COMMONWEALTH OF VIRGINIA
Meeting of the Board of Pharmacy

Perimeter Center, 9960 Mayland Drive, Second Floor
Henrico, Virginia 23233

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

Tentative Agenda of Regulation Committee Meeting
Periodic Regulatory Review

November 29, 2016

9AM

TOPIC	PAGES
Call to Order: Ryan Logan, Committee Chairman	
• Welcome & Introductions	
• Approval of Agenda	
Call for Public Comment	
Agenda Items	
• Continue Periodic Regulatory Review by Developing Draft Amendments to Parts I-III of *Regulations Governing the Practice of Pharmacy,* chapter 20	
○ Minutes from Regulation Committee Meeting, 11/3/15	1-4
○ Draft Regulatory Amendments Prepared by Staff	5-26
• Develop Draft Regulation for Continuing Education for Volunteering	
○ HB319	27-28
○ Draft Regulatory Amendment Prepared by Staff	29
• Consider Amendment to Practitioners of the Healing Arts to Sell Controlled Substances Proposed Regulations to Require Notification When Single Practitioner Site Becomes a Multi-Practitioner Site	30-38
• Consider Request Received to Delay Enforcement of USP Chapter <800>	
○ Written Request for Delay in Enforcement	39-40
○ General Information regarding Official Date of July 1, 2018	41-45
Adjourn	

FINAL/APPROVED

VIRGINIA BOARD OF PHARMACY
MINUTES OF REGULATION COMMITTEE MEETING – PERIODIC REGULATORY REVIEW

November 3, 2015
Second Floor
Board Room 2

Perimeter Center
9960 Mayland Drive
Henrico, Virginia 23233-1463

CALL TO ORDER: The meeting was called to order at 1:09pm

PRESIDING: Ellen B. Shinaberry, Chairman

MEMBERS PRESENT: Ryan Logan
Cynthia Warriner
Melvin Boone

MEMBER ABSENT: Rebecca Thornbury

STAFF PRESENT: Caroline D. Juran, Executive Director
J. Samuel Johnson, Deputy Executive Director
Cathy M. Reiniers-Day, Deputy Executive Director
Beth O'Halloran, Individual Licensing Manager
Elaine J. Yeatts, Senior Policy Analyst

APPROVAL OF AGENDA: The agenda was approved as presented.

PUBLIC COMMENT: There was no public comment offered.

ISSUANCE OF CONTROLLED SUBSTANCES REGISTRATIONS TO MULTIPLE MEDICAL CLINICS LOCATED WITHIN A MEDICAL OFFICE BUILDING WITH SAME OWNERSHIP:

Ms. Juran provided background on previous discussion at the September 2015 full board meeting and the previous historical discussions surrounding the requests for the issuance of a single Controlled Substance Registration (CSR) to multiple clinics that are located within a medical office building with the same owner. She stated she surveyed several states and that most do not issue CSRs for the purpose of stocking drugs. They issue the CSRs for prescriber purposes. Delaware, however, issues CSRs in a manner similar to Virginia and it currently does not issue a single CSR to a building of multiple clinics. It issues CSRs to individual clinics within the building.

RECOMMENDATION: **The Committee voted unanimously to recommend to the full board that it not issue a single controlled substances registration (CSR) to multiple medical clinics that are located within the same medical**

office building with shared ownership.

- Review of Parts I-IV and XIII-XVII of *Regulations Governing the Practice of Pharmacy, Chapter 20*

Ms. Yeatts reviewed the procedure with the Committee for the periodic regulatory review process. She stated a notice of periodic regulatory review has been posted on Town Hall and shared with the public participation guidelines list maintained by board staff. The public comment period is from November 30, 2015 until December 30, 2015. She indicated the Committee must first identify regulations that it will consider amending and that these regulations will be listed in the Notice of Intended Regulatory Action (NOIRA) once the board completes its review of the regulations in chapters 20 and 50. Because chapter 20 has become quite lengthy, she also recommended the board consider breaking chapter 20 into 3 separate chapters: one chapter for addressing individuals such as pharmacists, pharmacy technicians, and interns; one for addressing pharmacies; and one for addressing facilities other than pharmacies. The Committee then began identifying such regulations in chapter 20 (Attachment 1) and will continue this work at subsequent Regulatory Committee meetings until this first step is completed.

ADJOURN:

Next meeting will take place on January 6, 2016.

With all business concluded, the meeting concluded at approximately 5:00 pm.

Ellen B. Shinaberry, Chairman

12/28/15
DATE:

Caroline D. Juran, Executive Director

12/1/15
DATE:

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FINAL/APPROVED
Attachment 1

Below are regulations in Chapter 20, Parts I-IV and XIII-XVII identified by the Regulation Committee to be considered by the full board for inclusion in the Notice of Intended Regulatory Action (NOIRA) as part of the periodic regulatory review.

Part I. General Provisions

18VAC110-20-10 Definitions.

18VAC110-20-15 Criteria for delegation of informal fact-finding proceedings to an agency subordinate

- Should be moved to its own separate chapter

18VAC110-20-20 Fees

- Consider staggering renewals for pharmacist licenses and pharmacy technician registrations. Committee recommended no change to facility renewals. (Note: a change in renewals for pharmacists and pharmacy technicians necessitates amendments of 18VAC110-20-80 A and B and 18VAC110-20-105.)

18VAC110-20-25 Unprofessional conduct

- Ms. Reiniers-Day to research other boards' language.

Part II. Licensure Requirements For Pharmacists

18VAC110-20-50 Curriculum and approved schools of pharmacy

- Consider striking subsection B to eliminate language for "first" professional degree. Staff to do further research on implications of this recommendation and will discuss at future meeting.

18VAC110-20-60 Content of the examination and grades required; limitation on admittance to examination

- Discussed limiting validity of law exam score to 2 years, but recommended limiting to 3 years based on record retention.

18VAC110-20-80 Renewal and reinstatement of license

- Recommended clarifying language in E that the required payment should equal the difference between the active and inactive renewal fee as staff is currently requiring and not the current active renewal fee.
- Staff will review to ensure the terms "reactivate" and "reinstate" are being used correctly.

18VAC110-20-90 Requirements for continuing education

- Consider ability to accept inter-professional continuing education; staff to research how it is currently being awarded and by whom.

FINAL/APPROVED
Attachment 1

- Suggested wording in (B) (2) be changed from "Category I Continuing Medical Education" to "American Medical Association" which appears to be the current title for this type of CE
- Consider striking ability for board to approve and accept board-approved CE programs
- Committee discussed recommendations for requiring live CE and having ability to carry over hours into subsequent year, but concluded a statutory amendment would be necessary. Staff will research what other state boards of pharmacy may require live CE.
- Committee discussed recommendation for requiring CE annually in the subject of opioids. Statutory ability to specify topic for CE annually also discussed. No final recommendation was made.

18VAC110-20-100 Approval of continuing education programs

- Suggestion to remove ability for board to approve CE programs.

PART III Requirements For Pharmacy Technician Registration

18VAC110-20-102 Criteria for approval of training programs

- Consider including training program approval number to be printed on certificate awarded by training program.
- Consider requiring copy of sample certificate with application for approval of training program and requirement to notify board of changes to certificate.

18VAC110-20-106 Requirements for continued competency

- Consider changing "certificates" to "documentation" in both sentences of subsection D.

PART IV Pharmacies

18VAC110-20-110 Pharmacy permits generally

- Consider specifying minimum number of hours PIC must practice at the location listed on the pharmacy permit application
- Consider requiring minimum number of years of experience for PIC eligibility. There was discussion for a possible ability for exceptions, but no final recommendation made.

18VAC110-20-130 Pharmacy closings; going out of business; change of ownership

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider requirement for inspection during change of ownership.

18VAC110-20-140 New pharmacies, acquisitions and changes to existing pharmacies

- Clarify requirements for acquisitions with regard to inspection and inventory
- Consider amending to allow Board to rescind pharmacy permit if not opened within 60 days of issuing permit. Concern raised that board counsel may recommend criteria if the term "may" is used as proposed in the agenda packet.

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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:

9960 Mayland Drive, Suite 300
Henrico, VA 23233-1464

Phone: 804-367-4456
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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

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Commonwealth of Virginia

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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~~ January 31	$90
2. Pharmacist inactive license – due no later than ~~December~~ January 31	$45
3. Pharmacy technician registration – due no later than ~~December~~ January 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

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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, 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; (Nursing)

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; (Dentistry, Nursing, Medicine)

13. Violating any provision of this chapter or Chapters 33 or 34 of Title 54.1 of the Code of Virginia; (multiple boards)

14. Performing any act likely to deceive, defraud, or harm the public; (Medicine, Dentistry) or

15. Having a restriction of a license to practice in another U. S. jurisdiction. (Medicine)

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.

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. <u>If an applicant has not subsequently been issued a license by any U. S. jurisdiction with three years of achieving a passing score, he shall retake the examination in order to be licensed in Virginia.</u>

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.

18VAC110-20-75. 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.

18VAC110-20-80. Renewal and reinstatement of license.

A. Pharmacist licenses expire on ~~December~~ January 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~~ November 1 shall not be required to renew that license until ~~December~~ January 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. (discussion of live or interactive CE – see chart of requirements in 15 other states)

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. 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. 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

18VAC110-20-101. 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 may perform tasks restricted to pharmacy technicians for no more than nine months without becoming registered as a pharmacy technician.

E. 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 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.

18VAC110-20-102. 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.

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

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

18VAC110-20-103. 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.

18VAC110-20-104. 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.

18VAC110-20-105. Renewal and reinstatement of registration.

A. Pharmacy technician registrations expire on ~~December~~ January 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~~ August 1 shall not be required to renew that registration until ~~December~~ January 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.

18VAC110-20-106. 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.

Live Continuing Education (CE) Requirements of selected states

State	Live CE Requirement
Arizona	• During the two years preceding the application for renewal, participate in 30 contact hours (3.0 CEU's) of continuing education activity sponsored by an Approved Provider
Georgia	• As a requirement for the biennial renewal of his/her license, a pharmacist must complete not less than thirty (30) hours of approved continuing education. • One hour of C.E. is defined as 0.1 C.E.U.
Kentucky	• A pharmacist shall: Complete a minimum of one and five-tenths (1.5) CEU (fifteen (15) contact hours) annually between January 1 and December 31
Louisiana	• A minimum of 1 1/2 ACPE or board-approved CPE units, or 15 hours, shall be required each year as a prerequisite for pharmacist licensure renewal. Of this number, no less than 3/10 ACPE or board-approved CPE units, or three hours, shall be acquired through live presentations, as designated by ACPE or the board. • Alternatively, should a pharmacist choose to not acquire at least 3/10 ACPE or board-approved CPE units, or three hours, through live presentations, then he shall acquire an additional 5/10 ACPE or board-approved CPE units, or five hours, through any other acceptable method, over and above the minimum requirement, for a total of two ACPE or board-approved CPE units, or 20 hours
Maryland	• Earn 30 hours of approved CE within the 2-year period immediately preceding the license expiration date that include: 2 hours of CE obtained through live instruction
Massachusetts	• 20 total CEU per calendar year, of those 5 being live
Michigan	• The Michigan Public Health Code and board administrative rules require every pharmacist who has held their license for a full two-year period, to complete,

	during the 2-year period prior to the renewal of the license, at least 30 hours of board-approved continuing education, with not less than 10 (ten) hours in live programs or courses • Live courses or programs must provide for direct interaction between faculty and participants, including but not limited to, lectures, symposia, live teleconferences, and workshops.
Nebraska	• On or before January 1 of each even-numbered year, every Pharmacist who is licensed in the State of Nebraska must as a condition for renewal of his/her license: Complete 30 hours of acceptable continued education during the preceding 24 month period
New Jersey	• Each applicant for biennial license renewal shall complete a minimum of 30 credits of continuing education during the preceding biennial period. At least 10 of the continuing education credits shall be obtained through didactic instruction. • For purposes of this subsection, "didactic instruction" means in-person instruction and may include telephonic or electronic instruction that is interactive, but shall not include videotaped instruction.
North Carolina	• As a condition of license renewal, a pharmacist shall accumulate 15 hours of continuing education annually. • Eight of these continuing education hours shall be obtained through contact programs. Contact programs are those in which there is an opportunity for live two-way communication between the presenter and attendee. An on-line continuing education course may satisfy this contact-hour requirement provided that the live two-way communication standard is met. • Pharmacists may record 1 Live hour of CE per renewal year for attending a Board meeting

Live Continuing Education (CE) Requirements of selected states

	• A pharmacist who instructs a student for at least 400 hours can receive five (5) live hours of continuing education
Ohio	• 6.0 CEUs (60 Hours) minimum, reported every three years, earned during the three years prior to license renewal • Any format (live, home study) is acceptable
Oregon	• During the period from July 1 through June 30 of each biennial license renewal cycle, each pharmacist must have satisfactorily completed three (3) continuing pharmacy education units (CEU's) in an approved continuing pharmacy education program prior to submission of the license renewal. Ten contact hours equals 1 CEU. Fifty minutes equals 1 contact hour
Tennessee	• Every person licensed as a pharmacist shall complete at least thirty (30) hours of continuing pharmaceutical education during each two (2) year license cycle. The required thirty (30)hours shall consist of at least fifteen (15) hours obtained through live contract programs. • In order to fulfill the fifteen (15) live contact hour requirement, a pharmacist shall obtain the hours from a program designated as "live" by the ACPE-approved provider from a program that is approved by the Board prior to the expiration of the pharmacist's license or from an out-of-state program that is approved by the board of pharmacy in the state where the program was presented.
Washington	• The equivalent of 1.5 continuing education unit (equal to fifteen contact hours) of continuing education shall be required annually of each applicant for renewal of licensure. 0.1 CEU will be given for each contact hour. A pharmacist may claim an incentive of 0.15 CEU for each contact hour for

	successfully completing a patient education training program which meets the criteria listed below, provided that the incentive credits shall not exceed 1.2 CEU (equal to eight contact hours and four incentive hours) • The continuing professional pharmaceutical education courses may consist of post-graduate studies, institutes, seminars, lectures, conferences, workshops, extension studies, correspondence courses and other similar methods of conveying continuing education as may be approved by the board.
West Virginia	• A licensed pharmacist shall complete a minimum of thirty (30) CPE hours every two (2) years, inclusive of any CPE requirements for consultant pharmacist registration, pharmacist immunization registration, and drug diversion training and best practice prescribing of controlled substances training • Six (6) hours of the thirty (30) CPE hours required every two (2) years shall be obtained through a live presentation requiring the physical presence of the pharmacist at the CPE program

CHAPTER 82

An Act to amend and reenact § 54.1-2400 of the Code of Virginia, relating to continuing education requirements; volunteer health services.

[H 319]

Approved March 1, 2016

Be it enacted by the General Assembly of Virginia:

1. That § 54.1-2400 of the Code of Virginia is amended and reenacted as follows:

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

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

1. To establish the qualifications for registration, certification, licensure or the issuance of a multistate licensure privilege in accordance with the applicable law which are necessary to ensure competence and integrity to engage in the regulated professions.

2. To examine or cause to be examined applicants for certification or licensure. Unless otherwise required by law, examinations shall be administered in writing or shall be a demonstration of manual skills.

3. To register, certify, license or issue a multistate licensure privilege to qualified applicants as practitioners of the particular profession or professions regulated by such board.

4. To establish schedules for renewals of registration, certification, licensure, and the issuance of a multistate licensure privilege.

5. To levy and collect fees for application processing, examination, registration, certification or licensure or the issuance of a multistate licensure privilege and renewal that are sufficient to cover all expenses for the administration and operation of the Department of Health Professions, the Board of Health Professions and the health regulatory boards.

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

7. To revoke, suspend, restrict, or refuse to issue or renew a registration, certificate, license or multistate licensure privilege which such board has authority to issue for causes enumerated in applicable law and regulations.

8. To appoint designees from their membership or immediate staff to coordinate with the Director and the Health Practitioners' Monitoring Program Committee and to implement, as is necessary, the provisions of Chapter 25.1 (§ 54.1-2515 et seq.) of this title. Each health regulatory board shall appoint one such designee.

9. To take appropriate disciplinary action for violations of applicable law and regulations, and to accept, in their discretion, the surrender of a license, certificate, registration or multistate licensure privilege in lieu of disciplinary action.

10. To appoint a special conference committee, composed of not less than two members of a health regulatory board or, when required for special conference committees of the Board of Medicine, not less than two members of the Board and one member of the relevant advisory board, or, when required for special conference committees of the Board of Nursing, not less than one member of the Board and one member of the relevant advisory board, to act in accordance with § 2.2-4019 upon receipt of information that a practitioner or permit holder of the appropriate board may be subject to disciplinary action or to consider an application for a license, certification, registration, permit or multistate licensure privilege in nursing. The special conference committee may (i) exonerate; (ii) reinstate; (iii) place the practitioner or permit holder on probation with such terms as it may deem appropriate; (iv) reprimand; (v) modify a previous order; (vi) impose a monetary penalty pursuant to § 54.1-2401, (vii) deny or grant an application for licensure, certification, registration, permit, or multistate licensure privilege; and (viii) issue a restricted license, certification, registration, permit or multistate licensure privilege subject to terms and conditions. The order of the special conference committee shall become final 30 days after service of the order unless a written request to the board for a hearing is received within such time. If service of the decision to a party is accomplished by mail, three days shall be added to the 30-day period. Upon receiving a timely written request for a hearing, the board or a panel of the board shall then proceed with a hearing as provided in § 2.2-4020, and the action of the committee shall be vacated.

This subdivision shall not be construed to limit the authority of a board to delegate to an appropriately qualified agency subordinate, as defined in § 2.2-4001, the authority to conduct informal fact-finding proceedings in accordance with § 2.2-4019, upon receipt of information that a practitioner may be subject to a disciplinary action. The recommendation of such subordinate may be considered by a panel consisting of at least five board members, or, if a quorum of the board is less than five members, consisting of a quorum of the members, convened for the purpose of issuing a case decision. Criteria for the appointment of an agency subordinate shall be set forth in regulations adopted by the board.

11. To convene, at their discretion, a panel consisting of at least five board members or, if a quorum of the board is less than five members, consisting of a quorum of the members to conduct formal proceedings pursuant to § 2.2-4020, decide the case, and issue a final agency case decision. Any decision rendered by majority vote of such panel shall have the same effect as if made by the full board and shall be subject to court review in accordance with the Administrative Process Act. No member who participates in an informal proceeding conducted in accordance with § 2.2-4019 shall serve on a panel conducting formal proceedings pursuant to § 2.2-4020 to consider the same matter.

12. To issue inactive licenses or certificates and promulgate regulations to carry out such purpose. Such regulations shall include, but not be limited to, the qualifications, renewal fees, and conditions for reactivation of licenses or certificates.

13. To meet by telephone conference call to consider settlement proposals in matters pending before special conference committees convened pursuant to this section, or matters referred for formal proceedings pursuant to § 2.2-4020 to a health regulatory board or a panel of the board or to consider modifications of previously issued board orders when such considerations have been requested by either of the parties.

14. To request and accept from a certified, registered or licensed practitioner or person holding a multistate licensure privilege to practice nursing, in lieu of disciplinary action, a confidential consent agreement. A confidential consent agreement shall be subject to the confidentiality provisions of § 54.1-2400.2 and shall not be disclosed by a practitioner. A confidential consent agreement shall include findings of fact and may include an admission or a finding of a violation. A confidential consent agreement shall not be considered either a notice or order of any health regulatory board, but it may be considered by a board in future disciplinary proceedings. A confidential consent agreement shall be entered into only in cases involving minor misconduct where there is little or no injury to a patient or the public and little likelihood of repetition by the practitioner. A board shall not enter into a confidential consent agreement if there is probable cause to believe the practitioner has (i) demonstrated gross negligence or intentional misconduct in the care of patients or (ii) conducted his practice in such a manner as to be a danger to the health and welfare of his patients or the public. A certified, registered or licensed practitioner who has entered into two confidential consent agreements involving a standard of care violation, within the 10-year period immediately preceding a board's receipt of the most recent report or complaint being considered, shall receive public discipline for any subsequent violation within the 10-year period unless the board finds there are sufficient facts and circumstances to rebut the presumption that the disciplinary action be made public.

15. When a board has probable cause to believe a practitioner is unable to practice with reasonable skill and safety to patients because of excessive use of alcohol or drugs or physical or mental illness, the board, after preliminary investigation by an informal fact-finding proceeding, may direct that the practitioner submit to a mental or physical examination. Failure to submit to the examination shall constitute grounds for disciplinary action. Any practitioner affected by this subsection shall be afforded reasonable opportunity to demonstrate that he is competent to practice with reasonable skill and safety to patients. For the purposes of this subdivision, "practitioner" shall include any person holding a multistate licensure privilege to practice nursing.

2. That the provisions of this act shall become effective on January 1, 2017.

Compliance with HB319 on CE credit for Volunteer Practice

18VAC110-20-90. 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 110-20-100.

C. 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. 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.

E. 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 services. One hour of continuing education may be credited for three hours of providing such volunteer services, as documented by the health department or free clinic.

BOARD OF PHARMACY

Permits for physician selling drugs facilities

Proposed regulations

18VAC110-30-15. Fees.

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

B. ~~Fee for initial license for a practitioner of the healing arts to sell controlled substances~~ Initial application fees.

1. ~~The application fee for initial licensure shall be $240.~~ License for practitioner of the healing arts to sell controlled substance $180

2. ~~The application fee for reinstatement of a license that has been revoked or suspended indefinitely shall be $500.~~ Permit for facility in which practitioners of the healing arts sell controlled substance $240

C. ~~Renewal of license for a practitioner of the healing arts to sell controlled substances~~ Annual renewal fees.

1. ~~The annual fee for renewal of an active license shall be $90. For the annual renewal due on or before December 31, 2009, the fee shall be $50.~~ License for practitioner of the healing arts to sell controlled substance $90

2. ~~The late fee for renewal of a license within one year after the expiration date is $30 in addition to the annual renewal fee.~~ Permit for facility in which practitioners of the healing arts sell controlled substance $240

~~3. The fee for reinstatement of a license expired for more than one year shall be $210.~~

D. 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.

1. License for practitioner of the healing arts to sell controlled substance $30

2. Permit for facility in which practitioners of the healing arts sell controlled substance $40

E. Reinstatement fees.

Any person or entity attempting to renew a license or permit more than one year after the expiration date shall submit an application for reinstatement with any required fees.

1. License for practitioner of the healing arts to sell controlled substances $150

2. Permit for facility in which practitioner of the healing arts to sell controlled substances $240

3. Application fee for reinstatement of a license or permit that has been revoked or suspended indefinitely $500

F. Facilities in which only one practitioner of the healing arts is licensed by the board to sell controlled substances shall be exempt from fees associated with obtaining and renewing a facility permit. [Facilities that change from only one practitioner to more than one shall notify the board within 30 days of such change.]

~~D.~~ G. The fee for reinspection of any facility shall be $150.

~~E.~~ H. The fee for a returned check shall be $35.

Part II

Licensure Requirements

18VAC110-30-20. Application for licensure.

A. Prior to engaging in the sale of controlled substances, a practitioner shall make application on a form provided by the board and be issued a license. After June 4, 2016, the practitioner shall engage in such sale from a location that has been issued a facility permit.

B. In order to be eligible for a license to sell controlled substances, a practitioner shall possess a current, active license to practice medicine, osteopathic medicine, or podiatry issued by the Virginia Board of Medicine. Any disciplinary action taken by the Board of Medicine against the practitioner's license to practice shall constitute grounds for the board to deny, restrict, or place terms on the license to sell.

~~C. For good cause shown, the board may issue a limited-use license, when the scope, degree or type of services provided to the patient is of a limited nature. The license to be issued shall be based on conditions of use requested by the applicant or imposed by the board in cases where certain requirements of regulations may be waived. The following conditions shall apply:~~

~~1. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion must accompany the application. The application shall list the regulatory requirements for which a waiver is requested and a brief explanation as to why each requirement should not apply to that practice; and~~

~~2. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.~~

18VAC110-30-21. Application for facility permit.

A. After June 4, 2016, any location at which practitioners of the healing arts sell controlled substances shall have a permit issued by the board in accordance with § 54.1-3304.1 of the Code of Virginia. A licensed practitioner shall make application for the facility permit on a form provided by the board.

B. For good cause shown, the board may issue a limited-use facility permit, when the scope, degree or type of services provided to the patient is of a limited nature. The permit to be issued shall be based on conditions of use requested by the applicant or imposed by the board in case where certain requirements of the regulations may be waived.

1. The limited-use facility permit application shall list the regulatory requirements for which a waiver is requested, if any, and a brief explanation as to why each requirement should not apply to that practice.

2. A policy and procedure manual detailing the type and volume of controlled substances to be sold and safeguards against diversion shall accompany the application.

3. The issuance and continuation of such license shall be subject to continuing compliance with the conditions set forth by the board.

C. The executive director may grant a waiver of the security system when storing and selling multiple strengths and formulations of no more than five different topical Schedule VI drugs intended for cosmetic use.

18VAC110-30-30. Renewal of license or permit.

A. A license or facility permit so issued shall be valid until December 31 of the year of issue. Renewal of the license shall be made on or before December 31 of each year.

B. If a practitioner fails to renew his license or facility permit to sell within the Commonwealth by the renewal date, he must pay the renewal fee plus the late fee. He may renew his license or facility permit by payment of these fees for one year from the date of expiration.

C. Failure to renew the license or facility permit to sell within one year following expiration shall cause the license or permit to lapse. The selling of controlled substances with a lapsed license or permit shall be illegal and may subject the practitioner to disciplinary action by the board. To reinstate a lapsed license or permit, a practitioner shall submit an application for reinstatement and pay the reinstatement fee, plus the reinspection fee if a reinspection is required as set forth in subsection D of this section. Reinstatement is at the discretion of the board and may be granted by the executive director on the board's behalf provided no grounds exist to deny said reinstatement.

D. Prior to reinstatement of a license or facility permit that has been lapsed for more than one year, a reinspection of the storage and selling area shall be conducted ~~unless another practitioner at the same location has held an active license to sell controlled substances during that period~~. A practitioner seeking reinstatement of a facility permit shall not stock drugs until approved by the board or its authorized agent.

E. The selling of controlled substances without a current, active license or facility permit is unlawful and shall constitute grounds for disciplinary action by the board.

18VAC110-30-50. Licensees ceasing to sell controlled substances; inventory required prior to disposal.

A. Any licensee who intends to cease selling controlled substances shall notify the board 10 days prior to cessation and surrender his license, and his license will be placed on expired status. If no other practitioner of the healing arts licensed to sell controlled substances intends

to sell controlled substances from the same location, the practitioner shall also surrender the facility permit, and the permit will be placed on expired status.

B. Any Schedule II through V controlled substances shall be inventoried and may be disposed of by transferring the controlled substance stock to another licensee or other person authorized by law to possess such drugs or by destruction as set forth in this chapter.

C. The licensee or other responsible person shall inform the board of the name and address of the licensee to whom the controlled substances are transferred.

D. A licensee who has surrendered his license or facility permit pursuant to this section may request that it be made current again at any time within the same renewal year without having to pay an additional fee, provided the licensee is selling from the same location or from another location that has been inspected and approved by the board.

Part III

Inspection Requirements, Standards, and Security for Storage Areas; Disposal of Controlled Substances

18VAC110-30-70. ~~Maintenance of a common stock of controlled substances~~ Practitioner in charge in a permitted facility.

~~Any two or more licensees who elect to maintain a common stock of~~ A facility with a permit for practitioners of the healing arts to sell controlled substances ~~for dispensing~~ shall:

1. Designate a ~~licensee~~ practitioner with a license to sell controlled substances who shall be the primary person responsible for the stock, the required inventory, the records of receipt and destruction, safeguards against diversion and compliance with this chapter;

2. Report to the board the name of the licensee and the location of the controlled substance stock on a form provided by the board;

3. Upon a change in the licensee so designated, an inventory of all Schedule II through V controlled substances shall be conducted in the manner set forth in § 54.1-3404 of the Drug Control Act of the Code of Virginia and such change shall immediately be reported to the board; and

4. Nothing shall relieve the other individual licensees who sell controlled substances at the location of the responsibility for the requirements set forth in this chapter.

18VAC110-30-80. Inspection and notice required.

A. The area designated for the storage and selling of controlled substances shall be inspected by an agent of the board prior to the issuance of the first license to sell controlled substances from that site. Inspection prior to issuance of subsequent licenses at the same location shall be conducted at the discretion of the board.

B. Applications for ~~licenses~~ facility permits which indicate a requested inspection date, or requests which are received after the application is filed, shall be honored provided a 14-day notice to the board is allowed prior to the requested inspection date.

C. Requested inspection dates which do not allow a 14-day notice to the board may be adjusted by the board to provide 14 days for the scheduling of the inspection.

D. At the time of the inspection, the controlled substance selling and storage area shall comply with 18VAC110-30-90, 18VAC110-30-100, 18VAC110-30-110, 18VAC110-30-120 and 18VAC110-30-130.

E. If an applicant substantially fails to meet the requirements for issuance of a ~~license~~ facility permit and a reinspection is required, or if the applicant is not ready for the inspection on the established date and fails to notify the inspector or the board at least 24 hours prior to the inspection, the applicant shall pay a reinspection fee as specified in 18VAC110-30-15 prior to a reinspection being conducted.

F. No ~~license~~ facility permit shall be issued to sell controlled substances until adequate safeguards against diversion have been provided for the controlled substance storage and selling area and approved by the the inspector or board staff.

G. The licensee shall notify the board of any substantive changes to the approved selling and storage area including moving the location of the area, making structural changes to the area, or making changes to the alarm system for the area prior to the changes being made and pay a reinspection fee. An inspection shall be conducted prior to approval of the new or altered selling and storage area.

18VAC110-30-90. Physical standards.

Physical standards for the controlled substance selling and storage area:

1. The building in which the controlled substances selling and storage area is located shall be constructed of permanent and secure materials. Trailers and other movable facilities shall not be permitted;

2. There shall be an enclosed area of not less than 40 square feet that is designated as the controlled substances selling and storage area, which shall be used exclusively for storage, preparation, and dispensing. Records related to the sale of controlled substances may be maintained outside the selling and storage area with access limited to the licensee and those persons authorized to assist in the area. The work space used in preparation of the drugs shall be contained within the enclosed area. A controlled substance selling and storage area inspected and approved prior to November 3, 1993, shall not be required to meet the size requirement of this chapter;

3. Controlled substances maintained for ultimate sale shall be maintained separately from any other controlled substances maintained for other purposes. Controlled substances maintained for other purposes such as administration or samples may be

stored within the selling and storage area provided they are clearly separated from the stock maintained for sale;

4. The selling and storage area, work counter space and equipment in the area shall be maintained in a clean and orderly manner;

5. A sink with hot and cold running water shall be available within ~~the immediate vicinity~~ 20 feet of the selling and storage area and not located within an examination room or restroom; and

6. The entire area described in this chapter shall be well lighted and ventilated; the proper storage temperature shall be maintained to meet official specifications for controlled substance storage.

SEP 19 2016
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September 12, 2016

Caroline Juran
Executive Director
Virginia Board of Pharmacy
Perimeter Center, 9960 Mayland Drive, Suite 300
Henrico, VA 23233-1463

Dear Caroline Juran,

Our organizations are writing today in regards to a new general chapter from the U.S. Pharmacopeial Convention (USP), *General Chapter <800>, Hazardous Drugs—Handling in Healthcare Settings.* The purpose of the chapter, per USP, is "to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection."

Chapter <800> will apply to all healthcare personnel who handle hazardous drug preparations, including members of our organizations. Also impacted will be nurses, physicians, physician assistants, home healthcare workers, veterinarians, and veterinary technicians and the entities where they practice.

General Chapter <800> utilizes the National Institute for Occupational Safety and Health (NIOSH) list of antineoplastic and other hazardous drugs to define a hazardous drug preparation. There are multiple commonly dispensed drugs on this list, including estrogen and progestin containing drugs, anticonvulsants, immunosuppressive agents, antifungal agents, atypical antipsychotics and warfarin. The impact of General Chapter <800> on our members is substantial from both an economic and operational perspective and compliance with the new general chapter will require changes such as the use of Personal Protective Equipment (PPE) and the potential for reconstruction of facilities.

General Chapter <800> was published on February 1, 2016. In recognizing that it will take facilities time to conform to the new requirements, USP extended the official implementation date until July 1, 2018. However, given such highly complex, resource intensive, and time consuming compliance requirements, we respectfully request that the Virginia Board of Pharmacy carefully consider any actions related to pharmacy compliance with the standards.

Employee safety must always be a top priority. Our members are currently held to and comply with regulations and guidelines from entities such as the Environmental Protection Agency (EPA), the Occupational Safety and Health Administration (OSHA), and The Joint Commission (TJC), which detail the handling of hazardous material that serve to protect employees. We appreciate the intent of the proposed chapter <800>, however, the impact on our members and their patients in relation to a 2018 enforcement date is too great at this time and full compliance would be extremely difficult to the vast majority of our members.

In order to give our members the opportunity to perform the proper analyses, including budget implications and the impact upon the delivery of services to patients, and to fully integrate General Chapter <800> into their practice settings, we feel that a delay in enforcement is warranted, similar to the phased in approach that accompanied the introduction of USP *General Chapter <797> Pharmaceutical Compounding – Sterile.*

A delay in enforcement of USP <800> allows healthcare organizations sufficient time to plan and gradually implement changes. Budgeting capital expenses is a multistep, multi-year process that is not under the control of many pharmacies. Some organizations may have to justify their <800> project proposal to numerous organizational stakeholders, spread expenditures over more than one budget cycle, and integrate their project into existing organizational project timelines.

If the Virginia Board of Pharmacy agrees that a graduated approach to implementing General Chapter <800> is consistent with its mission and goals, we respectfully request that the Virginia Board of Pharmacy grant a five year delay in enforcement of General Chapter <800> until July 1, 2021. This grace period allows state-licensed practitioners to assess and plan for the significant operational and structural changes needed as well as budget and obtain the necessary resources in an already strained financial environment.

We appreciate your thoughtful consideration of our comments regarding *General Chapter <800>, Hazardous Drugs--Handling in Healthcare Settings.*

Sincerely,

American Pharmacists Association (APhA)
American Society of Consultant Pharmacists (ASCP)
College of Psychiatric and Neurologic Pharmacists (CPNP)
International Academy of Compounding Pharmacists (IACP)
National Alliance of State Pharmacy Associations (NASPA)
National Association of Chain Drug Stores (NACDS)
National Community Pharmacists Association (NCPA)

General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

Type of Posting	Notice of Intent to Revise
Posting Date	13–Oct–2014; updated 01–Dec–2014
Targeted Official Date	TBD
Expert Committee	Compounding

In accordance with section 7.05(c) of the 2010–2015 Rules and Procedures of the Council of Experts, this is to provide notice that the Compounding Expert Committee intends to republish General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings in the Pharmacopeial Forum (PF). The General Chapter, which was originally published in PF 40(3) [May–Jun. 2014], provides standards to protect personnel and the environment when handling hazardous drugs.

The Compounding Expert Committee is republishing General Chapter <800> in PF 41(2) [Mar.–Apr. 2015] due to the nature and significance of the comments received on the original PF proposal. The revision clarifies wording and reflects new and revised guidance documents and stakeholder input.

General Chapter <800> is being presented in advance of its publication in PF 41(2) to allow additional time for public review and comment. To ensure that all comments are addressed, please indicate the line number(s) corresponding to your comments and submit to CompoundingSL@usp.org. The General Chapter is available with line numbers at the link below. Comments will be accepted until May 31, 2015.

Download the proposed <800> Hazardous Drugs—Handling in Healthcare Settings

Should you have any questions, please contact Healthcare Quality Standards staff at CompoundingSL@usp.org.

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A change is coming: Proposed USP <800>

April 01, 2015

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Specialty Pharmacy Section

The U.S. Pharmacopeial (USP) Convention is a nonprofit organization that sets legally recognized standards for drugs. USP's mission is "to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods." These standards are enforceable by FDA.

Recently, a new chapter was proposed for addition to *The United States Pharmacopeia and the National Formulary* (*USP–NF*), "USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings," or simply "USP <800>."

Guidelines for safe handling

The proposed chapter provides guidelines for the safe handling of hazardous drugs (HDs). According to the National Institute for Occupational Safety and Health (NIOSH), an HD exhibits one or more of the following six characteristics in humans or animals:

1. Carcinogenicity
2. Teratogenicity or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing drugs determined hazardous by the above criteria

Safe handling refers to various steps including, but not limited to, receiving and unpacking, storing, preparing, compounding, dispensing, and administering. It requires designating an individual who is responsible for compliance with all standards, from maintaining proper environmental controls to appropriate training of all personnel.

Public review, input

Whenever a new chapter to the *USP–NF* is proposed, there is a 90-day period of public review and comment. The statement that there is no acceptable level of exposure to HDs, originally included in the proposed chapter, was removed because this goal may be unattainable, even when all guidelines are followed.

Revised hazardous drugs list

In the summer of 2014, NIOSH revised its list of HDs. The revised list now includes three categories of HD: antineoplastic drugs, non–antineoplastic drugs that meet one or more NIOSH criteria for an HD, and non–antineoplastic drugs that have primarily adverse reproductive effects. The chapter was revised to allow entities to perform a risk assessment for nonneoplastic drugs and final dosage forms to determine alternative containment strategies and/or work practices.

Entities that do not compound may erroneously assume that this chapter does not apply to their practice. Any entity involved in the receipt, storage, labeling, transport, or dispensing of HDs must follow these new standards.

Per the proposed chapter, dispensing of final dosage forms will require clean equipment dedicated to use with these drugs. Counting or packaging machines may not be used with tablet or capsule forms of HDs. Physical stress could introduce powder contaminants into the work space, resulting in exposure to the HD.

Revisions allow for either external venting or redundant high-efficiency particulate air (HEPA) filtration of containment primary engineering controls used for nonsterile compounding.

Complement to <795>, <797>

USP <800> is designed to complement both USP <795> and USP <797>. Some facility requirements will necessitate a revision to USP <797>. It is no longer acceptable for facilities that prepare a low number of HDs to use a biologic safety cabinet (BSC) or a compounding aseptic containment isolator (CACI) in a nonnegative pressure room. HD compounding can be done only in an HD-designated area.

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12 air changes per hour for use when compounding HDs. Low- and medium-risk HD compounded sterile preparation (CSP) may be prepared in a BSC or CACI located in an C-SCA, provided the beyond-use date of the CSP does not exceed 12 hours.

New terminology is used in the revised chapter. The word "shall" has been replaced with "must," indicating an enforceable guideline. The word "should" indicates a recommendation. All future revisions of USP standards will use this language.

Steps to prepare

Affected entities should take the following steps to prepare for deployment of the proposed standards:

- Review the NIOSH list and identify the HDs used in your establishment.
- Make any modifications to your facility to meet the new requirements.
- Establish appropriate training and monitoring of personnel.
- Use appropriate personal protective equipment.
- Document competencies.
- Follow designated cleaning procedures.
- Certify appropriate environmental quality and controls.

The current revision is being published on the USP website under Notices. Please provide the line numbers when submitting comments. The public comment period will end on May 31, 2015.

References

1. www.usp.org/support-home/frequently-asked-questions/usp-and-its-standards
2. www.usp.org/about-usp/legal-recognition/working-us-fda www.usp.org/sites/default/files/usp_pdf/EN/m7808.pdf
3. Department of Health and Human Services (NIOSH) Publication No. 2004-165

Susan Pennell, BSPharm, CCN, ABAAHP, Compounding Clinical Director, Diplomat, Flint, MI

PharmacyToday

Spotlight Image:

PharmacyToday

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<800> Hazardous Drugs—Handling in Healthcare Settings

Type of Posting	Notice of Intent to Revise
Posting Date	15–Apr–2016; updated 29–Apr–2016*
Targeted Official Date	26–May–2016; Errata
Expert Committee	Compounding Expert Committee

In accordance with section 7.04 (c) of the 2015–2020 Rules and Procedures of the Council of Experts, this is to provide notice that the USP Compounding Expert Committee intends to revise General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings.*

The Expert Committee proposes to revise the General Chapter to remove the requirement that the Containment Secondary Engineering Control (C-SEC) be externally vented through high-efficiency particulate air (HEPA) filtration. *Section 5.3 FACILITIES AND ENGINEERING CONTROLS, Compounding* will be revised to indicate that the C-SEC used for sterile and nonsterile compounding must be externally vented. The C-SEC does not need to be vented through HEPA filtration.

The proposed revisions will be published as Errata pursuant to section 7.02 of the Rules and Procedures. The proposed Errata will be included in the Errata table update on May 26, 2016, which will become official on June 1, 2016. The correction will be incorporated into the next USP–NF publication. The official date of General Chapter <800> will remain July 1, 2018.

Should you have any questions, please contact Jeanne Sun, Scientific Liaison to the Compounding Expert Committee (JHS@usp.org).

*The notice was updated on April 29, 2016 to specify that the revision will be published as *Errata* on May 26, 2016.

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Classroom: USP General Chapter 800 Hazardous Drugs—Handling in Healthcare Settings

Classroom
September 22, 2016

Course Description
This course describes the standards of the newly developed *USP* General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*. The purpose of the chapter is to provide standards to protect personnel, patients, and the environment when handling hazardous drugs (HDs). Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.
The chapter applies to all healthcare personnel and all entities that handle HDs.
General Chapter <800> will be published on February 1, 2016, in the *First Supplement* to *USP* 39–*NF* 34 and will have a delayed implementation date of July 1, 2018.

Course Descriptions

Classroom: USP General Chapter 800 Hazardous Drugs—Handling in Healthcare Settings

Course Description
This course describes the standards of the newly developed *USP* General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings*. The purpose of the chapter is to provide standards to protect personnel, patients, and the environment when handling hazardous drugs (HDs). Handling HDs includes, but is not limited to, the receipt, storage, compounding, dispensing, administration, and disposal of sterile and nonsterile products and preparations.
The chapter applies to all healthcare personnel and all entities that handle HDs.
General Chapter <800> will be published on February 1, 2016, in the *First Supplement* to *USP* 39–*NF* 34 and will have a delayed implementation date of July 1, 2018.

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