

FINAL/APPROVED

**VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING**

November 29, 2016
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 9:09am

PRESIDING: Ryan Logan, Committee Chairman

MEMBERS PRESENT: Sheila K. W. Elliott
Ellen B. Shinaberry
Cynthia Warriner – arrived at 9:14am
Freeda Cathcart

STAFF PRESENT: Caroline D. Juran, Executive Director
Cathy Reiniers-Day, Deputy Executive Director
Elaine J. Yeatts, Senior Policy Analyst – arrived at 9:56am
Beth O'Halloran, Individual Licensing Manager

APPROVAL OF AGENDA: Agenda presented for review to include continued periodic regulatory review by developing draft amendments to Parts I-III of *Regulations Governing the Practice of Pharmacy*, chapter 20, developing draft regulation for continuing education for volunteering, considering amendment to practitioner of the healing arts to sell controlled substances proposed regulations to require notification when single practitioner site becomes a multi-practitioner site, and consideration of a request received to delay enforcement of USP Chapter <800>. Ms. Juran requested that the order of the topics presented on the tentative agenda be reordered since Ms. Yeatts would be arriving late to the meeting and her presence is necessary during some of the discussions.

MOTION: **The Committee voted unanimously to approve the amended agenda as presented for the Regulation Committee meeting (motion by Shinaberry, second by Elliott)**

PUBLIC COMMENT: John Beckner, Senior Director of Strategic Initiatives at National Community Pharmacists Association, provided comment on delaying the enforcement of USP <800>. Mr. Beckner spoke about how USP <800> utilizes the NIOSH list to identify hazardous drugs and that this list is vastly inclusive. Drugs such as warfarin, anti-coagulants and anxiolytics are on the NIOSH list and the implementation of USP <800> will result in substantial financial and operational considerations. Mr. Beckner stated that NCPA feels its members would be greatly impacted by this requirement and suggested a gradual implementation of this chapter. The requested delay is for 5 years from the 2018 effective date of Chapter 800. Ms. Shinaberry asked Mr. Beckner if there was an estimation of

cost for this financial impact. Mr. Beckner stated he is not aware of any studies that give cost estimates for these changes. Ms. Cathcart asked Mr. Beckner to clarify the strained economic environment mentioned by Mr. Beckner. Mr. Beckner stated that pharmacies have eroding reimbursement rates and therefore have challenging economic issues.

AGENDA ITEMS:

- Consider amendment to Practitioner of the Healing Arts to Sell Controlled Substances Proposed Regulations to require notification when single practitioner site becomes a multi-practitioner site

Ms. Juran provided the proposed regulations for permits for physicians selling drugs facilities. She stated that since the fees are different for single practitioner and multi-practitioner practices, and those fees are tied to our licensing and renewal system, requiring the practitioners to notify the Board upon changing from a single to multi-practitioner site would allow staff to assign the appropriate fee to renewal and reduce confusion.

MOTION:

The Committee voted unanimously to include language “Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change” to subsection F in Regulation 18VAC110-30-15. (motion by Warriner, second by Cathcart)

- Consider request received to delay enforcement of USP Chapter <800>

Ms. Juran reviewed the written request received on September 19, 2016 to delay the enforcement of USP Chapter <800> for five years from the 2018 effective date of the chapter which was included in the agenda packet. The letter was from the American Pharmacists Association, American Society of Consultant Pharmacists, College of Psychiatric and Neurologic Pharmacists, International Academy of Compounding Pharmacists, National Alliance of State Pharmacy Associations, National Association of Chain Drug Stores, and the National Community Pharmacists Association. Ms. Juran stated that the board did allow a delay in the enforcement of certain aspects of Chapter <797> when last revised. However, USP intentionally provided a delayed effective date chapter <800> to assist pharmacies with coming into compliance. Ms. Juran stated that the North Carolina Board of Pharmacy determined that it will not delay enforcement of chapter <800>. Ms. Juran also shared that she had heard from pharmacist Alexander Pytlarz who also requested delay of enforcement.

Ms. Warriner stated she feels USP <800> affects almost all pharmacies where USP <797> was a limited number of pharmacies. There was discussion regarding a lack of evidence to for the financial implications.

ACTION ITEM:

The committee asked staff to gather more information in regards to the requirements for chapter <800>, what decisions other states were making on this subject, what position the hospital pharmacies were taking, and to share this information with the Board at the December Board meeting.

- Develop draft regulation for continuing education for volunteering

Ms. Yeatts provided background on the legislation that was enacted on July 1, 2016 that directs health regulatory boards to allow volunteer services provided without compensation to low-income individuals to be used partly to satisfy board requirements for obtaining continuing

education. The board discussed draft regulatory language to allow pharmacists to obtain up to two hours of continuing education by volunteering their services in accordance with §54.1-2400 (6). One hour of continuing education may be obtained for three hours of volunteer services. The committee reviewed the draft regulatory language and offered two amendments. The draft paragraph added regarding the volunteer hours for continuing education will be moved to be letter "D" and the current paragraph "D" will be moved to letter "E". Also, similar language in letter "D" will be added to Regulation 18VAC110-20-106 to allow for up to 1 hour of continuing education for pharmacy technicians who provide these volunteer services. One hour of continuing education may be obtained for three hours of volunteered services.

MOTION:

The Committee voted unanimously to recommend to the full board that it amend Regulation 18VAC110-20-90 by creating a new subsection D to read "Up to two hours of the 15 hours required for annual renewal may be satisfied through delivery of pharmacy services, without compensation, to low-income individuals receiving health services through a local health department or a free clinic organized in whole or primarily for the delivery of those service. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic." and to amend Regulation 18VAC110-20-106 with similar language for obtaining up to 1 hour of the required 5 hours of continuing education for three hours of volunteer service. (motion by Warriner, second by Elliott)

- Continue periodic regulatory review by developing draft amendments to Parts I-III of *Regulations Governing the Practice of Pharmacy*, Chapter 20

The Committee reviewed draft regulatory amendments prepared by staff. The final regulatory amendments recommended by the committee which will be presented to the full board are included in Attachment 1. The following discussions, comments, and motions were made.

18VAC110-20-20

The committee initially suggested changing the renewal date for pharmacists and pharmacy technicians to a different time of year to avoid the end of December since there are two state holidays with the offices closed. After review by the Department it has been suggested that the only financially viable option based on the potential loss of revenue for staggering license renewals would be to move all of these renewals to the end of January. It was decided that the benefit of moving these renewals by one month would not outweigh the confusion this may cause the licensees and therefore, the committee determined the renewals should be left at the end of December.

MOTION:

The Committee voted unanimously to recommend to the full board that it maintain the annual renewal fees for pharmacists and pharmacy technicians due no later than December 31st (motion by Warriner, second by Elliott).

18VAC110-20-25

There are several suggested additions to the Regulations regarding unprofessional conduct. These are more specific to the types of cases that arise in practice. The committee discussed one of the suggestions, #11 which states "Obtaining money or property of a patient or client by fraud, misrepresentation or duress. Giving to or accepting from a patient or

client property or money for any reason other than fee for service or a nominal token of appreciation". Ms. Juran stated that there may be a conflict with the allowance in Regulation 18VAC110-20-390 regarding kickbacks when reading the second sentence. It was decided to remove the second sentence. Ms. Warriner was not comfortable with the word duress as she stated there are several definitions for this word and did not feel it should be in this regulation.

MOTION:

The Committee voted unanimously to recommend to the full board that it approve the proposed changes to the Regulation with one change to #11 to state "Obtaining money or property of a patient or client by fraud or misrepresentation." (motion by Warriner, second by Shinaberry).

18VAC110-20-50

Ms. Juran and Ms. Yeatts provided information regarding the possible changes to the first professional degree wording to clarify foreign trained applicants who completed programs within the United States that were traditional pharmacy programs. After some discussion it was decided that further research and wordsmithing will need to be completed on this section.

ACTION ITEM:

Ms. Juran and Ms. Yeatts to draft proposed language in 18VAC110-20-50 and 18VAC110-20-70 regarding the first professional degree.

18VAC110-20-60

Language to be added regarding if an applicant for pharmacist licensure has not subsequently been issued a license by any U.S. jurisdiction within three years of achieving a passing score, he shall retake the examination in order to be licensed in Virginia. This was added since there was no other expiration date for a passing score, and there may be some time passing while a candidate is not practicing or completing coursework in the pharmacy field and therefore may be unsafe to practice.

MOTION:

The Committee voted unanimously to accept the proposed language in 18VAC110-20-60 as written (motion by Warriner, second by Elliott)

18VAC110-20-90

Ms. Juran provided the committee with several other states requirements for live continuing education requirements. The Committee discussed a suggestion that 5 of the 15 required continuing education courses for pharmacists should be live (real time interactive) courses. Other suggestions included that one of the 5 could be attendance at a Board meeting and max of 1 hour for precepting a student

MOTION:

The Committee voted unanimously to approve changes to 18VAC110-20-90 to include requiring for pharmacists 5 out of 15 hours of continuing education to be live real-time interactive courses, to allow 1 of the 5 live to be attendance at a Board meeting, and to allow a maximum of 1 hour credit for serving as a preceptor for a student intern either through an ACPE accredited school, ASHP accredited residency program or precepting a foreign graduate intern. (motion by Warriner, second by Shinaberry)

ACTION ITEM:

Amend Guidance Document for continuing education to clarify and acknowledge the acceptance of jointly accredited programs that include ACPE.

18VAC110-20-101

Discussion to amend this regulation is to clarify the allowance for a pharmacy technician enrolled in a training program to perform technician duties for a period of nine months to be consecutive nine months.

MOTION:

The Committee voted unanimously to remove "D" from the Regulation and add "Every pharmacy that employs or uses a person enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia shall allow such person to conduct tasks restricted to pharmacy technicians for no more than nine consecutive months without that person becoming registered as a pharmacy technician with the board as set forth in this section. Every pharmacy using such a person shall have documentation on site and available for inspection showing that the person is currently enrolled in an approved training program and the start date for each pharmacy technician in training." (motion by Warriner, second by Shinaberry)

18VAC110-20-102

The committee reviewed proposed language to add the requirement for a training program to submit a sample certificate upon application and upon sending a certificate of completion for a student, to include the board approved program number on the certificate. Included in the proposed regulation was wording obtained from another section regarding training programs that was in error and the suggestion was to remove these two additions.

MOTION:

The Committee voted unanimously to accept the proposed changes to 18VAC110-20-102 as presented by removing "I" and "J" (motion by Warriner, second by Elliott)

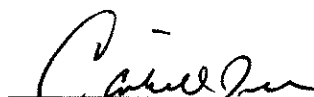
ADJOURN:

Next meeting TBD.

With all business concluded, the meeting concluded at approximately 12:35 pm.



Ryan Logan, Chairman



Caroline D. Juran, Executive Director

12/12/16
DATE

12/12/16
DATE

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:

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Chapter 21
REGULATIONS GOVERNING THE LICENSURE OF PHARMACISTS AND
REGISTRATON OF PHARMACY TECHNICIANS

Part I. General Provisions

18VAC110-21-10. Definitions.

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

"ACPE" means the Accreditation Council for Pharmacy Education.

"Board" means the Virginia Board of Pharmacy.

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

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

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

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

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

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

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

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

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

18VAC110-21-20. Fees.

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

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

C. Initial application fees.

1. Pharmacist license	\$180
2. Pharmacy intern registration	\$15
3. Pharmacy technician registration	\$25
4. Pharmacy permit	\$270
5. Approval of a pharmacy technician training program	\$150
6. Approval of a continuing education program	\$100

D. Annual renewal fees.

1. Pharmacist active license – due no later than December 31	\$90
2. Pharmacist inactive license – due no later than December 31	\$45
3. Pharmacy technician registration – due no later than December 31	\$25
4. Approval of a pharmacy technician training program	\$75 every two years

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

1. Pharmacist license	\$30
2. Pharmacist inactive license	\$15
3. Pharmacy technician registration	\$10
4. Approval of a pharmacy technician training program	\$15

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

1. Pharmacist license	\$210
2. Pharmacist license after revocation or suspension	\$500
3. Pharmacy technician registration	\$35
4. Pharmacy technician registration after revocation or suspension	\$125

5. A pharmacy technician training program that ceases operation and wishes to resume shall not be eligible for reinstatement but shall apply for a new registration. A training program that failed to renew and continued to operate for more than one renewal cycle shall pay the current and all back renewal fees for the years in which they were operating plus a reinstatement fee of \$50

H. Miscellaneous fees.

1. Duplicate wall certificate	\$25
2. Returned check	\$35

- | | |
|--|------|
| 3. Duplicate license or registration | \$10 |
| 4. Verification of licensure or registration | \$25 |

18VAC110-21-21. Current address.

A. It shall be the duty and responsibility of each licensee to inform the board of his current address. A licensee shall notify the board within 14 days in writing or electronically of any change of an address of record. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification.

B. All notices required by law or by these rules and regulations are deemed to be legally given when mailed sent to the address of record and shall not relieve the licensee of the obligation to comply.

(highlighted language moved from renewal section)

C. An individual licensed by or registered with the board who has provided the board with a public address that is different from the address of record shall notify the board in writing if there is a change in the address.

18VAC110-21-25. Unprofessional conduct.

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

1. Failing to comply with provisions of § 32.1-127.1:03 of the Code of Virginia related to the confidentiality and disclosure of patient records or related to provision of patient records to another practitioner or to the patient or his personal representative;
2. Willfully or negligently breaching the confidentiality of a patient unless otherwise required or permitted by applicable law;
3. Failing to maintain confidentiality of information received from the Prescription Monitoring Program, obtaining such information for reasons other than to assist in determining the validity of a prescription to be filled, or misusing information received from the program;
4. Engaging in disruptive or abusive behavior in a pharmacy or other health care setting that interferes with patient care or could reasonably be expected to adversely impact the quality of care rendered to a patient;
5. Engaging or attempting to engage in a relationship with a patient that constitutes a professional boundary violation in which the practitioner uses his professional position to take advantage of the vulnerability of a patient or his family, including but not limited to sexual misconduct with a patient or a member of his family or other conduct that results or could result in personal gain at the expense of the patient;

6. Failing to maintain adequate safeguards against diversion of controlled substances;
7. Failing to appropriately respond to a known dispensing error in a manner that protects the health and safety of the patient;
8. Delegating a task within the practice of pharmacy to a person who is not adequately trained to perform such a task;
9. Failing by the PIC to ensure that pharmacy interns and pharmacy technicians working in the pharmacy are registered and that such registration is current; ~~or~~
10. Failing to exercise professional judgment in determining whether a prescription meets requirements of law before dispensing;
11. Obtaining money or property of a patient or client by fraud or misrepresentation;
12. Providing false information or failing to cooperate with an employee of the Department of Health Professions in the conduct on an investigation or inspection;
13. Violating any provision of this chapter or Chapters 33 or 34 of Title 54.1 of the Code of Virginia;
14. Performing any act likely to deceive, defraud, or harm the public; or
15. Having a restriction of a license to practice in another U. S. jurisdiction.

18VAC110-21-26. Kickbacks, fee-splitting, interference with supplier.

- A. A pharmacist shall not solicit or foster prescription practice with a prescriber of drugs or any other person providing for rebates, "kickbacks," fee-splitting, or special charges in exchange for prescription orders unless fully disclosed in writing to the patient and any third party payor.
- B. A pharmacist shall not interfere with the patient's right to choose his supplier of medication or cooperate with any person or persons in denying a patient the opportunity to select his supplier of prescribed medications.

Part II. Licensure Requirements for Pharmacists

18VAC110-21-30. Requirements for pharmacy practical experience.

- A. Each applicant for licensure as a pharmacist shall have gained practical experience in the practice of pharmacy as set forth in this section and 18VAC110-21-40.
- B. An applicant for licensure as a pharmacist shall attain a minimum of 1,500 hours of practical experience.
- C. 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.

D. 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. Credit shall not be given for more than 50 hours in one week and not less than an average of 20 hours per week averaged over a month. The board may grant an exception to the minimum number of hours for good cause shown.

E. In accordance with § 54.1-3312 of the Code of Virginia, all practical experience required by this section shall be gained within the United States.

18VAC110-21-40. Procedure for gaining practical experience.

A. Each person desiring to gain practical pharmacy experience in Virginia shall first register with the board as a pharmacy intern on a form provided by the board prior to becoming so engaged as a pharmacy intern. This requirement shall apply to any person gaining practical experience within the Commonwealth whether for licensure in Virginia or in another state.

B. In order to be eligible to register as a pharmacy intern, an applicant shall meet at least one of the following criteria:

1. The applicant shall be enrolled in and have started course work in a professional degree program of a board-approved school of pharmacy. Such registration is only valid while the student is enrolled in the school of pharmacy and is satisfactorily progressing toward meeting the requirements for licensure as a pharmacist. An expiration date shall be assigned to the registration to cover the estimated time period for the student to complete the school program and pass the required examinations. If the student is no longer enrolled in the school program, takes a voluntary break from the program, or is otherwise not actively participating in the school program, except for regularly scheduled school breaks, the registration is no longer valid and shall be returned to the board immediately;

2. The applicant is a graduate of a board-approved school of pharmacy or a graduate of a foreign school of pharmacy, has established educational equivalency and proficiency in English by obtaining the FPGEC certificate, and desires to gain required practical experience required for licensure as a pharmacist. Such applicant shall provide documentation on a board-approved form of current employment or an employment start date within 90 days in a pharmacy in Virginia with approval by the supervising pharmacist. An expiration date shall be assigned to cover the estimated time period needed to obtain the required practical experience hours and take the required examinations to become licensed as a pharmacist;

3. The applicant has already gained the required practical experience, but is an otherwise qualified applicant awaiting examination for licensure. A three-month expiration date shall be assigned to allow the applicant time to take required examinations; or

4. The applicant is an applicant for reactivation or reinstatement of a previously issued pharmacist license and is meeting board requirements for relicensure. An expiration date shall be assigned to reasonably cover the period of time necessary to meet the board requirements.

C. For documented, good cause shown, the executive director of the board may extend the expiration date of the intern registration upon submission of an application form approved by the board and payment of the initial application fee.

D. 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.

E. The intern registration of a pharmacy student shall be valid only while the student is enrolled in a school of pharmacy. The registration card issued by the board shall be returned to the board upon failure to be enrolled.

F. Practical experience gained within any other state must be registered with and certified by the board of that state in order to be accepted or certified by this board. In the event that a state relies on the pharmacy school to certify the hours of experience, an affidavit from the pharmacy school certifying the hours of experience gained in the United States may be accepted in lieu of board certification.

G. All practical experience of the pharmacy intern shall be evidenced by an affidavit approved by the board, which shall be filed prior to or with the application for examination for licensure.

H. An applicant for licensure by endorsement may provide verification acceptable to the board of practical experience hours worked as a pharmacist in another state within the United States in lieu of prelicensure intern hours in order to meet the practical experience requirement.

I. A pharmacy intern shall notify the board in writing of any change in address of record within 14 days of such change.

18VAC110-21-50. Curriculum and approved schools of pharmacy.

A. The following minimum educational requirements for the specified periods shall be recognized by the board for the purpose of licensure.

1. On and after June 1, 1936, but before June 1, 1964, the applicant for licensure shall have been graduated from a four-year course of study with a Bachelor of Science degree in pharmacy awarded.

2. On and after June 1, 1964, the applicant for licensure shall have been graduated from at least a five-year course of study with a Bachelor of Science degree in pharmacy or a Doctorate of Pharmacy degree awarded.

B. In order to be licensed as a pharmacist within this Commonwealth, the applicant shall have been granted the first professional degree from a program of a school of pharmacy which meets

the requirements of §54.1-3312 of the Code of Virginia or shall satisfy the requirements of 18VAC110-21-70.

18VAC110-21-60. Content of the examination and grades required; limitation on admittance to examination.

A. Prior to admission to any examination required for licensure, the applicant shall have met all other requirements to include education and practical experience requirements, but in no case shall the applicant be admitted if grounds exist to deny licensure under §54.1-3316 of the Code of Virginia.

B. The applicant shall achieve a passing score as determined by the board on the licensure examination which is approved by the board and which shall consist of an integrated examination of pharmacy practice, pharmacology, pharmacy mathematics, and such other subjects as are necessary to assure that the candidate possesses the necessary knowledge and skills to practice pharmacy.

C. When an applicant for licensure by examination fails to meet the passing requirements of the board-approved integrated pharmacy examination on three occasions, he shall not be readmitted to the examination until he has completed an additional 1,000 hours of practical experience as a pharmacy intern as set forth in 18VAC110-21-40.

D. The applicant shall also achieve a passing score as determined by the board on an examination that tests the candidate's knowledge of federal and state laws related to pharmacy practice. If an applicant has not subsequently been issued a license by any U. S. jurisdiction within three years of achieving a passing score, he shall retake the examination in order to be licensed in Virginia.

E. When an applicant fails to pass the law examination, he shall not be allowed to retake it for a period of 30 days.

F. If an applicant requests a testing accommodation for either examination based on a physical or mental impairment that substantially limits one or more major life activities, subject to the Americans with Disabilities Act, the board may approve a reasonable accommodation that does not compromise the security or integrity of the examination.

1. Supporting documentation shall be provided by the applicant to include the following to be considered for review:

a. A letter of request from the candidate that specifies the testing accommodation requested;

b. A written report of an evaluation (educational, psychological, or physical) within the preceding two years from a qualified professional that states a diagnosis of the disability, describes the disability, recommends specific accommodations, and provides justification that the accommodation is appropriate and necessary for the diagnosed disability. If the comprehensive evaluation was done more than two years ago and the condition is one that is not

subject to change, the original evaluation report may be submitted along with a current letter from the qualified professional stating that there has been no change in the condition since the time of the evaluation; and

c. A written statement from the appropriate person at the applicant's school of pharmacy that describes any testing accommodations made while the student was enrolled, if applicable.

2. The applicant will be notified in writing of the decision. If the request for accommodation is granted, the approval information will be forwarded to the examination contractor and the form of the accommodation will be coordinated with the contractor.

18VAC110-21-70. Requirements for foreign-trained applicants.

A. Applicants for licensure who were trained in foreign schools of pharmacy shall obtain the FPGEC certificate prior to being allowed to register as a pharmacy intern and gain required practical experience in Virginia.

B. After obtaining the FPGEC certificate, the applicant may apply for a pharmacy intern registration and shall fulfill the requirements for practical experience set forth in 18VAC110-21-30 and 18VAC110-21-40 before being admitted to examinations required by 18VAC110-21-60.

C. Applicants for licensure who were trained in foreign schools of pharmacy shall also complete and achieve passing scores on the examinations set forth in 18VAC110-21-60 before being licensed as a pharmacist.

D. Applicants for licensure who were trained in foreign schools of pharmacy, but who subsequently have been granted a professional degree from a program of a school of pharmacy which meets the requirements of §54.1-3312 of the Code of Virginia, as specified in 18VAC110-21-50, shall be exempt from the requirement for a FPGEC certificate but shall fulfill the requirements for practical experience set forth in 18VAC110-21-30 and 18VAC110-21-40 before being admitted to examinations required by 18VAC110-21-60.

18VAC110-21-75. Registration for voluntary practice by out-of-state licensees.

Any pharmacist who seeks registration to practice on a voluntary basis pursuant to subdivision 12 of §54.1-3301 of the Code of Virginia under the auspices of a publicly supported, all volunteer, nonprofit organization that sponsors the provision of health care to populations of underserved people shall:

1. File a complete application for registration on a form provided by the board at least five business days prior to engaging in such practice;

2. Provide a complete list of each state in which he has held a pharmacist license and a copy of any current license;

3. Provide the name of the nonprofit organization and the dates and location of the voluntary provision of services;
4. Pay a registration fee of \$10; and
5. Provide a notarized statement from a representative of the nonprofit organization attesting to its compliance with the provisions of subdivision 12 of §54.1-3301 of the Code of Virginia.

18VAC110-21-80. Renewal and reinstatement of license.

- A. Pharmacist licenses expire on December 31 and shall be renewed annually prior to that date by the submission of a renewal fee, renewal form, and statement of compliance with continuing education requirements.
- B. A pharmacist newly licensed on or after October 1 shall not be required to renew that license until December 31 of the following year.
- C. A pharmacist who fails to renew his license by the expiration date may renew his license at any time within one year of its expiration by submission of the renewal fee and late fee, renewal form, and statement of compliance with continuing education requirements.
- D. A pharmacist who fails to renew his license for more than one year following expiration and who wishes to reinstate such license shall submit an application for reinstatement, pay the current renewal fee and a reinstatement fee, and submit documentation showing compliance with continuing education requirements. Reinstatement is at the discretion of the board and may be granted by the executive director of the board provided no grounds exist to deny said reinstatement.
- E. A pharmacist who has been registered as inactive for more than one year must apply for ~~reinstatement~~ reactivation, submit documentation showing compliance with continuing education requirements, and pay the difference between the inactive fee and the current year active renewal fee in order to resume active licensure.
- F. In order to reactivate or reinstate a license to active status, a pharmacist who holds an inactive license, who has allowed his license to lapse, or who has had his license suspended or revoked must submit evidence of completion of CEU's or hours equal to the requirements for the number of years in which his license has not been active, not to exceed a total of 60 hours of CE.
- G. A pharmacist whose license has been lapsed, in inactive status, or suspended or revoked for more than five years shall, as a condition of reinstatement or reactivation in addition to 60 hours CE, take and receive a passing score on the board-approved law examination and furnish acceptable documentation of one of the following:
 1. Active pharmacy practice within the past five years as a properly licensed pharmacist in another state; or

2. Practical experience as a pharmacy intern registered with the board of at least 160 hours within six months immediately prior to being reinstated or reactivated.

H. The practice of pharmacy without a current, active pharmacist license is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-21-90. Requirements for continuing education.

A. A pharmacist shall be required to have completed a minimum of 1.5 CEUs or 15 contact hours of continuing pharmacy education in an approved program for each annual renewal of licensure. CEUs or hours in excess of the number required for renewal may not be transferred or credited to another year.

B. A pharmacy education program approved for continuing pharmacy education is:

1. One that is approved by the Accreditation Council for Pharmacy Education (ACPE);
2. One that is approved as a Category I Continuing Medical Education (CME) course, the primary focus of which is pharmacy, pharmacology or drug therapy; or
3. One that is approved by the board in accordance with the provisions of 18 VAC 110-21-100.

C. Of the 15 contact hours required for annual renewal, at least five hours shall be obtained in courses or programs that are live or real-time interactive. Included in the five hours, the following may be credited:

1. One hour for attendance at a board meeting or formal hearing; or
2. One hour for serving as a preceptor for a pharmacy student or resident in an accredited school or program.

~~C.D.~~ The board may grant an extension pursuant to §54.1-3314.1 E of the Code of Virginia. Any subsequent extension shall be granted only for good cause shown.

~~D.E.~~ Pharmacists are required to attest to compliance with CE requirements in a manner approved by the board at the time of their annual license renewal. Following each renewal period, the board may conduct an audit of the immediate past two years' CE documents to verify compliance with requirements. Pharmacists are required to maintain, for two years following renewal, the original certificates documenting successful completion of CE, showing date and title of the CE program or activity, the number of CEUs or contact hours awarded, and a certifying signature or other certification of the approved provider. Pharmacists selected for audit must provide these original documents to the board by the deadline date specified by the board in the audit notice.

18VAC110-21-100. Approval of continuing education programs.

A. The board will approve without application or further review any program offered by an ACPE-approved provider and will accept for credit certificates bearing the official ACPE logo and program number.

B. The board may approve an individual CE program under the following provisions:

1. An approved individual program is a course, activity, or lecture which includes subject matter related to the competency of the practice of pharmacy and which has been approved for CE credit by the board.
2. In order to receive approval for an individual program, the sponsor or provider must apply prior to the program offering on a form provided by the board. The information which must be provided shall include but not be limited to: name of provider, location, date and time of program, charges to participants, description of program content and objectives, credentials of speaker or author, method of delivery, evaluation procedure, evidence of a post assessment, credits requested, mechanism for recordkeeping, and any such information as the board deems necessary to assure quality and compliance.
3. The sponsor applying for board approval of an individual program must pay a fee as required in 18VAC110-21-20 C 6.
4. The board shall notify the provider or sponsor within 60 days following the receipt of a completed application of approval or disapproval of a program and the number of credits which may be awarded. The board shall also assign an expiration date for approval of the program not to exceed two years from the date of approval.
5. The provider of an approved program shall provide to each participant who completes the required hours and passes the post test a certification with the name of the provider, name of the participant, description of course and method of delivery, number of hours credited, date of completion, and program identification number.
6. The provider of an approved program shall maintain all records on that program, its participants, and hours awarded for a period of five years and shall make those records available to the board upon request.
7. The board shall periodically review and monitor programs. The provider of a CE program shall waive registration fees for a representative of the board for that purpose.
8. Any changes in the information previously provided about an approved program or provider must be submitted or the board may withdraw its approval. If a provider wants to give a live program more than once, all program dates must either be submitted on the original application or provided to the board in subsequent correspondence at least five days prior to giving the program.

Part III. Requirements for Pharmacy Technician Registration

18VAC110-21-101. Application for registration as a pharmacy technician.

- A. Any person wishing to apply for registration as a pharmacy technician shall submit the application fee and an application on a form approved by the board.
- B. In order to be registered as a pharmacy technician, an applicant shall provide evidence of the following:
1. Satisfactory completion of an approved training program, and
 2. A passing score on a board-approved examination.
- C. In lieu of the requirements of subsection B of this section, an applicant may provide evidence of current PTCB certification.
- D. A pharmacy technician trainee enrolled in an approved pharmacy technician training program pursuant to §54.1-3321 D of the Code of Virginia may perform tasks restricted to pharmacy technicians for no more than nine consecutive months without becoming registered as a pharmacy technician. (Language differs from that recommended by Regulation Committee but is adapted for regulation of techs, not pharmacies.)

18VAC110-21-102. Criteria for approval for training programs.

- A. Any person wishing to apply for approval of a pharmacy technician training program shall submit the application fee, a sample certificate, and an application on a form approved by the board and meet the criteria established in this section.
- B. The curriculum of a training program for pharmacy technicians shall include instruction in applicable, current laws and regulations and in the tasks that may be performed by a pharmacy technician to include the following or any other task restricted to pharmacy technicians in regulation:
1. The entry of prescription information and drug history into a data system or other recordkeeping system;
 2. The preparation of prescription labels or patient information;
 3. The removal of the drug to be dispensed from inventory;
 4. The counting, measuring, or compounding of the drug to be dispensed;
 5. The packaging and labeling of the drug to be dispensed and the repackaging thereof;

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

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

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

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

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

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

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

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

18VAC110-21-103. Examination.

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

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

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

D. Any requests for testing accommodations under the Americans with Disabilities Act shall be in accordance with the provisions of 18VAC110-21-60 F.

18VAC110-21-104. Address of record; maintenance of certificate.

A. It shall be the duty and responsibility of each pharmacy technician to inform the board of his current address. A pharmacy technician shall notify the board in writing or electronically of any change of an address of record within 14 days. Properly updating address of record directly through the board's web-based application or other approved means shall constitute lawful notification. All notices required by law or by these rules and regulations are deemed to be legally given when mailed to the address of record and shall not relieve the registrant of the obligation to comply.

B. A pharmacy technician shall maintain his current registration certificate at his principal place of practice available for inspection upon request. A pharmacy technician who does not have a principal place of practice may maintain it at any pharmacy in which he practices or his address of record.

18VAC110-21-105. Renewal and reinstatement of registration.

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

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

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

D. A person who fails to reinstate a pharmacy technician registration within five years of expiration, shall not be eligible for reinstatement and shall repeat an approved training program

and repeat and pass the examination, or hold current PTCB certification, before applying to be reregistered.

18VAC110-21-106. Requirements for continued competency.

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

B. An approved continuing education program shall meet the requirements as set forth in subsection B of 18VAC110-21-90 or subsection B of 18VAC110-21-100.

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

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