COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

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

Tentative Agenda of Virtual Regulation Committee Meeting

May 3, 2021

9AM

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

TOPIC	PAGES
Call to Order: Cheryl Nelson, Committee Chair	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Chart of Regulatory Actions	**1-2**
• Chart of Regulatory/Workgroups from 2021 General Assembly Actions	**3-4**
• Petition for Rulemaking 18VAC110-20-290; Request to Shorten Expiration Date of Schedule II Prescription	**5-7**
• Periodic Review of Chapters 20, 21, 30, 40, and 50	**8-15**
• Revision/Re-adoption of Guidance Documents 110-17 and 110-2	**16-51**
• Feedback on ACPE Standards 2025	**52-58**
• Identify Subjects for Possible Legislative Proposals for 2022 General Assembly Session	**59-96**
Adjourn	

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

Virginia Board of Pharmacy

Instructions for Accessing May 3, 2021 Virtual Regulation Committee Meeting and Providing Public Comment

- **Access:** Perimeter Center building access is restricted to the public due to the COVID-19 pandemic. To observe this virtual meeting, use one of the options below. Participation capacity is limited and is on a first come, first serve basis due to the capacity of CISCO WebEx technology.
- **Public comment:** Comments will be received during the meeting from those persons who have submitted an email to caroline.juran@dhp.virginia.gov **no later than 8am on May 3, 2021** indicating that they wish to offer comment. Verbal comment may be offered by these individuals when their names are announced by the chairman. Comments should be restricted to 3-5 minutes each.
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Agenda Item: Regulatory Actions - Chart of Regulatory Actions
As of April 16, 2021

Chapter		Action / Stage Information
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Reporting of immunizations to VIIS [Action 5598] Emergency - *Register Date: 10/12/20*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Use of medication carousels and RFID technology [Action 5480] Proposed - *AT Attorney General's Office* [Stage 9236]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Implementation of legislation for pharmacists initiating treatment [Action 5604] Proposed - *AT Attorney General's Office* [Stage 9242]
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Handling fee [Action 5519] Fast-Track - *Register Date: 2/1/21 Effective: 3/18/21*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Prohibition against incentives to transfer prescriptions [Action 4186] Final - *At Governor's Office for 1059 days*
[18 VAC 110 - 20]	Regulations Governing the Practice of Pharmacy	Brown bagging and white bagging [Action 4968] Final - *Register Date: 5/10/21 Effective: 6/9/21*
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	Implementation of legislation for registration of pharmacy technicians [Action 5603] Proposed - *AT Attorney General's Office* [Stage 9243]
[18 VAC 110 - 21]	Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians	CE credit for volunteer hours [Action 5546] Fast-Track - *Register Date: 2/1/21 Effective: 3/18/21*
[18 VAC 110 - 30]	Regulations for Practitioners of the Healing Arts to Sell Controlled Substances	Limited license for prescribing Schedule VI drugs in non-profit clinics [Action 5605] Proposed - *AT Attorney General's Office* [Stage 9244]
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Amendments resulting from SB976 of the

		2020 General Assembly [Action 5629] Emergency/NOIRA - *Register Date: 3/1/21* *Comment closed: 3/31/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Response to petition for rulemaking [Action 5611] NOIRA - *Register Date: 3/1/21* *Comment closed: 3/31/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Registered agents and wholesale distribution [Action 5398] Proposed - *Register Date: 3/1/21* *Comment closes: 4/30/21*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Prohibition of products for vaping or inhalation with vitamin E acetate [Action 5452] Proposed - *At Secretary's Office for 56 days*
[18 VAC 110 - 60]	Regulations Governing Pharmaceutical Processors	Acquisition of industrial hemp [Action 5602] Fast-Track - *Register Date: 2/1/21* *Effective: 3/18/21*

Department of Health Professions
Regulatory/Policy Actions – 2021 General Assembly

EMERGENCY REGULATIONS:

Legislative source	Mandate	Promulgating agency	Board adoption date	Effective date Within 280 days of enactment
HB2079	Authorization for a pharmacist to initiate treatment certain drugs, devices, controlled paraphernalia, and supplies and equipment described in § 54.1-3303.1	Pharmacy	9/24/21	

EXEMPT REGULATORY ACTIONS

Legislative source	Mandate	Promulgating agency	Adoption date	Effective date
HB1988	Changes to pharmaceutical processors	Pharmacy	?	By Sept. 1st
HB2218/SB1333	Sale of cannabis botanical products	Pharmacy	?	By Sept. 1st
HB2218/SB1333	Revision of fee schedule for pharmaceutical processors and dispensaries to cover cost of new data system	Pharmacy	?	
SB1464	Deletion of sections of 322 with chemicals now scheduled in Code	Pharmacy	9/24/21	

NON-REGULATORY ACTIONS

Legislative source	Affected agency	Action needed	Due date
HB1304/SB830 (2020)	Pharmacy	To convene a workgroup composed of stakeholders including representatives of the Virginia Association of Chain Drug Stores, Virginia Pharmacists Association, Virginia Healthcareer Association, Virginia Society of Health-System Pharmacies, and any other stakeholders that the Board of Pharmacy may deem appropriate to develop recommendations related to the addition of duties and tasks that a pharmacy technician registered by the Board may perform.	November 1, 2021
HB1987	Boards with prescriptive authority	Revise guidance documents with references to 54.1-3303	As boards meeting after July 1
HB2079	Pharmacy (with Medicine & VDH)	To establish protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment available over-the-counter by pharmacists in accordance with § 54.1-3303.1. Such	Concurrent with emergency regulations

		protocols shall address training and continuing education for pharmacists regarding the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment.	
HB2079	Pharmacy (with Medicine)	To convene a work group to provide recommendations regarding the development of protocols for the initiation of treatment with and dispensing and administering of drugs, devices, controlled paraphernalia, and supplies and equipment by pharmacists to persons 18 years of age or older, including (i) controlled substances, devices, controlled paraphernalia, and supplies and equipment for the treatment of diseases or conditions for which clinical decision-making can be guided by a clinical test that is classified as waived under the federal Clinical Laboratory Improvement Amendments of 1988, including influenza virus, urinary tract infection, and group A Streptococcus bacteria, and (ii) drugs approved by the U.S. Food and Drug Administration for tobacco cessation therapy, including nicotine replacement therapy. The work group shall focus its work on developing protocols that can improve access to these treatments while maintaining patient safety.	November 1, 2021
HB2218/SB1333	Pharmacy	To work on acquisition of a new data system/analysis of costs	

Future Policy Actions:

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

Agenda Item: Petition for rulemaking:

Included in your package are:

Copy of petition from Leslie Duval

Copy of Notice on Townhall

Copy of Comments on the petition

Copy of section 290 of regulations for which amendment requested

Committee action:

The Committee has the option to recommend that the Board:

1) Initiate rulemaking with publication of a NOIRA, or

2) Deny the petitioner's request.

COMMONWEALTH OF VIRGINIA
Board of Pharmacy

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

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

Petition for Rule-making

The Code of Virginia (§ 2.2-4007) and the Public Participation Guidelines of this board require a person who wishes to petition the board to develop a new regulation or amend an existing regulation to provide certain information. Within 14 days of receiving a valid petition, the board will notify the petitioner and send a notice to the Register of Regulations identifying the petitioner, the nature of the request and the plan for responding to the petition. Following publication of the petition in the Register, a 21-day comment period will begin to allow written comment on the petition. Within 90 days after the comment period, the board will issue a written decision on the petition. If the board has not met within that 90-day period, the decision will be issued no later than 14 days after it next meets.

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

Petitioner's full name (Last, First, Middle initial, Suffix,) DuVal, Leslie J		
Street Address 4016 Laurel Rd	**Area Code and Telephone Number** 703-987-8720	
City Alexandria	**State** VA	**Zip Code** 22309
Email Address (optional) ljopharmd@yahoo.com	**Fax (optional)**	

Respond to the following questions:

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

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

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

I propose that **opioid prescriptions** be valid for a shorter period of time than the current 6 month expiration date standard for all controlled substances. Several other states currently have shortened expiration dates for CII prescriptions, including DC, DE, HI, ID, IL, ME, MD, MA, MN, NV, RI, SC, VT, and WI (https://www.aafp.org/fpm/2011/1100/fpm20111100p16-rt1.pdf).

I am a retail pharmacist. My store is located very close to an Emergency Room and we receive opioid prescriptions quite often. Situations arise where an opioid is e-prescribed, received and filled at my pharmacy. A week goes by without the patient picking it up, so it is placed "on hold" in our system. The prescription itself is valid for 6 months. The patient comes after a month or 2 (or even 3 or 4) and wants the opioid prescription filled. In general, we refuse to fill an ER script after that amount of time due to the acute nature of ER visits. However, we have also had situations where the script is from a PCP or Pain Management but the PMP shows inconsistent use, a significant gap in therapy, or a dosage change and we are faced with the same dilemma: the script is in-date but therapeutically questionable due to time lapse.

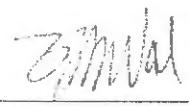
The current CDC guidelines suggest dispensing no more than a 7 day supply for acute conditions. Several insurance policies limit dispensing to a 7 day supply for opioid naïve patients. I propose that *all* opioid prescriptions be valid for 7 calendar days from the date written: i.e. Monday-Sunday, Tuesday-Monday, etc...This way there is a clear definition of expiration with no argument that some months are longer or shorter. Furthermore, with electronic prescribing now the law (§ 54.1-3408.02 B), doctor offices arguably have a more efficient and better tracking system to determine when chronic patients are due for continuing prescriptions, and can therefore create a streamlined corresponding e-timeline for sending continuing opioid prescriptions.

In general, chronic opioid prescriptions are renewed monthly. E-prescribing provides the added benefit of "seeing" (and controlling) which pharmacy the patient frequents and offers an opportunity to establish a collaborative relationship with that pharmacy regarding that patient, to ultimately monitor usage in real time and enhance patient care. As mentioned before, we have had situations where continuing prescriptions for chronic conditions have been sent to the pharmacy but not picked up in a timely manner (or there is clarification needed and the prescriber does not respond in a timely manner), and it creates therapeutic timeline confusion as the chart is not reflecting what the patient is actually doing. Shortening the prescription validity window serves to open the communication between prescriber, pharmacy, and patient to address actual usage discrepancies, *which holds all parties more accountable.*

The opioid epidemic continues. Decreasing the amount of time an opioid prescription is valid will significantly reduce the window of opportunity in which to fill a prescription and will curb potential abuse of opioids intended for acute, short-term medical issues, will afford enhanced monitoring of chronic usage, and increases accountability from all participants.

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

Authority provided in § 54.1-2400 of the Code of Virginia.

Signature:  **Date:** 2-14-21

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VIRGINIA REGULATORY TOWN HALL

Secretariat Health and Human Resources

Agency Department of Health Professions

Board Board of Pharmacy

Edit Petition

Petition 338

Petition Information	
Petition Title	Dispensing of Schedule II drugs
Date Filed	2/23/2021 [Transmittal Sheet]
Petitioner	Leslie DuVal
Petitioner's Request	To require prescriptions for opioids to be valid for a shorter period of time than the current 6-month expiration standard for all controlled substances.
Agency's Plan	In accordance with Virginia law, the petition has been filed with the Register of Regulations and will be published on March 15, 2021. Comment on the petition may be sent by email, regular mail or posted on the Virginia Regulatory Townhall at **www.townhall.virginia.gov**; comment will be requested until April 14, 2021. Following receipt of all comments on the petition to amend regulations, the Board will decide whether to make any changes to the regulatory language in Regulations Governing the Practice of Pharmacy. This matter will be on the Board's agenda for its meeting scheduled for June 4, 2021, and the petitioner will be informed of the Board's decision after that meeting.
Comment Period	Ended 4/14/2021 **3 comments**
Agency Decision	Pending

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

This petition was created by Elaine J. Yeatts on 02/23/2021 at 11:32am

KAISER PERMANENTE®

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

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

April 13, 2021

Re: Proposed Amendment 18VAC110-20. Regulations Governing the Practice of Pharmacy (amending 18VAC110-20-290)

Dear Ms. Juran,

Thank you for the opportunity to provide comment on proposed new regulations 18VAC 110-20. Established in 1980, Kaiser Permanente is the trade name for the total health organization comprised of Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc., the Mid-Atlantic Permanente Medical Group, P.C., an independent medical group that features approximately 1,600 physicians who provide or arrange care for patients throughout the area, and Kaiser Foundation Hospitals, which contracts with community hospitals for the provision of hospital services to our patients. We provide and coordinate comprehensive health care services for approximately 780,000 members throughout the metropolitan area. Our organization operates thirteen pharmacies across ten medical facilities in the Commonwealth of Virginia with several more planned in the near future.

While we appreciate the Board of Pharmacy's commitment to ensure the safe dispensing of controlled substances, we have concerns about changing the current regulatory requirement. Kaiser Permanente takes seriously the potential inappropriate use of opioids has on the community. Our health plan undertakes a number of efforts to combat fraud, waste, abuse, and addiction. We understand that misuse of prescription opioids risks addiction and contributes to the opioid overdose epidemic. It is perhaps possible requiring prescriptions for opioids to be valid for a shorter period of time than the current 6-month expiration standard could help mitigate opioid abuse practices by reducing the opportunity for medication stockpiling. That said, we support the concept of dispensing opioids only in "good faith." To that end, pharmacists are strongly encouraged to use professional judgement when dispensing. Specifically, resources such as Prescription Drug Monitoring Programs or medication profiles and histories are valuable tools when determining the appropriateness of a prescription.

The current petition does not define what a "shorter period of time" entails or provide specific language to amend the current regulation. It is important patients still have adequate time to fill their opioid prescription – not all of which are CII – to ensure access to medication is not compromised. The Virginia Board of Medicine promulgated prescribing guidelines in their regulations, which set

parameters on supply limits, quantity limits and the strength of medication. When appropriately prescribed, there are many instances whereby patients may not be able to fill their prescriptions immediately. For example, prescribers may write prescriptions with a "do not dispense date" to prevent future gaps in therapy for the patient. Certain conditions such as sickle cell anemia, multiple sclerosis, and renal calculi (kidney stones) may warrant pain management approaches requiring intermittent use of opioids that result in a patient's delayed pursuit of filling a controlled substances prescription. Further, upon discharge from an acute care episode, patients may transfer to several different sites of care before released to the home setting. It is not until that time that the patients may fill their discharge medications.

For these reasons, Kaiser Permanente is taking a cautious approach and, respectfully, does not support the current petition as presented to amend 18VAC 110-20-290.

Feel free to contact me at monet.stanford@kp.org or (202) 465-6410 should any further inquiries arise. Thank you for your time and consideration.

Sincerely,

Monet M. Stanford

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

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Chapter

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

3 comments

All good comments for this forum Show Only Flagged

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Commenter: George Roberts Jr / Remington Drug Company 3/21/21 6:38 pm

Dispensing of Schedule II Medications

This petition request is not necessary. As a Standard of Practice, most if not all pharmacists would question a patient when filling a Schedule II medication if the date written is more than a few days before the date of the request to fill the prescription. The majority of Schedule II prescriptions are transmitted electronically so a pharmacist would have time to contact the provider or even call the patient to discuss the delay in filling a medication in this class. The major exceptions are medications for ADHD and pain management. In at least these two cases multiple prescriptions are issued on the same day with "Do Not Fill Dates" on the second and third prescriptions. In these situations the intent is communicated by the "Do Not Fill" dates. Currently, following a conversation with either the provider and/or the patient, a stale dated prescription could be filled based upon professional evaluation and clinical judgement by the pharmacist. This petition is an attempt, probably not the intention, to remove professional/clinical decision making on the part of a licensed pharmacist. Currently a pharmacist could refuse to fill the prescription, make clinical notes on the prescription/sign the prescription, and either keep the prescription (if requested by provider) or return the prescription to the patient. This petition would make the prescription invalid when presented for filling. What if the provider intended the prescription to be used "in case the previously treated condition presented suddenly"? This petition would not allow such an option. The petition is unnecessary and adds an excessive burden to the decision making ability of a pharmacist. I respectfully ask this petition not be considered for adoption.

CommentID: 97406

Commenter: Leslie DuVal 4/10/21 8:05 pm

CDC Guidelines

Current CDC guidelines for opioid prescribing are:

Acute pain-"Clinicians should prescribe the lowest effective dose of immediate release opioid and no greater quantity than needed *for the expected duration of pain severe enough to require opioids*. ***Three days*** *or less* is often sufficient; more than 7 days is rarely needed" (cdc.gov).

Chronic pain- "*Clinicians should evaluate benefits and harms with patients* ***within 1 to 4 weeks*** *of starting opioid therapy* for chronic use or of dose escalation. *Clinicians should evaluate benefits and harm of continued therapy with patients* ***every 3 months or more frequently***. If benefits do

not outweigh the harms of continued opioid therapy, clinicians should optimize other therapies and work with patients to taper opioids to lower doses or to taper and discontinue opioids"(cdc.gov).

Current VA law states:

"A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than *six months* after the date on which the prescription was issued"(18VAC110-20-290, law.lis.virginia.gov).

Decreasing the length of time during which an opioid prescription is viable for dispensing will more effectively align VA law with the CDC guidelines, and reinforce the current Virginia laws regarding treatment with opioids. This change will hold all parties more accountable for responsible opioid use.

Regarding acute prescriptions: the intention of any acute treatment is immediate mitigation or resolution. The CDC guidelines state that opioid prescriptions for acute conditions "should be for a quantity no more than the expected duration of pain severe enough to require opioids", and more than a 7 day supply is rarely required. Additionally, Virginia law currently states that "a prescriber providing treatment for acute pain shall not prescribe a controlled substance containing an opioid in a quantity that exceeds a 7 day supply as determined by the manufacturer's directions for use, unless extenuating circumstances are clearly documented in the medical record" (18VAC85-21-40, law.lis.virginia.gov). It therefore logically follows that a prescription issued for an acute condition should be filled immediately and a 7 day window from the date written is a reasonable time frame during which said prescription should be dispensed. Beyond 7 days the pain should either be at a level controllable by non-opioid measures, or the patient should be re-evaluated.

Regarding chronic prescriptions: the CDC guidelines state that (stable) patients should be re-evaluated at a minimum of every 3 months. Additionally, current Virginia law states that prescribers treating chronic pain "shall document the rationale to continue opioid therapy every 3 months" (18VAC85-21-70, law.lis.virginia.gov). It therefore is a reasonable expectation that a prescription issued for a chronic condition should be dispensed within 3 months from the date written.

Both scenarios support the argument that opioid prescriptions should be viable for less than 6 months. Additionally, opioid prescriptions are required to be electronically issued (54.1-3408.02, law.lis.virginia.gov), which affords clinicians tighter control over prescribing, determines where the opioid is dispensed, and allows greater visibility of patient compliance. This further upholds the recommendation of curtailing the expiration date of opioid prescriptions. The opioid epidemic continues. The intention of this petition is to block unnecessary dispensing of potentially therapeutically irrelevant opioids. I earnestly ask that this Board actively considers this petition.

References

cdc.gov. CDC Guideline for Prescribing Opioids for Chronic Pain - United States, 2016.MMWR. (www.cdc.gov/mmwr).

Administrative Code of Virginia. (law.lis.virginia.gov).

CommentID: 97790

Commenter: Mark Hickman, on behalf of Virginia Society of Health-System Pharmacists 4/14/21 11:05 am

VSHP recommends referral to Regulation Committee

The Virginia Society of Health-System Pharmacists (VSHP) supports a collaborative, multidisciplinary approach to opioid stewardship. This petition may not address systemic issues with current challenges that dispensing pharmacists encounter in enforcing or maintaining certain stewardship practices. VSHP understands the intent of the petition; however, this is a complex issue and deserves further consideration by the Regulation Committee, as well as the Board of Medicine. VSHP recommends referral of this matter to the Board of Pharmacy's Regulation Committee.

CommentID: 97708

18VAC110-20-290. Dispensing of Schedule II drugs.

A. A prescription for a Schedule II drug shall be dispensed in good faith but in no case shall it be dispensed more than six months after the date on which the prescription was issued.

B. A prescription for a Schedule II drug shall not be refilled except as authorized under the conditions for partial dispensing as set forth in 18VAC110-20-310.

C. In case of an emergency situation, a pharmacist may dispense a drug listed in Schedule II upon receiving oral authorization of a prescribing practitioner provided that:

1. The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period;

2. The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in § 54.1-3410 of the Drug Control Act, except for the signature of the prescribing practitioner;

3. If the pharmacist does not know the practitioner, the pharmacist shall make a reasonable effort to determine that the oral authorization came from a practitioner using the practitioner's phone number as listed in the telephone directory or other good-faith efforts to ensure the practitioner's identity; and

4. Within seven days after authorizing an emergency oral prescription, the prescribing practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of § 54.1-3410 of the Drug Control Act, the prescription shall have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail postmarked within the seven-day period or transmitted as an electronic prescription in accordance with federal law and regulation to include annotation of the electronic prescription with the original authorization and date of the oral order. Upon receipt, the dispensing pharmacist shall attach the paper prescription to the oral emergency prescription, which had earlier been reduced to writing. The pharmacist shall notify the nearest office of the Drug Enforcement Administration and the board if the prescribing practitioner fails to deliver a written prescription to the pharmacist. Failure of the pharmacist to do so shall void the authority conferred by this subdivision to dispense without a written prescription of a prescribing practitioner.

D. When presented a prescription written for a Schedule II controlled substance, a pharmacist may add or correct the patient's address upon verification, correct the patient's name upon verification, or add the prescriber's DEA registration number to the prescription. The pharmacist may add or change the dosage form, drug strength, directions for use, drug quantity, or issue date only after oral consultation directly with and agreement of the prescriber. Such consultations and corresponding changes shall be noted by the pharmacist on the prescription. The pharmacist shall not add or change the prescriber's signature or make changes to the controlled substance prescribed, except for dispensing therapeutically equivalent drugs as permitted by law.

Statutory Authority

§§ 54.1-2400 54.1-3307 of the Code of Virginia.

Historical Notes

Derived from VR530-01-1 § 6.3, eff. October 25, 1989; amended, Virginia Register Volume 9, Issue 4, eff. December 16, 1992; Volume 10, Issue 1, eff. November 4, 1993; Volume 11, Issue 21, eff. August 9, 1995; Volume 12, Issue 21, eff. August 7, 1996; Volume 15, Issue 8, eff. February 3, 1999; Volume 26, Issue 22, eff. August 4, 2010; Volume 36, Issue 6, eff. December 11, 2019.

Agenda Item: Periodic Review of Chapters 20, 21, 30, 40, and 50

Included in your package are:

- Crosswalk of Regulatory Changes Resulting from Most Recent Periodic Review, Effective December 11, 2019
- Minutes from Last Regulation Committee Meeting, November 12, 2020
- Postings on Town Hall of Periodic Review, Public Comment Period Ended 1/25/21, No comments received
- *Issues to be considered for a Periodic Review*- deferred to this meeting
- Table of Contents for Chapters 20, 21, 30, 40, and 50
- Periodic Regulatory Review and Standard Regulatory Review Basic Outlines

Committee Action:

To recommend to the full board which regulations within chapters 20, 21, 30, 40, and 50 should be considered for amendment and the general concept of the amendment.

Crosswalk for Changes to Pharmacy Regulations Resulting from Periodic Review, Effective December 11, 2019

General Summary:

- Regulations related to pharmacists, pharmacy technicians, and pharmacy interns were removed from Chapter 20, *Regulations Governing the Practice of Pharmacy* and placed into a new Chapter 21, *Regulations Governing Pharmacists, Pharmacy Interns, & Pharmacy Technicians*; regulations remaining in Chapter 20 primarily address pharmacies, medical equipment suppliers, and the practice of pharmacy.
- Regulations in Chapter 50, *Regulations Governing Wholesale Distributors, Manufacturers, Warehousers, and Third-Party Logistic Providers* were revised.
- Requirements for use of an agency subordinate were moved from Chapter 20 and placed into a new Chapter 15, *Regulations Governing Delegation to an Agency Subordinate.*

Chapter 20 – Regulations Governing the Practice of Pharmacy

Regulation	New regulation number, if applicable	Requirement	Change, intent, rationale, and likely impact of new requirements
18VAC110-20-10	n/a	Sets out definitions for words and terms used in the Chapter	Since Chapter 20 no longer applies to pharmacists and pharmacy technicians, terms applicable to educational credentials and CE were deleted. The term "initial or initials" were defined to be inclusive of other unique personal identifiers. The definition of "robotic pharmacy system" was amended to clarify that such a system may be used in the performance of "compounding" in addition to other uses. The definition of "electronic prescription" was amended to be consistent with the definition used in HB2165 and SB1230.
18VAC110-20-15	n/a	Sets out criteria for delegation to an agency subordinate	Repealed in Chapter 20 and placed in new Chapter 15 (18VAC110-15-10).
18VAC110-20-20	n/a	Sets out fees associated with licensure	All fees related to regulation of pharmacists and pharmacy technicians were deleted and moved to Chapter 21. Fees for humane society permits were deleted since the fee is no longer charged. Humane societies (now animal shelters) used to get a permit and a controlled substance registration (CSR). Now only the CSR is required.

18VAC110-20-21	n/a	Sets requirements for submission of a public address by individuals regulated by the board	Deleted in Chapter 20; replaced in Chapter 21.
18VAC110-20-25	n/a	Sets out practices that may constitute unprofessional conduct	Those that pertain exclusively to actions by a pharmacist or pharmacy technician were deleted and moved to Chapter 21. Additional practices were included based on situations encountered in disciplinary cases and/or included in other chapters enacted by other health regulatory boards.
Part II 18VAC110-20-30 through 18VAC110-20-100	n/a	Sections 30 – 100 pertain to licensure of pharmacists	Deleted in Chapter 20; replaced in Chapter 21
Part III 18VAC110-20-101 through 18VAC110-20-106	n/a	Sections 101 – 106 pertain to registration of pharmacy technicians	Deleted in Chapter 20, replaced in Chapter 21
18VAC110-20-110	n/a	Sets out the general requirements for a pharmacy permit	Subsection D was amended to require a pharmacist to have a minimum of 2 years of experience before becoming a PIC (pharmacist-in-charge). The Board has authority to grant an exception. *There are numerous responsibilities of a PIC for the inventory and security of the pharmacy (see Guidance Document 110-27). The Board was concerned that inexperienced pharmacists do not have the broad knowledge of pharmacy operations sufficient to serve as PIC. The change is intended to protect the public but also the pharmacists who might be assigned the job of PIC by an employer before he/she is ready to assume such a responsibility.*
18VAC110-20-270	18VAC110-20-112	Sets out the requirement for supervision of pharmacy technicians within a pharmacy.	The requirement in subsections A and B of 18VAC110-20-112 were previously found in subsections A and B of 18VAC110-20-270. They did not seem to belong in the Part on Prescription Orders And Dispensing Standards so were moved to Part III on Pharmacies.
18VAC110-20-140	n/a	Sets out the requirements for new pharmacies, acquisitions and changes to existing pharmacies	Subsection C was added to clarify that a closing inventory by a PIC is not required, but that on the date a pharmacist first engages in business under new ownership, a complete and accurate inventory is required. All inventories must be performed in compliance with 18VAC110-20-110.

			Subsection G was added to specify that if the pharmacy is not operational within 90 days from issuance of the permit, the permit may be rescinded unless an extension is granted.
18VAC110-20-150	n/a	Sets out the physical standards for all pharmacies	Subsection F was amended to exempt pharmacies with a limited-use permit that does not stock prescription drugs from the requirement to have a sink with hot and cold running water. *There are some entities that have a pharmacy permit for consulting or medication management purposes only; they do not need to have a sink with hot and cold water.* To protect the integrity and safety of drugs that must be maintained in cold storage, a specific requirement was added in Subsection H for daily recording of the temperature and adjustment necessary to ensure the appropriate range. The temperature record has to be maintained for two years so it is available for board inspectors to review and ensure compliance.
18VAC110-20-180	n/a	Sets out requirements for a pharmacy security system	Subsection A 2 was amended to require a device for detection of breaking to have at least one hard-wired communication method, so if the power is cut, the device will still be capable of sending an alarm signal. Subsection A 5 was added to require that the alarm system include notification to the PIC or a pharmacist working at the pharmacy in the event of a breach.
18VAC110-20-200	n/a	Sets out requirements for storage	Subsection B was amended to allow a pharmacy to use a combination of the methods for dispersion of Schedule II drugs. Those drugs may either be dispersed with other schedules or maintained in a securely locked cabinet or safe. The amendment, allowing both methods to be used, is the current guidance found in Guidance Document 110-40.
18VAC110-20-240	n/a	Sets out the manner of maintaining records, prescriptions, and inventory records	Currently, Guidance Document 110-16 offers the Board's interpretation of requirements for performing inventories. Amendments to section 240 were consistent with guidance on inventories for Schedules I and II drugs and require a physical count to be performed. The perpetual inventory of

			Schedule II drugs should indicate the physical count of drugs on hand at the time of the inventory and must include a written explanation for any difference between the physical count and the theoretical count. *Schedule II drugs are the most likely to be diverted, so a pharmacy is required to keep a "running" count of dispensing. At the monthly reconciliation of inventory for Schedule II drugs, the physical count and the "running" count should be the same.* *While inventories of Schedules I and II drugs must include a physical count, inventories of Schedules III through V may be performed by estimated the count unless the container contains greater than 1,000 tablets or there has been a theft or unusual loss of drugs. In which case, a physical count is required. The amendment was consistent with federal rules, which allows the count to be estimated if it is less than 1,000 tablets.* *Subsection C 2 on chart orders was amended to specify that an order for out-patient dispensing must meet the minimum requirements for a prescription, found in 18VAC110-20-286. Since the order is going to be dispensed by an outside pharmacy, the pharmacist will need the same information as a regular prescription for purposes of record-keeping, etc.*
18VAC110-20-270	n/a	Sets out the requirements for dispensing and certification of a completed prescription	Subsections A and B, relating to supervision of pharmacy technicians were deleted and moved to General Provisions. A new subsection A was added to specify that a prescription must include the quantity or duration of the order, so the pharmacist can calculate the authorized quantity using directions for use. It also provides that a written prescription must include the prescriber's manual signature. *The additional requirements were intended to ensure that the prescription was ordered by the prescriber himself or herself and that the pharmacist has enough information to provide appropriate directions to the patient.*

			Subsection D was amended to give a pharmacist who is presented with a forged prescription the option of returning it to the customer or keeping it for law enforcement. *Current regulation prohibits the return of a forged prescription but pharmacists sometimes feel threatened by refusing to return it. For their protection, the amended regulation gives them the option depending on the situation.* *Subsection F added language currently found in Guidance Document 32 on the use of a drop-box for refill prescriptions. The drop-box must be secure and made confidential, and the pharmacist must inform the public that containers left in the drop-box should not have unused drugs.*
18VAC110-20-280	n/a	Sets out requirements for transmission of a prescription order by facsimile machine	An amendment to subsections B and D clarified that a faxed prescription is considered a written prescription and must contain the prescriber's manual signature.
18VAC110-20-290	n/a	Sets out requirements for dispensing of Schedule II drugs	Subsection D was added to include language currently found in Guidance Document 110-41 regarding the additions or corrections a pharmacist is allowed to make on a Schedule II prescription, including those that require consultation with the prescriber. It also specified those changes the pharmacist is never allowed to make.
18VAC110-20-355	n/a	Sets out requirements for repackaging of drugs and the records and labeling required	Subsection C was added to specify that repackaging must be in compliance with USP-NF standards.
18VAC110-20-390	n/a	Sets out prohibitions on kickbacks, fee-splitting, etc.	Previously, prohibitions pertained to actions by a pharmacist so provisions of this section were duplicated in Chapter 21. However, a pharmacy is also prohibited from engaging in these acts, and the Board could take disciplinary actions against a pharmacy permit. Therefore, the language in Section 390 was modified to pertain to pharmacies.
18VAC110-20-425	n/a	Sets out requirements for use of robotic pharmacy systems	In review of this section and recommendations from health systems that use robotic systems, the Board amended to delete counts and procedures that were not necessary to ensure proper functioning and accuracy. Instead, regulations now require performance of a root cause

			analysis if the robot makes an error and correction of the source of the discrepancy. Subsection B was amended to clarify that intravenous admixture robotics may be used to compound and do not require a separate approval from the board.
18VAC110-20-490	n/a	Sets out requirements for automated devices for dispensing & administering drugs	Subsection B was amended to clarify that the policy and procedure manual must include provisions for granting and terminating user access. *It is vital that only appropriately qualified users have access to automated devices that dispense drugs to prevent diversion for personal use or for sale.* *Subsection C 2 was amended to provide that the PIC is responsible for "ensuring" reconciliation of any discrepancy or properly reporting of the loss of drugs. The amendment allows the PIC to delegate that to another pharmacist rather than being personally responsible for the reconciliation of reporting.* *Subsection D allows records of automated dispensing devices to be maintained electronically.* *Subsection E was amended to clarify that a discrepancy report is required for all Schedule II through V drugs and any drug of concern; without the specification of schedules, the regulation could be interpreted to include Schedule VI drugs. The regulation was further amended to provide that a discrepancy report must be "initiated" or resolved within 72 hours. Sometimes, it isn't possible to resolve the discrepancy within 72 hours, but the report should at least be initiated.* *Subsection F 3 was amended to clarify that the monthly audit of a device should review the dispensing and administration records of Schedule II through V drugs.*
18VAC110-20-530	n/a	Sets out the pharmacists responsibilities for drugs in long-term care facilities	The amendment in new subsection B was requested by a pharmacist through a petition for rulemaking. The Board agreed with the request but determined that the change could be included in the periodic review. Subsection B allows a provider pharmacy for a long

			term care facility to share a prescription with a back-up pharmacy to dispense no more than a seven–day supply without transferring the prescription. It facilitates coverage when the provider pharmacy experiences a temporary shortage in a medication that is needed at the facility.
18VAC110-20-550	n/a	Provides requirements for use of a stat-drug box in long-term care	The amendment in Subsection A clarifies that the stat-drug box may include a substitution of liquid for solid dosage unit for each drug schedule. New subsection B was amended to allow a long-term care facility to have more than one stat-drug box with varying contents.
18VAC110-20-580	n/a	Sets out requirements for drugs in humane societies and animal shelters	Amendments conform terminology to language in the Code of Virginia, which no longer refers to "animal shelters."
18VAC110-20-630	n/a	Sets out conditions for issuance of a permit as a medical equipment supplier	This section was amended to clarify that the medical equipment supplier must designate the hours of operation when it is open to the public and to require notification to the Board and to the public if those hours change. *These requirements are similar to those for pharmacies. Medical equipment suppliers are sometimes open for limited hours; the Board needs to know the hours of operation and when the facility is open to know when an inspection can occur.*
18VAC110-20-680	n/a	Sets out rules for medical equipment suppliers (MES)	A new subsection E was added to allow the transfer of a valid order from one MES to another for dispensing. Rules establish how the transfer may occur and the recordkeeping required to ensure all necessary information is conveyed and records maintained.

Chapter 50 *Regulations Governing Wholesale Distributor, Manufacturers, Third-Party Logistics Providers, and Warehousers*

Section number	Requirement	Content
18VAC110-50-40	Sets out requirements for safeguards against diversion of drugs	Subsection B was amended to add the same requirement as that for pharmacies in section 18VAC110-20-180. Subsection B 2 was amended to require a device for detection of breaking to have at least one hard-wired communication method and wireless motion sensors, so if the power is cut, the device will still be capable of sending an alarm signal. Subsection B 3 was added to require that the alarm system include notification to the monitoring device if the communication line is not operational.

18VAC110-50-60	Sets out requirements for issuance of special or limited-use licenses	To allow the issuance of a limited-use license to manufacturers, that category was added in this section. An amendment further specifies that the issuance of such a license is subject to continued compliance with conditions set by the board. For example, if a facility does not stock controlled substances and devices, it may not be necessary to have the extensive security system required for other such facilities.
18VAC110-50-80	Sets out minimum qualifications, eligibility for licensure of wholesale distributors and third-party logistics providers	Subsection C was amended to change the reference from "Central Criminal Records Exchange" to a "federal criminal history record check."

Chapter 15 – *Regulations Governing Delegation to an Agency Subordinate*

Regulation	New regulation number, if applicable	Current requirement	Change, intent, rationale, and likely impact of new requirements
18VAC110-20-15	18VAC110-15-10	Sets out the criteria for delegation to an informal fact-finding proceeding to an agency subordinate.	The new section in Chapter 15 is identical to the section previously found in Chapter 20. Since Chapter 20 will only regulate pharmacies, a new chapter was necessary to make the criteria for an agency subordinate applicable to all persons and entities regulated by the Board.

Chapter 21 – *Regulations Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians*

Regulation	New regulation number, if applicable	Requirement	Content
18VAC110-20-10	18VAC110-21-10	Sets out definitions for words and terms used in the chapter	Definitions for words and terms used in Chapter 21 are identical to those previously found in Chapter 20.
18VAC110-20-20	18VAC110-21-20	Establishes fees required for initial licensure or registration; for renewal; and other miscellaneous charges	All fees are identical to those previously found in Chapter 20.
18VAC110-20-21 and 110-20-104	18VAC110-21-30	Sets requirements for maintenance of current address.	Regulations in Chapter 21 are identical to those previously found in Chapter 20, except there is also are requirement to notify the Board of a name change.
18VAC110-20-25	18VAC110-21-40	Establishes those practices that may constitute unprofessional conduct	The provisions in the unprofessional conduct section are identical to those previously found in Chapter 20 and there are several additions. Numbers 11 through 15 are new and were

		within the meaning of § 54.1-3316.	recommended to address actions that are clearly unprofessional but were not previously identified in regulation. All of the additional causes for discipline are found in other health professional regulations.
18VAC110-20-390	18VAC110-21-45	Sets out prohibition on kickbacks, fee-splitting, or interference with suppliers	The prohibitions in Section 45 are identical to those previously found in Chapter 20.
18VAC110-20-30	18VAC110-21-50	Sets out the requirements for pharmacy practical experience	The requirements in Section 50 are identical to those previously found in Chapter 20.
18VAC110-20-40	18VAC110-21-60	Sets out the requirements for gaining practical experience	The requirements in Section 60 are identical to those previously found in Chapter 20.
18VAC110-20-50	18VAC110-21-70	Establishes the curriculum and approved schools of pharmacy	The requirements in Section 70 are identical to those previously found in Chapter 20.
18VAC110-20-60	18VAC110-21-80	Establishes the content of the examination and limitation to admittance to examination	The requirements in Section 80 are identical to those previously found in Chapter 20, except a sentence is added in subsection D to specify that an applicant who has not passed the law examination within 3 years must retake it to be licensed in Virginia.
18VAC110-20-70	18VAC110-21-90	Establishes the requirements for foreign-trained applicants	Addition of section D that exempts the requirement for FPGEC certification for foreign trained pharmacists who subsequently have been granted a professional degree from an ACPE accredited school of pharmacy, but requires the practical experience to be met prior to being admitted to exams.
18VAC110-20-75	18VAC110-21-100	Sets out requirements for registration of voluntary practice by out-of-state licensees	The requirements in Section 100 are identical to those previously found in Chapter 20.
18VAC110-20-80	18VAC110-21-110	Establishes the requirements for renewal and reinstatement	The requirements in Section 110 are identical to those previously found in Chapter 20.
18VAC110-20-90	18VAC110-21-120	Establishes the requirements for continuing education	The requirements in Section 120 are identical to those previously found in Chapter 20 with the exception of subsection C, which requires that three of the required 15 hours of continuing education for pharmacists be obtained in courses or programs that are live or real-time interactive. A maximum of one hour of live credit annually may be awarded for attending a board meeting or hearing

			and a maximum of one hour of live credit annually may be awarded for serving as a preceptor for a pharmacy student or resident.
18VAC110-20-100	18VAC110-21-130	Establishes the requirements for approval of continuing education programs	The requirements in Section 130 are identical to those previously found in Chapter 20.
18VAC110-20-101	18VAC110-21-140	Sets out requirement for registration as a pharmacy technician	The requirements in Section 140 are identical to those previously found in Chapter 20 *with the exception of subsection D*.
18VAC110-20-102	18VAC110-21-150	Establishes the criteria for approval of pharmacy technician training programs	The requirements in Section 150 are identical to those previously found in Chapter 20 with the exception of the requirement that a program submit a sample certificate when applying for program approval.
18VAC110-20-103	18VAC110-21-160	Establishes the requirements for pharmacy technician examination	The requirements in Section 160 are identical to those previously found in Chapter 20.
18VAC110-20-105	18VAC110-21-170	Establishes the requirements for renewal and reinstatement	The requirements in Section 170 are identical to those previously found in Chapter 20.
18VAC110-20-106	18VAC110-21-180	Establishes the requirements for continuing education	The requirements in Section 180 are identical to those previously found in Chapter 20.

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF VIRTUAL REGULATION COMMITTEE MEETING

November 12, 2020
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: A virtual Webex meeting of the Regulation Committee was called to order at 9:08AM. Due to the COVID-19 declared state of emergency and consistent with Amendment 28 to HB29 (Budget Bill for 2018-2020) and the applicable provisions of § 2.2-3708.2 in the Freedom of Information Act, the committee convened a virtual meeting to consider such business matters as was presented on the agenda necessary for the board to discharge its lawful purposes, duties, and responsibilities.

PRESIDING: Cheryl Nelson, Committee Chairman

MEMBERS PRESENT:
Glen Bolyard, Jr.
Dale St.Clair
William Lee
Patricia Richards-Spruill

STAFF PRESENT:
Caroline D. Juran, Executive Director
Ellen B. Shinaberry, Deputy Executive Director
J. Samuel Johnson, Jr., Deputy Executive Director
Beth O'Halloran, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst, DHP
James Rutkowski, Assistant Attorney General
Matt Treacy, Media Production Specialist

QUORUM: With four members of the Committee present, a quorum was established.

APPROVAL OF AGENDA: Agenda was approved as provided.

PUBLIC COMMENT: Natalie Nguyen, PharmD, representing VSHP stated they support the intent of remote order processing by a pharmacy technician. She recommended the Board consider recent COVID experience. She recommended a hard upper limit for a pharmacist to pharmacy technician ratio. She reminded the board that space in a pharmacy is limited.

Cindy Warriner, RPh, representing Appalachian College of Pharmacy reacted to several items in the agenda packet. She recommended amending #2 in Guidance Document 110-13, expressed concern for removing personal supervision of a pharmacy technician, opposed a store

manager having the ability to determine the number of pharmacy technicians, and recommended keeping the square footage for a pharmacy.

Monet Stanford, PharmD representing Kaiser Permanente stated that pharmacy technicians can complete remote processing tasks under secure technology and can increase capacity of healthcare workforce.

Christina Barrille, Executive Director, VPhA encouraged the Board to strike B3 of 18VAC110-40-20. She recommended allowing a pharmacist to use professional discretion regarding the closing of the pharmacy during a required break. Regarding page 29 of the agenda packet, she recommended waiting until the pharmacy technician workgroup meets. She stated they oppose removing pharmacist supervision and ridding of pharmacist to pharmacy technician ratio. She commented that a pharmacy square footage can be waived, if necessary.

Update on Regulatory Actions

A more current version of the Chart of Regulatory Actions was shared on the screen via WebEx. Ms. Yeatts provided an overview of the chart.

Amendments to Guidance Documents

Ms. Yeatts indicated several guidance documents need to be amended based on recent statutory changes.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Documents 110-1 (Categories of Facility Licensure), 110-29 (Guidance on Physician Dispensing Licenses), and 110-44 (Naloxone Protocol) as presented. (motion by Richards-Spruill, second by Bolyard)

The committee considered public comment received to amend #2 of Guidance Document 110-13, but concluded that such an amendment would require a regulatory change.

MOTION:

The committee voted unanimously to recommend to the full board that it amend Guidance Document 110-13 (Guidance Regarding Collaborative Practice Agreements) as presented. (motion by St.Clair, second by Richards-Spruill)

Staff indicated that Guidance Document 110-41 was recently incorporated into regulation during the last periodic regulatory review.

MOTION:

The committee voted unanimously to recommend to the full board that it repeal Guidance Document 110-41 (Changes a Pharmacist May Make to a Prescription Written for a Schedule II Controlled Substance) as presented. (motion by Bolyard, second by St.Clair)

There was much discussion regarding Guidance Document 110-39

(Guidance for Continuous Hours Worked by Pharmacists and Breaks). There was general support for a pharmacist exercising discretion regarding whether he or she would close the pharmacy during a required pharmacist break, however, the Committee believed it was important to post in advance for the public the time period that the pharmacy may be closed.

MOTION:

The committee voted in favor 4:1 to recommend to the full board that it amend Guidance Document 110-39 to allow the pharmacist on-duty to determine if the pharmacy will close during a required pharmacist break, but to require the pharmacy to post in advance the time period that the pharmacy may be closed. (motion by Bolyard, second by Richards-Spruill; St.Clair opposed)

The Board discussed the draft guidance document regarding contract employees accessing the premises of a pharmaceutical processor.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the guidance document (Contracted Employee Access to Pharmaceutical Processor) as presented. (motion by St.Clair, second by Bolyard)

Consideration of Remote Order Processing by a Pharmacy Technician Outside of a Pharmacy

Staff reminded the Board that this issue resulted from a petition from rulemaking from Bioscript. In June 2020, the Board voted to not initiate rulemaking but to refer the issue to the Regulation Committee for further consideration. An excerpt of minutes from a 10/5/2020 special conference committee denying a request for a pilot was included in the agenda packet. There was discussion regarding the appropriate level of pharmacist supervision and use of technology to monitor pharmacy technician activities.

MOTION:

The committee voted in favor 3:2 to defer consideration of remote order processing by a pharmacy technician outside of a pharmacy to the workgroup to be convened in 2021 pursuant to HB 1304 to consider additional duties that a pharmacy technician may perform. (motion by Lee, second by Richards-Spruill; opposed by Bolyard and St.Clair)

Consideration of Amendments – Medication Carousels and RFID Technology

There was discussion regarding whether the preliminary text language requiring scanning of each drug unit, blister card, and unopened container was appropriate. Some commenters stated that it may not be efficient to scan each unit, particularly in a large hospital. Other commenters stated it was necessary for patient protection. The committee did not believe any changes were necessary to the preliminary text on RFID technology.

MOTION:

The committee voted unanimously to recommend to the full board that it adopt the proposed language as amended by: requiring the same safety processes for "spoke and wheel", i.e., allowing drugs to be pulled from the med carousel for wholesale distribution to an offsite entity; in 18VAC110-20-425(C), changing the second "3" to

"4" and replacing "the robotic pharmacy system to guide" with "barcode scanning technology to verify the accuracy of"; and inserting a requirement for a pharmacist 5% verification as is currently required in the innovative pilots for using med carousels. (motion by Lee, second by St.Clair)

Adoption of NOIRA/Notice of Periodic Review

The committee did not review each item previously submitted following the last periodic review, but rather decided to recommend to the full board that it notice the public of a periodic review and request comments on changes it would like to have considered. If published, a 30-day public comment period would open.

MOTION:

The committee voted unanimously to recommend to the full board that it issue a Notice of Periodic Regulatory Review for Chapters 20, 21, 30, 40, and 50 and that it request comments on changes that the public would like to have considered. (motion by St.Clair, second by Richards-Spruill)

ADJOURN:

With all business concluded, the meeting adjourned at approximately 12:10 PM.

Cheryl Nelson, Chairman

12-7-20
DATE

FAR Caroline D. Juran, Executive Director

12/10/2020
DATE

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VIRGINIA REGULATORY TOWN HALL

Agency **Department of Health Professions**

Board **Board of Pharmacy**

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

Edit Review

Review 2013

Periodic Review of this Chapter

Includes a Small Business Impact Review

Date Filed: 12/10/2020

Review Announcement

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, this regulation is undergoing a periodic review.

The review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018). http://TownHall.Virginia.Gov/EO-14.pdf.

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

In order for you to receive a response to your comment, your contact information (preferably an email address or, alternatively, a U.S. mailing address) must accompany your comment. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

Contact Information	
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Telephone:	(804)367-4456 FAX: (804)527-4472 TDD: ()-

Publication Information and Public Comment Period

Published in the Virginia Register on 1/4/2021 [Volume: 37 Issue: 10]

Comment Period begins on the publication date and ends on 1/25/2021

Comments Received: 0

Review Result

Pending

Attorney General Certification

Pending

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

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

Edit Review

Review 2014

Periodic Review of this Chapter

Includes a Small Business Impact Review

Date Filed: 12/10/2020

Review Announcement

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, this regulation is undergoing a periodic review.

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VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations for Practitioners of the Healing Arts to Sell Controlled Substances [18 VAC 110 - 30]

Edit Review

Review 2015

Periodic Review of this Chapter

Includes a Small Business Impact Review

Date Filed: 12/10/2020

Review Announcement

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, this regulation is undergoing a periodic review.

The review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018). http://TownHall.Virginia.Gov/EO-14.pdf.

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

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Publication Information and Public Comment Period

Published in the Virginia Register on 1/4/2021 [Volume: 37 Issue: 10]

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Comments Received: 0

Review Result

Pending

Attorney General Certification

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing Collaborative Practice Agreements [18 VAC 110 - 40]

Review 2016

Periodic Review of this Chapter

Includes a Small Business Impact Review

Date Filed: 12/10/2020

Review Announcement

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, this regulation is undergoing a periodic review.

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

In order for you to receive a response to your comment, your contact information (preferably an email address or, alternatively, a U.S. mailing address) must accompany your comment. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

Contact Information	
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Publication Information and Public Comment Period

Published in the Virginia Register on 1/4/2021 [Volume: 37 Issue: 10]

Comment Period begins on the publication date and ends on 1/25/2021

Comments Received: 0

Review Result

Pending

Attorney General Certification

Pending

Virginia.gov Agencies | Governor

VIRGINIA REGULATORY TOWN HALL

Agency Department of Health Professions

Board Board of Pharmacy

Chapter Regulations Governing Wholesale Distributors, Manufacturers and Warehousers [18 VAC 110 - 50]

Edit Review

Review 2017

Periodic Review of this Chapter

Includes a Small Business Impact Review

Date Filed: 12/10/2020

Review Announcement

Pursuant to Executive Order 14 (as amended July 16, 2018) and §§ 2.2-4007.1 and 2.2-4017 of the Code of Virginia, this regulation is undergoing a periodic review.

The review of this regulation will be guided by the principles in Executive Order 14 (as amended July 16, 2018). http://TownHall.Virginia.Gov/EO-14.pdf.

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

In order for you to receive a response to your comment, your contact information (preferably an email address or, alternatively, a U.S. mailing address) must accompany your comment. Following the close of the public comment period, a report of both reviews will be posted on the Town Hall and a report of the small business impact review will be published in the Virginia Register of Regulations.

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Publication Information and Public Comment Period

Published in the Virginia Register on 1/4/2021 [Volume: 37 Issue: 10]

Comment Period begins on the publication date and ends on 1/25/2021

Comments Received: 0

Review Result

Pending

Attorney General Certification

Issues to be considered for a Periodic Review

Board of Pharmacy

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

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

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

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

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

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

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

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

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

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

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

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

In addition, the following issues have been raised:

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

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

Commonwealth of Virginia

REGULATIONS

GOVERNING THE PRACTICE OF PHARMACY

Title of Regulations: 18 VAC 110-20-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Revised Date: March 18, 2021

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Commonwealth of Virginia

REGULATIONS

Governing the Licensure of Pharmacists and Registration of Pharmacy Technicians

Title of Regulations: 18 VAC 110-21-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Revised Date: March 18, 2021

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Commonwealth of Virginia

VIRGINIA BOARD OF PHARMACY

REGULATIONS

FOR

PRACTITIONERS OF THE HEALING ARTS TO SELL CONTROLLED SUBSTANCES

Title of Regulations: 18 VAC 110-30-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Effective Date: March 18, 2021

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Commonwealth of Virginia

Virginia Board of Pharmacy
Virginia Board of Medicine

REGULATIONS
FOR
COLLABORATIVE PRACTICE AGREEMENTS

Title of Regulations: 18VAC110-40-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Effective Date: November 25, 2020

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Commonwealth of Virginia

REGULATIONS GOVERNING WHOLESALE DISTRIBUTORS, MANUFACTURERS, WAREHOUSERS, AND THIRD-PARTY LOGISTICS PROVIDERS

VIRGINIA BOARD OF PHARMACY

Title of Regulations: 18 VAC 110-50-10 et seq.

Statutory Authority: § 54.1-2400 and Chapters 33 and 34 of Title 54.1 of the *Code of Virginia*

Effective Date: March 18, 2021

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Periodic review of regulations using Feature on Town Hall

Every state regulation must be reviewed **every four years** to:

(1) ensure it is supported by statutory authority (as determined by the Office of the Attorney General),

(2) determine that the regulation is (a) necessary for the protection of public health, safety and welfare and (b) clearly written and easily understandable, and to

(3) make sure its economic impact on small businesses is minimized as much as possible.

******

Sources: Sections 2.2-4017 and 2-2-4007.1 of the Code of Virginia and Executive Order 14 (as amended July 16, 2018)

For more information, visit the Virginia Regulatory Town Hall at townhall.virginia.gov

How does the periodic review feature on Town Hall work?

Agency starts a periodic review of the regulation on the Virginia Regulatory Town Hall & submits an announcement for publication in *The Virginia Register of Regulations.*

↓

Ten days before publication in the *Register*: Automatic email notification is sent to Town Hall registered users.

↓

Periodic review announcement is published in the *Register.* Official public comment period (minimum 21 days) begins. Town Hall public comment forum opens.

↓

Public comment period ends. Public comment forum closes.

↓

No later than 120 days after the close of the public comment period/forum, the agency posts a periodic review result to appear in the *Register* & Town Hall, & is emailed to registered Town Hall users. **This report will indicate one of the following**:

↓

The regulation will be amended or repealed.

The regulation will be retained as is.

Produced by the Virginia Department of Planning and Budget's Planning, Evaluation, and Regulation Division, 11/2018

Standard regulatory process: Basic outline

Notice of Intended Regulatory Action (NOIRA)

Agency submits NOIRA for executive branch review.

Agency is authorized by Governor to submit NOIRA for publication.

NOIRA is published in *The Virginia Register of Regulations*.

Submit your comment during the 30-day public comment period.

Proposed regulation

Agency considers public comment and submits proposed regulation.

Governor approves proposed regulation.

Proposed regulation is published in the *Register* and notification is sent to all registered Town Hall users.

Submit your comment during the 60-day public comment period.

Final regulation

Agency/board considers public comment and adopts final regulation.

Governor approves final regulation.

Final regulation is published in the *Register* and email notification sent to registered public Town Hall users.

30-day final adoption period begins

Regulation becomes effective

(unless it is suspended or 25+ people request an additional public comment period).

A regulatory stage is announced as follows:

An automatic email notification is sent to registered Town Hall users.

Ten days later, a regulatory stage is published in *The Virginia Register of Regulations*, the official publication of legal record for regulations in Virginia.

When the stage is published in the *Register*, a public comment forum opens on the Town Hall and remains open through the end of the public comment period.

Source: Sections 2.2-4006 through 2.2-4017 of the Code of Virginia (Article 2 of the Administrative Process Act)

For more information, visit the Virginia Regulatory Town Hall at townhall.virginia.gov

Produced by the Virginia Department of Planning and Budget's Planning, Evaluation and Regulation Division, 11/18

Agenda Item: Amendments to Guidance Documents 110-2 and 110-17

Staff Note:

Guidance documents must be reviewed every four years. Guidance Documents 110-2 and 110-17 have outdated language and need to be revised.

Regulation Committee Action:

To recommend adoption of the revisions for Guidance Documents 110-2 and 110-17 as presented or amended.

VIRGINIA BOARD OF PHARMACY
Information for Applicants for a License as a Pharmacist

1. Licensure by Examination:

Application
The application is available on the Board of Pharmacy website at www.dhp.virginia.gov/pharmacy. Applications and fees are submitted online and received by the board the next business day.

Practical Experience Requirements
An applicant shall have accumulated a minimum of 1,500 hours of practical experience as a pharmacy intern. The applicant must have registered with the Board as a pharmacy intern prior to beginning to obtain practical experience. Credit will not be given for more than 50 hours in any one week, and not for less than an average of 20 hours per week averaged over a month. Practical experience that is gained within an ACPE-accredited school of pharmacy, that conforms to the current ACPE standards, and that allows the student to gain at least 1,500 hours of practical experience, shall meet the Board's practical experience requirements for licensure as a pharmacist. All practical experience credit gained outside of an ACPE-accredited school of pharmacy program shall only be gained after successful completion of the equivalent of at least two semesters in an ACPE-accredited school of pharmacy, or in the case of graduates of foreign colleges of pharmacy (see Guidance Document 110-17), after obtaining the FPGEC and registering as a pharmacy intern. All practical experience shall be gained within the United States.

Certificates of Practical Experience

- For graduates of an ACPE-approved School of Pharmacy, a "College Affidavit" form no longer needs to be submitted to the Board to document ~~For~~ practical experience gained within the college experiential program~~, documentation should be recorded and certified under the "College Affidavit" section of the application. No further affidavits are needed for this experience.~~ Graduation from an ACPE-approved School of Pharmacy indicates that the student has obtained the required hours of practical experience. Confirmation of compliance with the practical experience requirement will be assessed by NABP through the receipt of a college transcript from the applicant prior to allowing the applicant to schedule for NAPLEX or MPJE.

- Affidavits of experience gained in Virginia, outside the college experiential program, must be signed by the supervising pharmacist and the original form must be sent to the board.

- Certificates or documentation of practical experience gained in another state outside of an ACPE-approved school of pharmacy experiential program must be certified by the board of pharmacy in that state and must be received by this Board directly from that state. This documentation must show actual dates of employment, total hours worked, place of employment and names of supervising pharmacists, and the certifying Board shall verify current, unrestricted licensure status of the supervising pharmacists. ~~In the event that a state does not use internships to gain practical experience in pharmacy but relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the above information may be accepted in lieu of board certification~~.

Taking the NAPLEX
Applicants must directly register with and pay the required fee to the National Association of Boards of Pharmacy (NABP) in order to take the NAPLEX examination at www.nabp.pharmacy. NAPLEX is the competency assessment examination for initial pharmacist licensure that is accepted by all 50 states, the District of Columbia, and Puerto Rico. An applicant may either take NAPLEX designating Virginia as the primary state of licensure, or register with NABP to score transfer to Virginia. The Board will notify

NABP of a qualifying candidate's eligibility after reviewing the application for pharmacist licensure. The review is generally completed within five to seven business days. An applicant will not be allowed to schedule taking NAPLEX until he/she has been approved by the Board and NABP has received a college transcript conferring the date of graduation. Additional details about NAPLEX are also available on the NABP website.

2. Licensure by Endorsement (Reciprocity):

Virginia does allow licensure by a process called "endorsement" in which an applicant may transfer a pharmacist license from another state, provided the applicant's credentials for licensure in the other state meet Virginia's credentialing requirements with respect to education, practical experience, and required examinations, and provided grounds do not exist to deny an application such as disciplinary action by another state or criminal convictions. Applicants applying for licensure through endorsement should complete the following steps:

1. Follow NABP's instructions at www.nabp.pharmacy for submitting the application for licensure by endorsement to NABP. NABP will provide the board with relevant information regarding the applicant's licensure status, any criminal convictions, and any disciplinary action taken against the applicant. ~~Please note that as of April 2018, NABP has transitioned from a paper application to an online application process for endorsement.~~
2. Submit to the Virginia Board of Pharmacy the Application for Pharmacist License by Endorsement found at http://www.dhp.virginia.gov/pharmacy/pharmacy_forms.htm along with the required fee.
3. Follow NABP's instructions at www.nabp.pharmacy for submitting the application to take the Virginia Multistate Pharmacy Jurisprudence Examination (MPJE).

Once all steps have been completed and the board receives from NABP the applicant's relevant information for consideration, the board will notify NABP of the applicant's eligibility to take the MPJE.

3. Virginia Pharmacy Law Examination Required for Licensure by Examination or Endorsement:

As of July 1, 2016, Virginia ceased administering the Virginia Federal and State Drug Law Exam (FSDLE) and began requiring applicants for pharmacist licensure to successfully pass the Multistate Pharmacy Jurisprudence Examination (MPJE) administered by the NABP. Applicants must directly register with and pay the required fee to the NABP at www.nabp.pharmacy in order to take the MPJE. However, an applicant will not be allowed to schedule taking the MPJE until he has been approved by the Board. Approval from the Board is obtained after a review of the application for pharmacist licensure. Unless there are problems with an application, the application is generally approved within five to seven business days of receipt by the Board.

Detailed information about the MPJE, the registration process, scheduling an appointment to test, requirements on test day, and the MPJE blueprint, which contains a list of competency statements that comprises the topics covered on the exam, may be found at www.nabp.pharmacy .

4. Denial of An Application For Grounds:

Grounds to deny a license may be found in §54.1-3316 of the Code of Virginia on the Board's website.
If grounds exist to deny an application for licensure as a pharmacist, the application will not be approved by Board staff, and the applicant will be so notified and offered an opportunity to meet with an informal conference committee of the Board to determine if the license should be denied, issued, or issued

conditionally. An applicant will not be allowed to take any required examinations if grounds exist to deny the application, until reviewed and approved by the Board.

Virginia Board of Pharmacy

INSTRUCTIONS FOR GRADUATES OF FOREIGN SCHOOLS OF PHARMACY

Each step of the following requirements to be eligible for a pharmacist license in Virginia must be completed in the order listed:

1. FPGEC Certification Program

Graduates of foreign colleges of pharmacy must first obtain the Foreign Pharmacy Graduate Equivalency Committee (FPGEC) certification from the National Association of Boards of Pharmacy (NABP). Virginia has no alternative to this process for certifying the equivalency of pharmacy education and proficiency in written and spoken English. The FPGEC certification shows the following:

a. That the person is a graduate of a foreign college of pharmacy and that the educational and licensure credentials have been evaluated and found to be valid and substantively equivalent to those in the United States;

b. That the person has successfully completed the Foreign Pharmacy Graduate Equivalency Examination (FPGEE).

c. That the person has successfully completed the written and oral communication ability tests of English as follows:

- **Beginning March 1, 2014, all new candidates for FPGEC Certification must complete** the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 24, Speaking 26, Listening 21, and Reading 22

- **Between April 1, 2010 and February 28, 2014,** all new candidates for FPGEC Certification must complete the Internet Based Test of English as a Foreign Language (TOEFL iBT) with a minimum passing score for each component as follows: Writing 24, Speaking 26, Listening 18, and Reading 21; scores for this exam will no longer be accepted from an international Educational Testing Service (ETS) test site location. These candidates who are unsuccessful in meeting all requirements for certification prior to June 1, 2014, must meet the new minimum score requirements of the TOEFL iBT in order to obtain certification.

2. Practical Experience Requirement

One must obtain at least **1500 hours** practical experience within the United States. **Prior to** gaining practical experience in Virginia for credit, a person must register with this Board as a **"pharmacy intern"**. The online application for registration as a pharmacy intern may be found at www.dhp.virginia.gov/pharmacy/pharmacy_forms. The applicant must submit the application, pay the required fee and provide the Virginia pharmacy location where the experience is to be gained as well as the name of the supervising pharmacist. Once the practical experience has been obtained, the pharmacy intern must submit an affidavit to the Board documenting the practical experience. These hours must meet the following requirements:

a. Credit will not be given for more than 50 hours in any one week or for less than an average of 20 hours a week averaged over a month.

b. A pharmacy intern shall be supervised by a pharmacist who holds a current, unrestricted license and assumes full responsibility for the training, supervision and conduct of the intern.

c. Practical experience gained in another state within the U.S. must be certified by that state's board of pharmacy and may require registration as a pharmacy intern with that state board.

d. A temporary intern registration may be issued without a social security number **for 90 days only**.

3. A Completed Application

Once the requirements of sections 1 and 2 above are completed, one may submit an application for licensure as a pharmacist. The applicant should also apply ~~If the application is approved, the applicant will be authorized~~ to take NAPLEX (if applying for initial licensure by examination) and the Multistate Pharmacy Jurisprudence Examination (MPJE) offered by NABP. If the applicant is approved, authorization to test will be granted by the Board. Detailed information about the NAPLEX and MPJE, the registration process, scheduling an appointment to test, requirements on test day, and both the NAPLEX and MPJE blueprints which contain a list of competency statements that comprise the topics covered on the exams may be found at www.nabp.pharmacy

a. If applying for initial licensure in Virginia by examination, an applicant must apply online and submit the required fee. ~~The applicant may omit the college affidavit section.~~

b. If applying to transfer a pharmacist's license from another state within the United States (Licensure by Endorsement), an applicant must go through NABP's license transfer process ~~and, once the process is complete, submit NABP's "Official Application for Transfer of~~

~~Pharmaceutic License~~". In order to be eligible to transfer a license from another state, an applicant must also have met the requirements of sections 1 and 2 above.

All forms required are available on the Board of Pharmacy website under Forms and Applications at http://www.dhp.virginia.gov/pharmacy/default.htm. FPGEC, NAPLEX and MPJE information may be found at www.nabp.pharmacy.

Agenda Item: Feedback on ACPE Standards 2025

Staff Note:

- ACPE sent staff an electronic survey soliciting feedback on the next Standards Revision to be titled "Standards 2025". Feedback is being sought from various stakeholders during 2021.

Included in your package are:

- Printout of electronic survey

Committee Action:

To recommend to the full board what, if any, feedback should be provided to ACPE regarding Standards 2025.

ACCREDITATION COUNCIL
PHARMACY EDUCATIOI

Standards Revision Feedback

This survey will allow feedback on the next Standards Revision to be titled "Standards 2025"

The following questions have been designed for feedback regarding the standards in the following areas:

Educational Outcomes: Standards 1-4

Structure and Process

- Organization/Governance: Standards 5-9
- Curriculum: Standards 10-13
- Students: Standards 14-17
- Faculty/Preceptors: Standards 18-20
- Resources: Standards 21-23

Assessment: Standards 24-25

Under each area, standards have been listed to streamline comments, feedback, and suggestions. Each standard description and key element description has been provided.

Name

Caroline	Juran
First Name	Last Name

Program or Organization

Virginia Board of Pharmacy

Save and Resume Later

Next

Educational Outcomes

Standard 1: Foundational Knowledge: The professional program leading to the Doctor of Pharmacy degree (hereinafter "the program") develops in the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to apply the foundational sciences to the provision of patient-centered care.

Key Element:

1.1. Foundational knowledge – The graduate is able to develop, integrate, and apply knowledge from the foundational sciences (i.e., biomedical, pharmaceutical, social/behavioral/administrative, and clinical sciences) to evaluate the scientific literature, explain drug action, solve therapeutic problems, and advance population health and patient-centered care.

Standard 2: Essentials for Practice and Care: The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to provide patient-centered care, manage medication use systems, promote health and wellness, and describe the influence of population-based care on patient-centered care.

Key Elements:
2.1. Patient-centered care – The graduate is able to provide patient-centered care as the medication expert (collect and interpret evidence, prioritize, formulate assessments and recommendations, implement, monitor and adjust plans, and document activities).

2.2. Medication use systems management – The graduate is able to manage patient healthcare needs using human, financial, technological, and physical resources to optimize the safety and efficacy of medication use systems.

2.3. Health and wellness – The graduate is able to design prevention, intervention, and educational strategies for individuals and communities to manage chronic disease and improve health and wellness.

2.4. Population-based care – The graduate is able to describe how population-based care influences patient-centered care and the development of practice guidelines and evidence-based best practices.

Standard 3: Approach to Practice and Care: The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to solve problems; educate, advocate, and collaborate, working with a broad range of people; recognize social determinants of health; and effectively communicate verbally and nonverbally.

Key Elements:
3.1. Problem solving – The graduate is able to identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution.

3.2. Education – The graduate is able to educate all audiences by determining the most effective and enduring ways to impart information and assess learning.

3.3. Patient advocacy – The graduate is able to represent the patient's best interests.

3.4. Interprofessional collaboration – The graduate is able to actively participate and engage as a healthcare team member by demonstrating mutual respect, understanding, and values to meet patient care needs.

3.5. Cultural sensitivity – The graduate is able to recognize social determinants of health to diminish disparities and inequities in access to quality care.

3.6. Communication – The graduate is able to effectively communicate verbally and nonverbally when interacting with individuals, groups, and organizations.

Standard 4: Personal and Professional Development: The program imparts to the graduate the knowledge, skills, abilities, behaviors, and attitudes necessary to demonstrate self-awareness, leadership, innovation and entrepreneurship, and professionalism.

Key Elements:
4.1. Self-awareness – The graduate is able to examine and reflect on personal knowledge, skills, abilities, beliefs, biases, motivation, and emotions that could enhance or limit personal and professional growth.

4.2. Leadership – The graduate is able to demonstrate responsibility for creating and achieving shared goals, regardless of position.

4.3. Innovation and entrepreneurship – The graduate is able to engage in innovative activities by using creative thinking to envision better ways of accomplishing professional goals.

4.4. Professionalism – The graduate is able to exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society.

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 1: Foundational Knowledge
- ☐ Standard 2: Essentials for Practice and Care
- ☐ Standard 3: Approach to Practice and Care
- ☐ Standard 4: Personal and Professional Development

Which standards, as written, should NOT be included in Standards 2025?

- ☐ Standard 1: Foundational Knowledge
- ☐ Standard 2: Essentials for Practice and Care
- ☐ Standard 3: Approach to Practice and Care
- ☐ Standard 4: Personal and Professional Development

Which standards, as written, require revision to be included in Standards 2025?

- ☐ Standard 1: Foundational Knowledge
- ☐ Standard 2: Essentials for Practice and Care
- ☐ Standard 3: Approach to Practice and Care
- ☐ Standard 4: Personal and Professional Development

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 1: Foundational Knowledge
- ☐ Standard 2: Essentials for Practice and Care
- ☐ Standard 3: Approach to Practice and Care
- ☐ Standard 4: Personal and Professional Development

Please list any additional required elements (topics to add to the curriculum) that should be included in Standards 2025. (Listing of required elements/topics can be found in Appendix 1 of Standards 2016)

Please provide comments regarding the Educational Outcomes standards (1-4)

Administration/Organization

Standard 5: Eligibility and Reporting Requirements: The program meets all stated degree-granting eligibility and reporting requirements.

Key Elements:

5.1. Autonomy – The academic unit offering the Doctor of Pharmacy program is an autonomous unit organized as a college or school of pharmacy (within a university or as an independent entity). This includes autonomy to manage the professional program within stated policies and procedures, as well as applicable state and federal regulations.

5.2. Legal empowerment – The college or school is legally empowered to offer and award the Doctor of Pharmacy degree.

5.3. Dean's leadership – The college or school is led by a dean, who serves as the chief administrative and academic officer of the college or school and is responsible for ensuring that all accreditation requirements of ACPE are met.

5.4. Regional/institutional accreditation – The institution housing the college or school, or the independent college or school, has (or, in the case of new programs, is seeking) full accreditation by a regional/institutional accreditation agency recognized by the U.S. Department of Education.

5.5. Regional/institutional accreditation actions – The college or school reports to ACPE within 30 days any issue identified in regional/institutional accreditation actions that may have a negative impact on the quality of the professional degree program and compliance with ACPE standards.

5.6. Substantive change – The dean promptly reports substantive changes in organizational structure and/or processes (including financial factors) to ACPE for the purpose of evaluation of their impact on programmatic quality.

Standard 6: College or School Vision, Mission, and Goals: The college or school publishes statements of its vision, mission, and goals.

Key Elements:

6.1. College or school vision and mission – These statements are compatible with the vision and mission of the university in which the college or school operates.

6.2. Commitment to educational outcomes – The mission statement is consistent with a commitment to the achievement of the Educational Outcomes (Standards 1–4).

6.3. Education, scholarship, service, and practice – The statements address the college or school's commitment to professional education, research and scholarship, professional and community service, pharmacy practice, and continuing professional development.

6.4. Consistency of initiatives – All program initiatives are consistent with the college or school's vision, mission, and goals.

6.5. Subunit goals and objectives alignment – If the college or school organizes its faculty into subunits, the subunit goals are aligned with those of the college or school.

Standard 7: Strategic Plan: The college or school develops, utilizes, assesses, and revises on an ongoing basis a strategic plan that includes tactics to advance its vision, mission, and goals.

Key Elements:

7.1. Inclusive process – The strategic plan is developed through an inclusive process, including faculty, staff, students, preceptors, practitioners, and other relevant constituents, and is disseminated in summary form to key stakeholders.

7.2. Appropriate resources – Elements within the strategic plan are appropriately resourced and have the support of the university administration as needed for implementation.

7.3. Substantive change planning – Substantive programmatic changes contemplated by the college or school are linked to its ongoing strategic planning process.

Standard 8: Organization and Governance: The college or school is organized and staffed to advance its vision and facilitate the accomplishment of its mission and goals.

Key Elements:

8.1. Leadership collaboration – University leadership and the college or school dean collaborate to advance the program's vision and mission and to meet ACPE accreditation standards. The dean has direct access to the university administrator(s) with ultimate responsibility for the program.

8.2. Qualified dean – The dean is qualified to provide leadership in pharmacy professional education and practice, research and scholarship, and professional and community service.

8.3. Qualified administrative team – The dean and other college or school administrative leaders have credentials and experience that have prepared them for their respective roles and collectively have the needed backgrounds to effectively manage the educational program.

8.4. Dean's other substantial administrative responsibilities – If the dean is assigned other substantial administrative responsibilities, the university ensures adequate resources to support the effective administration of the affairs of the college or school.

8.5. Authority, collegiality, and resources – The college or school administration has defined lines of authority and responsibility, fosters organizational unit collegiality and effectiveness, and allocates resources appropriately.

8.6. College or school participation in university governance – College or school administrators and faculty are effectively represented in the governance of the university, in accordance with its policies and procedures.

8.7. Faculty participation in college or school governance – The college or school uses updated, published documents, such as bylaws, policies, and procedures, to ensure faculty participation in the governance of the college or school.

8.8. Systems failures – The college or school has comprehensive policies and procedures that address potential systems failures, including technical, administrative, and curricular failures.

8.9. Alternate pathway equitability* – The college or school ensures that any alternative pathways to the Doctor of Pharmacy degree are equitably resourced and integrated into the college or school's regular administrative structures, policies, and procedures, including planning, oversight, and evaluation.

Standard 9: Organizational Culture: The college or school provides an environment and culture that promotes self-directed lifelong learning, professional behavior, leadership, collegial relationships, and collaboration within and across academic units, disciplines, and professions.

Key Elements:

9.1. Leadership and professionalism – The college or school demonstrates a commitment to developing professionalism and to fostering leadership in

administrators, faculty, preceptors, staff, and students. Faculty and preceptors serve as mentors and positive role models for students.

9.2. Behaviors – The college or school has policies that define expected behaviors for administrators, faculty, preceptors, staff, and students, along with consequences for deviation from those behaviors.

9.3. Culture of collaboration – The college or school develops and fosters a culture of collaboration within subunits of the college or school, as well as within and outside the university, to advance its vision, mission, and goals, and to support the profession.

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 5: Eligibility and Reporting Requirements
- ☐ Standard 6: College or School Vision, Mission, and Goals
- ☐ Standard 7: Strategic Plan
- ☐ Standard 8: Organization and Governance
- ☐ Standard 9: Organizational Culture

Which standards, as written, should NOT be included in Standards 2025?

- ☐ Standard 5: Eligibility and Reporting Requirements
- ☐ Standard 6: College or School Vision, Mission, and Goals
- ☐ Standard 7: Strategic Plan
- ☐ Standard 8: Organization and Governance
- ☐ Standard 9: Organizational Culture

Which standards, as written, require revision to be included in Standards 2025?

- ☐ Standard 5: Eligibility and Reporting Requirements
- ☐ Standard 6: College or School Vision, Mission, and Goals
- ☐ Standard 7: Strategic Plan
- ☐ Standard 8: Organization and Governance
- ☐ Standard 9: Organizational Culture

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 5: Eligibili[redacted]nc Reporting Requirements

Standard 6: College or School Vision, Mission, and Goals

- [ ] Standard 7: Strategic Plan
- [ ] Standard 8: Organization and Governance
- [ ] Standard 9: Organizational Culture

Please provide any additional comments regarding the Administration/Organization standards (5-9)

Curriculum

Standard 10: Curriculum Design, Delivery, and Oversight; The curriculum is designed, delivered, and monitored by faculty to ensure breadth and depth of requisite knowledge and skills, the maturation of professional attitudes and behaviors, and the opportunity to explore professional areas of interest. The curriculum also emphasizes active learning pedagogy, content integration, knowledge acquisition, skill development, and the application of knowledge and skills to therapeutic decision-making.

Key Elements:
10.1. Program duration – The professional curriculum is a minimum of four academic years of full-time study or the equivalent.

10.2. Curricular oversight – Curricular oversight involves collaboration between faculty and administration. The body/bodies charged with curricular oversight: (1) are representative of the faculty at large, (2) include student representation, (3) effectively communicate and coordinate efforts with body/bodies responsible for curricular assessment, and (4) are adequately resourced to ensure and continually advance curricular quality.

10.3. Knowledge application – Curricular expectations build on a pre-professional foundation of scientific and liberal studies. The professional curriculum is organized to allow for the logical building of a sound scientific and clinical knowledge base that culminates in the demonstrated ability of learners to apply knowledge to practice.

10.4. Skill development – The curriculum is rigorous, contemporary, and intentionally sequenced to promote integration and reinforcement of content and the demonstration of competency in skills required to achieve the Educational Outcomes articulated in Section I.

10.5. Professional attitudes and behaviors development – The curriculum inculcates professional attitudes and behaviors leading to personal and professional maturity consistent with the Oath of the Pharmacist.

10.6. Faculty and preceptor credentials/expertise – All courses in the curriculum are taught by individuals with academic credentials and expertise that are explicitly linked to their teaching responsibilities.

10.7. Content breadth and depth – Programs document, through mapping or other comparable methods, the breadth and depth of exposure to curricular content areas deemed essential to pharmacy education at the doctoral level (Appendices 1 and 2).

10.8. Pharmacists' Patient Care Process – The curriculum prepares students to provide patient-centered collaborative care as described in the Pharmacists' Patient Care Process model endorsed by the Joint Commission of Pharmacy Practitioners.

10.9. Electives – Time is reserved within the core curriculum for elective didactic and experiential education courses that permit exploration of and/or advanced study in areas of professional interest.

10.10. Feedback – The curriculum allows for timely, formative performance feedback to students in both didactic and experiential education courses. Students are also provided the opportunity to give formative and/or summative feedback to faculty, including preceptors, on their perceptions of teaching/learning effectiveness.

10.11. Curriculum review and quality assurance – Curriculum design, delivery, and sequencing are regularly reviewed and, when appropriate, revised by program faculty to ensure optimal achievement of educational outcomes with reasonable student workload expectations.

10.12. Teaching and learning methods – The didactic curriculum is delivered via teaching/learning methods that: (1) facilitate achievement of learning outcomes, (2) actively engage learners, (3) promote student responsibility for self-directed learning, (4) foster collaborative learning, and (5) are appropriate for the student population (i.e., campus-based vs. distance-based).

10.13. Diverse learners – The didactic curriculum incorporates teaching techniques and strategies that address the diverse learning needs of students.

10.14. Course syllabi – Syllabi for didactic and experiential education courses, developed and updated through a faculty-approved process, contain information that supports curricular quality assurance assessment.

10.15. Experienti[illegible]uality assurance – A quality assurance procedure for all

pharmacy practice experiences is established and implemented to: (1) facilitate achievement of stated course expectations, (2) standardize key components of experiences across all sites offering the same experiential course, and (3) promote consistent assessment of student performance.

10.16. Remuneration/employment – Students do not receive payment for participating in curricular pharmacy practice experiences, nor are they placed in the specific practice area within a pharmacy practice site where they are currently employed.

10.17. Academic integrity* – To ensure the credibility of the degree awarded, the validity of individual student assessments, and the integrity of student work, the college or school ensures that assignments and examinations take place under circumstances that minimize opportunities for academic misconduct. The college or school ensures the correct identity of all students (including distance students) completing proctored assessments.

Standard 11: Interprofessional Education (IPE): The curriculum prepares all students to provide entry-level, patient-centered care in a variety of practice settings as a contributing member of an interprofessional team. In the aggregate, team exposure includes prescribers as well as other healthcare professionals.

Key Elements:
11.1. Interprofessional team dynamics – All students demonstrate competence in interprofessional team dynamics, including articulating the values and ethics that underpin interprofessional practice, engaging in effective interprofessional communication, including conflict resolution and documentation skills, and honoring interprofessional roles and responsibilities. Interprofessional team dynamics are introduced, reinforced, and practiced in the didactic and Introductory Pharmacy Practice Experience (IPPE) components of the curriculum, and competency is demonstrated in Advanced Pharmacy Practice Experience (APPE) practice settings.

11.2. Interprofessional team education – To advance collaboration and quality of patient care, the didactic and experiential curricula include opportunities for students to learn about, from, and with other members of the interprofessional healthcare team. Through interprofessional education activities, students gain an understanding of the abilities, competencies, and scope of practice of team members. Some, but not all, of these educational activities may be simulations.

11.3. Interprofessional team practice – All students competently participate as a healthcare team member in providing direct patient care and engaging in shared therapeutic decision-making. They participate in experiential educational activities with prescribers/student prescribers and other student/professional healthcare team members, including face-to-face interactions that are designed to advance interprofessional team effectiveness

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 10: Curriculum Design, Delivery, and Oversight
- ☐ Standard 11: Interprofessional Education (IPE)

Which standards, as written, should NOT be included in Standards 2025?

- ☐ Standard 10: Curriculum Design, Delivery, and Oversight
- ☐ Standard 11: Interprofessional Education (IPE)

Which standards, as written, require revision to be included in Standards 2025?

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- ☐ Standard 11: Interprofessional Education (IPE)

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 10: Curriculum Design, Delivery, and Oversight
- ☐ Standard 11: Interprofessional Education (IPE)

Please provide comments regarding the Curriculum standards (10-11)

Curriculum

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10.12. Teaching and learning methods – The didactic curriculum is delivered via teaching/learning methods that: (1) facilitate achievement of learning outcomes, (2) actively engage learners, (3) promote student responsibility for self-directed learning, (4) foster collaborative learning, and (5) are appropriate for the student population (i.e., campus-based vs. distance-based).

10.13. Diverse learners – The didactic curriculum incorporates teaching techniques and strategies that address the diverse learning needs of students.

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10.16. Remuneration/employment – Students do not receive payment for participating in curricular pharmacy practice experiences, nor are they placed in the specific practice area within a pharmacy practice site where they are currently employed.

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11.2. Interprofessional team education – To advance collaboration and quality of patient care, the didactic and experiential curricula include opportunities for students to learn about, from, and with other members of the interprofessional healthcare team. Through interprofessional education activities, students gain an understanding of the abilities, competencies, and scope of practice of team members. Some, but not all, of these educational activities may be simulations.

11.3. Interprofessional team practice – All students competently participate as a healthcare team member in providing direct patient care and engaging in shared therapeutic decision-making. They participate in experiential educational activities with prescribers/student prescribers and other student/professional healthcare team members, including face-to-face interactions that are designed to advance interprofessional team effectiveness

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 10: Curriculum Design, Delivery, and Oversight
- ☐ Standard 11: Interprofessional Education (IPE)

Which standards, as written, should NOT be included in Standards 2025?

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Which standards, as written, require revision to be included in Standards 2025?

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- ☐ Standard 11: Interprofessional Education (IPE)

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 10: Curriculum Design, Delivery, and Oversight
- ☐ Standard 11: Interprofessional Education (IPE)

Please provide comments regarding the Curriculum standards (10-11)

Experiential Education

Standard 12: Pre-Advanced Pharmacy Practice Experience (Pre-APPE) Curriculum: The Pre-APPE curriculum provides a rigorous foundation in the biomedical, pharmaceutical, social/administrative/behavioral, and clinical sciences, incorporates Introductory Pharmacy Practice Experience (IPPE), and inculcates habits of self-directed lifelong learning to prepare students for Advanced Pharmacy Practice Experience (APPE).

Key Elements:
12.1. Didactic curriculum – The didactic portion of the Pre-APPE curriculum includes rigorous instruction in all sciences that define the profession (see Appendix 1). Appropriate breadth and depth of instruction in these sciences is documented regardless of curricular model employed (e.g., blocked, integrated, traditional 'stand-alone' course structure, etc.).

12.2. Development and maturation – The Pre-APPE curriculum allows for the development and maturation of the knowledge, skills, abilities, attitudes, and behaviors that underpin the Educational Outcomes articulated in Standards 1 –4 and within Appendices 1 and 2.

12.3. Affective domain elements – Curricular and, if needed, co-curricular activities and experiences are purposely developed and implemented to ensure an array of opportunities for students to document competency in the affective domain-related expectations of Standards 3 and 4. Co-curricular activities complement and advance the learning that occurs within the formal didactic and experiential curriculum.

12.4. Care across the lifespan – The Pre-APPE curriculum provides foundational knowledge and skills that allow for care across the patient's lifespan.

12.5. IPPE expectations – IPPEs expose students to common contemporary U.S. practice models, including interprofessional practice involving shared patient care decision-making, professional ethics and expected behaviors, and direct patient care activities. IPPEs are structured and sequenced to intentionally develop in students a clear understanding of what constitutes exemplary pharmacy practice in the U.S. prior to beginning APPE.

12.6. IPPE duration – IPPE totals no less than 300 clock hours of experience and is purposely integrated into the didactic curriculum. A minimum of 150 hours of IPPE are balanced between community and institutional health-system settings.

12.7. Simulation for IPPE – Simulated practice experiences (a maximum of 60 clock hours of the total 300 hours) may be used to mimic actual or realistic pharmacist-delivered patient care situations. However, simulation hours do not substitute for the 150 clock hours of required IPPE time in community and institutional health-system settings. Didactic instruction associated with the implementation of simulated practice experiences is not counted toward any portion of the 300 clock hour IPPE requirement.

Standard 13: Advanced Pharmacy Practice Experience (APPE) Curriculum: A continuum of required and elective APPEs is of the scope, intensity, and duration required to support the achievement of the Educational Outcomes articulated in Standards 1–4 and within Appendix 2 to prepare practice-ready graduates. APPEs integrate, apply, reinforce, and advance the knowledge, skills, attitudes, abilities, and behaviors developed in the Pre-APPE curriculum and in co-curricular activities.

Key Elements:
13.1. Patient care emphasis – Collectively, APPEs emphasize continuity of care and incorporate acute, chronic, and wellness-promoting patient-care services in outpatient (community/ambulatory care) and inpatient (hospital/health system) settings.

13.2. Diverse populations – In the aggregate, APPEs expose students to diverse patient populations as related to age, gender, race/ethnicity, socioeconomic factors (e.g., rural/urban, poverty/affluence), and disease states.

13.3. Interprofessional experiences – In the aggregate, students gain in-depth experience in delivering direct patient care as part of an interprofessional team.

13.4. APPE duration – The curriculum includes no less than 36 weeks (1440 hours) of APPE. All students are exposed to a minimum of 160 hours in each required APPE area. The majority of APPE is focused on direct patient care.

13.5. Timing – APPEs follow successful completion of all IPPE and required

didactic curricular content. Required capstone courses or activities that provide opportunity for additional professional growth and insight are allowed during or after completion of APPEs. These activities do not compromise the quality of the APPEs, nor count toward the required 1440 hours of APPE.

13.6. Required APPE – Required APPEs occur in four practice settings: (1) community pharmacy; (2) ambulatory patient care; (3) hospital/health system pharmacy; and (4) inpatient general medicine patient care.

13.7. Elective APPE – Elective APPEs are structured to give students the opportunity to: (1) mature professionally, (2) secure the breadth and depth of experiences needed to
achieve the Educational Outcomes articulated in Standards 1–4, and (3) explore various sectors of practice.
13.8. Geographic restrictions – Required APPEs are completed in the United States or its territories or possessions. All quality assurance expectations for U.S.-based experiential education courses apply to elective APPEs offered outside of the U.S.

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 12: Pre-Advanced Pharmacy Practice Experience (Pre-APPE) Curriculum
- ☐ Standard 13: Advanced Pharmacy Practice Experience (APPE) Curriculum

Which standards, as written, should NOT be included in Standards 2025?

- ☐ Standard 12: Pre-Advanced Pharmacy Practice Experience (Pre-APPE) Curriculum
- ☐ Standard 13: Advanced Pharmacy Practice Experience (APPE) Curriculum

Which standards, as written, require revision to be included in Standards 2025?

- ☐ Standard 12: Pre-Advanced Pharmacy Practice Experience (Pre-APPE) Curriculum
- ☐ Standard 13: Advanced Pharmacy Practice Experience (APPE) Curriculum

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 12: Pre-Advanced Pharmacy Practice Experience (Pre-APPE) Curriculum
- ☐

Standard 13: Advanced Pharmacy Practice Experience (APPE) Curriculum

Please provide comments regarding the Experiential Education standards (12-13)

Save and Resume Later

Student Services

Standard 14: Student Services: The college or school has an appropriately staffed and resourced organizational element dedicated to providing a comprehensive range of services that promote student success and well-being.

Key Elements:

14.1. FERPA – The college or school has an ordered, accurate, and secure system of student records in compliance with the Family Educational Rights and Privacy Act (FERPA). Student services personnel and faculty are knowledgeable regarding FERPA law and its practices.

14.2. Financial aid – The college or school provides students with financial aid information and guidance by appropriately trained personnel.

14.3. Healthcare – The college or school offers students access to adequate health and counseling services. Appropriate immunization standards are established, along with the means to ensure that such standards are satisfied.

14.4. Advising – The college or school provides academic advising, curricular and career-pathway counseling, and information on post-graduate education and training opportunities adequate to meet the needs of its students.

14.5. Nondiscrimination – The college or school establishes and implements student service policies that ensure nondiscrimination as defined by state and federal laws and regulations.

14.6. Disability accommodation – The college or school provides accommodations to students with documented disabilities that are determined by the university Disability Office (or equivalent) to be reasonable, and provides support to faculty in accommodating disabled students.

14.7. Student services access* – The college or school offering multiple professional degree programs (e.g., PharmD/MPH) or pathways (campus and distance pathways) ensures that all students have equitable access to a comparable system of individualized student services (e.g., tutorial support, faculty advising, counseling, etc.).

Standard 15: Academic Environment: The college or school develops, implements, and assesses its policies and procedures that promote student success and well-being.

Key elements:

15.1. Student information – The college or school produces and makes available to enrolled and prospective students updated information of importance, such as governance documents, policies and procedures, handbooks, and catalogs.

15.2. Complaints policy – The college or school develops, implements, and makes available to students a complaints policy that includes procedures for how students may file complaints within the college or school and also directly to ACPE regarding their college or school's adherence to ACPE standards. The college or school maintains a chronological record of such student complaints, including how each complaint was resolved.

15.3. Student misconduct – The college or school develops and implements policies regarding academic and non-academic misconduct of students that clearly outline the rights and responsibilities of, and ensures due process for, all parties involved.

15.4. Student representation – The college or school considers student perspectives and includes student representation, where appropriate, on committees, in policy-development bodies, and in assessment and evaluation activities.

15.5. Distance learning policies* – For colleges and schools offering distance learning opportunities, admissions information clearly explains the conditions and requirements related to distance learning, including full disclosure of any requirements that cannot be completed at a distance.

Standard 16: Admissions: The college or school develops, implements, and assesses its admission criteria, policies, and procedures to ensure the selection of a qualified and diverse student body into the professional degree program.

Key elements:

16.1. Enrollment management – Student enrollment is managed by college or school administration. Enrollments are in alignment with available physical, educational, financial, faculty, staff, practice site, preceptor, and administrative resources.

16.2. Admission procedures – A duly constituted committee of the college or school has the responsibility and authority for the selection of students to be offered admission. Admission criteria, policies, and procedures are not compromised regardless of the size or quality of the applicant pool.

16.3. Program description and quality indicators – The college or school produces and ma[illegible] available to the public, including prospective students: (1)

a complete and accurate description of the professional degree program; (2) the program's current accreditation status; and (3) ACPE-required program performance information including on-time graduation rates and most recent NAPLEX first-attempt pass rates.

16.4. Admission criteria – The college or school sets performance expectations for admission tests, evaluations, and interviews used in selecting students who have the potential for success in the professional degree program and the profession. Applicant performance on admission criteria is documented; and the related records are maintained by the college or school as per program/university requirements.

16.5. Admission materials – The college or school produces and makes available to prospective students the criteria, policies, and procedures for admission to the professional degree program. Admission materials clearly state academic expectations, required communication skills, types of personal history disclosures that may be required, and professional and technical standards for graduation.

16.6. Written and oral communication assessment – Written and oral communication skills are assessed in a standardized manner as part of the admission process.

16.7. Candidate interviews – Standardized interviews (in-person, telephonic, and/or computer-facilitated) of applicants are conducted as a part of the admission process to assess affective domain characteristics (i.e., the Personal and Professional Development domain articulated in Standard 4).

16.8. Transfer and waiver policies – A college or school offering multiple professional degree programs, or accepting transfer students from other schools or colleges of pharmacy, establishes and implements policies and procedures for students who request to transfer credits between programs. Such policies and procedures are based on defensible assessments of course equivalency. A college or school offering multiple pathways to a single degree has policies and procedures for students who wish to change from one pathway to another.

Standard 17: Progression: The college or school develops, implements, and assesses its policies and procedures related to student progression through the PharmD program.

Key elements:

17.1. Progression policies – The college or school creates, makes available to students and prospective students, and abides by criteria, policies, and procedures relate[illegible]o:

- Academic progression
- Remediation
- Missed course work or credit
- Academic probation
- Academic dismissal
- Dismissal for reasons of misconduct
- Readmission
- Leaves of absence
- Rights to due process
- Appeal mechanisms (including grade appeals)

17.2. Early intervention – The college or school's system of monitoring student performance provides for early detection of academic and behavioral issues. The college or school develops and implements appropriate interventions that have the potential for successful resolution of the identified issues.

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 14: Student Services
- ☐ Standard 15: Academic Environment
- ☐ Standard 16: Admissions
- ☐ Standard 17: Progression

Which standards, as written, should NOT be included in Standards 2025?

- ☐ Standard 14: Student Services
- ☐ Standard 15: Academic Environment
- ☐ Standard 16: Admissions
- ☐ Standard 17: Progression

Which standards, as written, require revision to be included in Standards 2025?

- ☐ Standard 14: Student Services
- ☐

Standard 15: Academic Environment

☐ Standard 16: Admissions

☐ Standard 17: Progression

Which standards required revision of the required documentation (Appendix 3)?

☐ Standard 14: Student Services

☐ Standard 15: Academic Environment

☐ Standard 16: Admissions

☐ Standard 17: Progression

Please provide comments regarding the Student Services standards (14-17).

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Faculty, Staff, and Preceptors

Standard 18: Faculty and Staff—Quantitative Factors: The college or school has a cohort of faculty and staff with the qualifications and experience needed to effectively deliver and evaluate the professional degree program.

Key Elements:

18.1. Sufficient faculty – The college or school has a sufficient number of faculty members to effectively address the following programmatic needs:

- Teaching (didactic, simulation, and experiential)
- Professional development
- Research and other scholarly activities
- Assessment activities
- College/school and/or university service
- Intraprofessional and interprofessional collaboration
- Student advising and career counseling
- Faculty mentoring
- Professional service
- Community service
- Pharmacy practice
- Responsibilities in other academic programs (if applicable)
- Support of distance students and campus(es) (if applicable)*

18.2. Sufficient staff – The college or school has a sufficient number of staff to effectively address the following programmatic needs:

- Student and academic affairs-related services, including recruitment and admission
- Experiential education
- Assessment activities

- Research administration
- Laboratory maintenance
- Information technology infrastructure
- Pedagogical and educational technology support
- Teaching assistance
- General faculty and administration clerical support
- Support of distance students and campus(es) (if applicable)*

Standard 19: Faculty and Staff—Qualitative Factors: Faculty and staff have academic and professional credentials and expertise commensurate with their responsibilities to the professional program and their academic rank.

Key Elements:

19.1. Educational effectiveness – Faculty members have the capability and demonstrate a continuous commitment to be effective educators and are able to effectively use contemporary educational techniques to promote student learning in all offered pathways.

19.2. Scholarly productivity – The college or school creates an environment that both requires and promotes scholarship and also develops mechanisms to assess both the quantity and quality of faculty scholarly productivity.

19.3. Service commitment – In the aggregate, faculty engage in professional, institutional, and community service that advances the program and the profession of pharmacy.

19.4. Practice understanding – Faculty members, regardless of their discipline, have a conceptual understanding of and commitment to advancing current and proposed future pharmacy practice.

19.5. Faculty/staff development – The college or school provides opportunities for career and professional development of its faculty and staff, individually and collectively, to enhance their role-related skills, scholarly productivity, and leadership.

19.6. Policy application – The college or school ensures that policies and procedures for faculty and staff recruitment, performance review, promotion, tenure (if applicable), and retention are applied in a consistent manner.

Standard 20: Preceptors: The college or school has a sufficient number of preceptors (practice faculty or external practitioners) to effectively deliver and evaluate students in the experiential component of the curriculum. Preceptors have professional credentials and expertise commensurate with their responsibilities to the professional program.

Key Elements:
20.1. Preceptor criteria – The college or school makes available and applies quality criteria for preceptor recruitment, orientation, performance, and evaluation. The majority of preceptors for any given student are U.S. licensed pharmacists.

20.2. Student-to-preceptor ratio – Student to precepting pharmacist ratios allow for the individualized mentoring and targeted professional development of learners.

20.3. Preceptor education and development – Preceptors are oriented to the program's mission, the specific learning expectations for the experience outlined in the syllabus, and effective performance evaluation techniques before accepting students. The college or school fosters the professional development of its preceptors commensurate with their educational responsibilities to the program.

20.4. Preceptor engagement – The college or school solicits the active involvement of preceptors in the continuous quality improvement of the educational program, especially the experiential component.

20.5. Experiential education administration – The experiential education component of the curriculum is led by a pharmacy professional with knowledge and experience in experiential learning. The experiential education program is supported by an appropriate number of qualified faculty and staff.

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 18: Faculty and Staff - Quantitative Factors
- ☐ Standard 19: Faculty and Staff - Qualitative Factors
- ☐ Standard 20: Preceptors

Which standards, as written, should NOT be included in Standards 2025?

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Standard 18: Faculty and Staff - Quantitative Factors

- ☐ Standard 19: Faculty and Staff - Qualitative Factors
- ☐ Standard 20: Preceptors

Which standards, as written, require revision to be included in Standards 2025?

- ☐ Standard 18: Faculty and Staff - Quantitative Factors
- ☐ Standard 19: Faculty and Staff - Qualitative Factors
- ☐ Standard 20: Preceptors

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 18: Faculty and Staff - Quantitative Factors
- ☐ Standard 19: Faculty and Staff - Qualitative Factors
- ☐ Standard 20: Preceptors

Please provide comments regarding the Faculty, Staff, and Preceptors standards (18-20).

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Facilities/Financial Resources

Standard 21: Physical Facilities and Educational Resources: The college or school has adequate and appropriately equipped physical and educational facilities to achieve its mission and goals.

Key Elements:

21.1. Physical facilities – The college or school's physical facilities (or the access to other facilities) meet legal and safety standards, utilize current educational technology, and are clean and well maintained.

21.2. Physical facilities' attributes – The college or school's physical facilities also include adequate:

- Faculty office space with sufficient privacy to permit accomplishment of responsibilities
- Space that facilitates interaction of administrators, faculty, students, and interprofessional collaborators
- Classrooms that comfortably accommodate the student body and that are equipped to allow for the use of required technology
- Laboratories suitable for skills practice, demonstration, and competency evaluation
- Access to educational simulation capabilities
- Faculty research laboratories with well-maintained equipment including research support services within the college or school and the university
- Animal facilities that meet care regulations (if applicable)
- Individual and group student study space and student meeting facilities

21.3. Educational resource access – The college or school makes available technological access to current scientific literature and other academic and educational resources by students, faculty, and preceptors.

21.4 Librarian expertise access – The college or school has access to librarian resources with the expertise needed to work with students, faculty, and preceptors on effective literature and database search and retrieval strategies.

Standard 22: Practice Facilities: The college or school has the appropriate number and mix of facilities in which required and elective practice experiences are conducted to accommodate all students. Practice sites are appropriately licensed and selected based on quality criteria to ensure the effective and timely delivery of the experiential component of the curriculum.

Key Elements:

22.1. Quality criteria – The college or school employs quality criteria for practice facility recruitment and selection, as well as setting forth expectations and evaluation based on student opportunity to achieve the required Educational Outcomes as articulated in Standards 1–4.

22.2. Affiliation agreements – The college or school secures and maintains signed affiliation agreements with the practice facilities it utilizes for the experiential component of the curriculum. At a minimum, each affiliation agreement ensures that all experiences are conducted in accordance with state and federal laws.

22.3. Evaluation – Practice sites are regularly evaluated. Quality enhancement initiatives and processes are established, as needed, to improve student learning outcomes.

Standard 23: Financial Resources: The college or school has current and anticipated financial resources to support the stability of the educational program and accomplish its mission, goals, and strategic plan.

Key Elements:

23.1. Enrollment support – The college or school ensures that student enrollment is commensurate with resources.

23.2. Budgetary input – The college or school provides input into the development and operation of a budget that is planned, executed, and managed in accordance with sound and accepted business practices.

23.3. Revenue allocation – Tuition and fees for pharmacy students are not increased to support other educational programs if it compromises the quality of the professional program.

23.4. Equitable allocation – The college or school ensures that funds are sufficient to maintain equitable facilities (commensurate with services and activities) across all program pathways.

Which standards, as written, should be included in Standards 2025?

- ☐ Standard 21: Physical Facilities and Educational Resources
- ☐ Standard 22: Practice Facilities
- ☐ Standard 23: Financial Resources

Which standards, as written, should NOT be included in Standards 2025?

- ☐ Standard 21: Physical Facilities and Educational Resources
- ☐ Standard 22: Practice Facilities
- ☐ Standard 23: Financial Resources

Which standards, as written, require revision to be included in Standards 2025?

- ☐ Standard 21: Physical Facilities and Educational Resources
- ☐ Standard 22: Practice Facilities
- ☐ Standard 23: Financial Resources

Which standards required revision of the required documentation (Appendix 3)?

- ☐ Standard 21: Physical Facilities and Educational Resources
- ☐ Standard 22: Practice Facilities
- ☐ Standard 23: Financial Resources

Please provide comments regarding the Facilities/Financial Resources standards (21-23).

Save and Resume Later

Assessment

Standard 24: Assessment Elements for Section I: Educational Outcomes: The college or school develops, resources, and implements a plan to assess attainment of educational outcomes to ensure that graduates are prepared to enter practice.

Key Elements:

24.1. Formative and summative assessment – The assessment plan incorporates systematic, valid, and reliable knowledge-based and performance-based formative and summative assessments.

24.2. Standardized and comparative assessments – The assessment plan includes standardized assessments as required by ACPE (see Appendix 3) that allow for national comparisons and college- or school-determined peer comparisons.

24.3. Student achievement and readiness – The assessment plan measures student achievement at defined levels of the professional competencies that support attainment of the Educational Outcomes in aggregate and at the individual student level. In addition to college/school desired assessments, the plan includes an assessment of student readiness to:

- Enter advanced pharmacy practice experiences
- Provide direct patient care in a variety of healthcare settings
- Contribute as a member of an interprofessional collaborative patient care team

24.4. Continuous improvement – The college or school uses the analysis of assessment measures to improve student learning and the level of achievement of the Educational Outcomes.

Standard 25: Assessment Elements for Section II: Structure and Process: The college or school develops, resources, and implements a plan to assess attainment of the Key Elements within Standards 5–23.

Specific Key Elements:

25.1. Assessment of organizational effectiveness – The college or school's assessment plan is designed to provide insight into the effectiveness of the

organizational structure in engaging and uniting constituents and positioning the college or school for success through purposeful planning.

25.2. Program evaluation by stakeholders – The assessment plan includes the use of data from AACP standardized surveys of graduating students, faculty, preceptors, and alumni.

25.3. Curriculum assessment and improvement – The college or school systematically assesses its curricular structure, content, organization, and outcomes. The college or school documents the use of assessment data for continuous improvement of the curriculum and its delivery.

25.4. Faculty productivity assessment – The college or school systematically assesses the productivity of its faculty in scholarship, teaching effectiveness, and professional and community service.

25.5. Pathway comparability* – The assessment plan includes a variety of assessments that will allow comparison and establishment of educational parity of alternative program pathways to degree completion, including geographically dispersed campuses and online or distance learning-based programs.

25.6. Interprofessional preparedness – The college or school assesses the preparedness of all students to function effectively and professionally on an interprofessional healthcare team.

25.7. Clinical reasoning skills – Evidence-based clinical reasoning skills, the ability to apply these skills across the patient's lifespan, and the retention of knowledge that underpins these skills, are regularly assessed throughout the curriculum.

25.8. APPE preparedness – The Pre-APPE curriculum leads to a defined level of competence in professional knowledge, knowledge application, patient and population-based care, medication therapy management skills, and the attitudes important to success in the advanced experiential program. Competence in these areas is assessed prior to the first APPE.

25.9. Admission criteria – The college or school regularly assesses the criteria, policies, and procedures to ensure the selection of a qualified and diverse student body, members of which have the potential for academic success and the ability to practice in team-centered and culturally diverse environments.

Which standards, as written, should be included in Standards 2025?

Standard 24: Assessment Elements for Section I: Educational Outcomes

☐ Standard 25: Assessment Elements for Section II: Structure and Process

Which standards, as written, should NOT be included in Standards 2025?

☐ Standard 24: Assessment Elements for Section I: Educational Outcomes

☐ Standard 25: Assessment Elements for Section II: Structure and Process

Which standards, as written, require revision to be included in Standards 2025?

☐ Standard 24: Assessment Elements for Section I: Educational Outcomes

☐ Standard 25: Assessment Elements for Section II: Structure and Process

Which standards required revision of the required documentation (Appendix 3)?

☐ Standard 24: Assessment Elements for Section I: Educational Outcomes

☐ Standard 25: Assessment Elements for Section II: Structure and Process

Please provide comments regarding the Assessment standards (24-25)

Save and Resume Later

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