAC110-20-240	
<u>114.</u> Records of receipt (e.g. invoices) not on site or retrievable	54.1-3404 and 18VAC110-20-240	
<u>115.</u> Other records of distributions not maintained as required	54.1-3404 and 18VAC110-20-240	
<u>116.</u> Prescriptions do not include required information. Prescriptions not transmitted as required (written, oral, fax, electronic, etc.)	54.1-3408.01, 54.1-3408.02, 54.1-3410, 18VAC110-20-280 and 18VAC110-20-285	10% threshold
<u>117.</u> Minor Deficiency <u>117</u> combined with Minor Deficiency <u>116</u> -- 6/2011		
<u>118.</u> Schedule II emergency oral prescriptions not dispensed in compliance	54.1-3410 and 18VAC110-20-290	>3
<u>119.</u> Not properly documenting partial filling of prescriptions	54.1-3412, 18VAC110-20-255, 18VAC110-20-310, and 18VAC110-20-320	
<u>120.</u> Offer to counsel not made as required	54.1-3319	

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Minor Deficiency	Law/Regulation Cite	Conditions
121. Prospective drug review not performed as required	54.1-3319	
122. Engaging in alternate delivery not in compliance	18VAC110-20-275	
123. Engaging in remote processing not in compliance	18VAC110-20-276 and 18VAC110-20-515	
124. Labels do not include all required information	54.1-3410, 54.1-3411 and 18VAC110-20-330	10% Threshold Review 25 prescriptions
125. Compliance packaging or labeling does not comply with USP-NF standards for customized patient medication packages	18VAC110-20-340	
126. Special packaging not used or no documentation of request for non-special packaging	54.1-3426, 54.1-3427 and 18VAC110-20-350	10% threshold Review 25 prescriptions
Repackaging, specialty dispensing, compounding:		
127. Repackaging records and labeling not kept as required or in compliance	18VAC110-20-355	10% threshold
128. Unit dose procedures or records not in compliance	18VAC110-20-420	
129. Robotic pharmacy systems not in compliance	18VAC110-20-425	
130. Required compounding/dispensing/distribution records not complete and properly maintained	54.1-3410.2	
130a. Compounded products not properly labeled	54.1-3410.2	

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Minor Deficiency	Law/Regulation Cite	Conditions
131. Required "other documents" for USP-NF 797 listed on the pharmacy inspection report are not appropriately maintained	54.1-3410.2	
132. Personnel preparing compounded sterile preparations do not comply with cleansing and garbing requirements	54.1-3410.2	
133. Compounding facilities and equipment used in performing non-sterile compounds not in compliance with 54.1-3410.2	54.1-3410.2	
Hospital specific or long-term care specific:		
134. Policies and procedures for proper storage, security and dispensing of drugs in hospital not established or assured	18VAC110-20-440	
135. Policies and procedures for drug therapy reviews not maintained or followed	18VAC110-20-440	
136. After hours access to a supply of drugs or records not in compliance	18VAC110-20-450	10% threshold
137. Floor stock records not in compliance, pharmacist not checking, required reconciliations not being done	18VAC110-20-460	10% threshold
138. Automated dispensing device loading, records, and monitoring/reconciliation not in compliance	54.1-3434.02, 18VAC110-20-490 and 18VAC110-20-555	Cite if no documentation of monitoring. Review ADD in areas that do not utilize patient specific profile. Review 3 months of records – 30% threshold. Cite if exceeds threshold. Describe in comment section steps pharmacy is taking to comply. Educate regarding requirements.
139. Emergency medical services procedures or records not in compliance	18VAC110-20-500	10% threshold

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Minor Deficiency	Law/Regulation Cite	Conditions
<p><u>140.</u> Emergency kit or stat-drug box procedures or records not in compliance</p>	<p>18VAC110-20-540 and 18VAC110-20-550</p>	<p>10 % threshold</p>
<p><u>141.</u> Maintaining floor stock in a long-term care facility when not authorized</p>	<p>18VAC110-20-520 and 18VAC110-20-560</p>	
<p><u>142.</u> No record maintained and available for 12 months from date of analysis of dispensing errors or submission to patient safety organization, to include any zero reports. Record maintained and available for 12 months from date of analysis of dispensing error, to include any zero reports, but is not in compliance</p>	<p>18VAC110-20-418</p>	<p>20% Threshold. Do not cite deficiency until July 1, 2015</p>
<p><u>143.</u> Exceeds pharmacist to pharmacy technician ratio</p>	<p>54.1-3320</p>	<p>Per each technician over the ratio First offence – Minor Deficiency <u>143</u> deficiency Second Offense – Major Deficiency <u>6</u> deficiency</p>
<p><u>144.</u> Alarm incapable of sending an alarm signal to the monitoring entity when breached if the communication line is not operational. Alarm is operational but does not fully protect the prescription department and/or is not capable of detecting breaking by any means when activated.</p>	<p>18VAC110-20-180</p>	<p>Minor Deficiency <u>144</u> if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action. Major Deficiency <u>9a</u> if drug loss.</p>
<p><u>145.</u> Insufficient enclosures or locking devices</p>	<p>18VAC110-20-190</p>	<p>Minor Deficiency <u>145</u> if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application. Major Deficiency <u>11</u> if drug loss.</p>
<p><u>146.</u> Schedule II drugs are not dispersed with other schedules of drugs or maintained in a securely locked cabinet, drawer, or safe.</p>	<p>18VAC110-20-200</p>	<p>Minor Deficiency <u>146</u> if there is no evidence that non-compliance contributed to drug loss. Must submit corrective action and possible remodel application.</p>

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Minor Deficiency	Law/Regulation Cite	Conditions
<p><u>147.</u> Particle counts, environmental sampling, and smoke pattern testing not performed under dynamic conditions.</p>	<p>54.1-3410.2</p>	<p>Minor Deficiency 12a if drug loss.</p>

Virginia Board of Pharmacy

Physicians Dispensing Drugs

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

Permitted Physicians – Practice as a pharmacy

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

Physicians Selling Drugs

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

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

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

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

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

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

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

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

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

1. Interfere with any legally qualified practitioner of dentistry, or veterinary medicine or any physician acting on behalf of the Virginia Department of Health or local health departments, in the compounding of his prescriptions or the purchase and possession of drugs as he may require;
2. Prevent any legally qualified practitioner of dentistry, or veterinary medicine or any prescriber, as defined in § 54.1-3401, acting on behalf of the Virginia Department of Health or local health departments, from administering or supplying to his patients the medicines that he deems proper under the conditions of § 54.1-3303 or from causing drugs to be administered or dispensed pursuant to §§ 32.1-42.1 and 54.1-3408;
3. Prohibit the sale by merchants and retail dealers of proprietary medicines as defined in Chapter 34 (§ 54.1-3400 et seq.) of this title;
4. Prevent the operation of automated drug dispensing systems in hospitals pursuant to Chapter 34 (§ 54.1-3400 et seq.) of this title;
5. Prohibit the employment of ancillary personnel to assist a pharmacist as provided in the regulations of the Board;

- ~~6. Interfere with any legally qualified practitioner of medicine, osteopathy, or podiatry from purchasing, possessing or administering controlled substances to his own patients or providing controlled substances to his own patients in a bona fide medical emergency or providing manufacturers' professional samples to his own patients;~~
- ~~7. Interfere with any legally qualified practitioner of optometry, certified or licensed to use diagnostic pharmaceutical agents, from purchasing, possessing or administering those controlled substances as specified in §/n 54.1-3221 or interfere with any legally qualified practitioner of optometry certified to prescribe therapeutic pharmaceutical agents from purchasing, possessing, or administering to his own patients those controlled substances as specified in § 54.1-3222 and the TPA formulary or providing manufacturers' samples of these drugs to his own patients;~~
- ~~8. Interfere with any physician assistant with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2952.1, to prescribe according to his practice setting and a written agreement with a physician or podiatrist;~~
- ~~9. Interfere with any licensed nurse practitioner with prescriptive authority receiving and dispensing to his own patients manufacturers' professional samples of controlled substances and devices that he is authorized, in compliance with the provisions of § 54.1-2957.01, to prescribe according to his practice setting and a written agreement with a physician;~~
- ~~10. Interfere with any legally qualified practitioner of medicine or osteopathy participating in an indigent patient program offered by a pharmaceutical manufacturer in which the practitioner sends a prescription for one of his own patients to the manufacturer, and the manufacturer donates a stock bottle of the prescription drug ordered at no cost to the practitioner or patient. The practitioner may dispense such medication at no cost to the patient without holding a license to dispense from the Board of Pharmacy. However, the container in which the drug is dispensed shall be labeled in accordance with the requirements of § 54.1-3410, and, unless directed otherwise by the practitioner or the patient, shall meet standards for special packaging as set forth in § 54.1-3426 and Board of Pharmacy regulations. In lieu of dispensing directly to the patient, a practitioner may transfer the donated drug with a valid prescription to a pharmacy for dispensing to the patient. The practitioner or pharmacy participating in the program shall not use the donated drug for any purpose other than dispensing to the patient for whom it was originally donated, except as authorized by the donating manufacturer for another patient meeting that manufacturer's requirements for the indigent patient program. Neither the practitioner nor the pharmacy shall charge the patient for any medication provided through a manufacturer's indigent patient program pursuant to this subdivision. A participating pharmacy may charge a reasonable dispensing or administrative fee to offset the cost of dispensing, not to exceed the actual costs of such dispensing. However, if the patient is unable to pay such fee, the dispensing or administrative fee shall be waived;~~
- ~~11. Interfere with any legally qualified practitioner of medicine or osteopathy from providing controlled substances to his own patients in a free clinic without charge when such controlled substances are donated by an entity other than a pharmaceutical manufacturer as authorized by subdivision 10. The practitioner shall first obtain a controlled substances registration from the Board and shall comply with the labeling and packaging requirements of this chapter and the Board's regulations; or~~
- ~~12. Prevent any pharmacist from providing free health care to an underserved population in Virginia who (i) does not regularly practice pharmacy in Virginia, (ii) holds a current valid license or certificate to practice pharmacy in another state, territory, district or possession of the United States, (iii) volunteers to provide free health care to an underserved area of this Commonwealth under the auspices of a publicly supported all-volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people, (iv) files a copy of the license or certificate issued in such other~~

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

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

§ 54.1-3301. Exceptions.

This chapter shall not be construed to:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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