



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

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8/26/2020 2:10:29 PM

Office of West Virginia
Secretary Of State

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-
MAKING REVIEW COMMITTEE**

AGENCY: Pharmacy TITLE-SERIES: 15-03
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 15-03 Board of Pharmacy Rules for Continuing Education for Licensure of Pharmacists

PRIMARY CONTACT

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CITE STATUTORY AUTHORITY: 20-5-7

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

General Rulemaking Authority: Rule needed updated.

IS THIS FILING SOLELY FOR THE SUNSET PROVISION REQUIREMENTS IN W. VA. CODE §29A-3-19(e)? No

IF YES, DO YOU CERTIFY THAT THE ONLY CHANGES TO THE RULE ARE THE FILING DATE, EFFECTIVE DATE AND AN EXTENSION OF THE SUNSET DATE? No

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 7/22/2020

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 8/21/2020

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

none

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

This rule deals with continuing education requirements.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

Rule needs updated.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

none

B. ECONOMIC IMPACT ON SPECIAL REVENUE ACCOUNTS:

none

C. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

none

D. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2020 Increase/Decrease (use "-")	2021 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	00	0	0
2. Estimated Total Revenues	00	0	0

E. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

none

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Ryan L Hatfield -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 3
BOARD OF PHARMACY RULES FOR CONTINUING
EDUCATION FOR LICENSURE OF PHARMACISTS

§15-3-1. General.

1.1. Scope. -- W. Va. Code §30-5-3A authorizes the Board of Pharmacy to promulgate rules which are necessary to perform the duties and responsibilities of the board as they relate to requiring pharmacists to meet certain continuing education requirements in order to maintain their license to practice pharmacy in the State of West Virginia.

1.2. Authority. -- This legislative rule is issued under the authority of W. Va. Code §30-5-7.

1.3. Filing Date. -- ~~April 30, 2014.~~

1.4. Effective Date. -- ~~May 30, 2014.~~

1.5. Sunset Date -- This legislative rule shall terminate ~~May 30, 2024~~ unless renewed prior to that date.

§15-3-2. Definitions.

2.1. "Accreditation Council for Pharmacy Education" ("ACPE") means the national accreditation organization for continuing pharmacy education.

2.2. "Chronic Pain" means pain that has persisted after reasonable medical efforts have been made to relieve the pain or cure its cause and that has continued, either continuously or episodically, for longer than three (3) continuous months. For purposes of this rule, "chronic pain" does not include pain associated with a terminal condition or illness, or with a progressive disease that, in the normal course of progression, may reasonably be expected to result in a terminal condition or illness.

2.3. "Continuing Pharmacy Education" ("CPE") means planned and accredited learning experiences beyond a formal degree program designed to promote the continual development of knowledge, skills, and attitudes on the part of the pharmacist or pharmacy technician: which promotes problem-solving and critical thinking and is applicable to the practice of pharmacy.

2.4. "Continuing Pharmacy Education Committee" ("CPE Committee") means that committee appointed by the board responsible for approval of the content of each CPE ~~program activity~~, which is not otherwise automatically approved by this rule for CPE credit, offered by a non-accredited ACPE provider of CPE.

2.5. "Continuing Pharmacy Education Coordinator" ("CPE Coordinator") means that individual or organization who may be retained by the board for the purpose of coordinating CPE ~~programming activities~~ and licensure renewal requirements.

2.6. "Continuing Pharmacy Education Hour" ("CPE Hour") means one hour of participation in a board accredited continuing pharmacy education ~~program activity~~ under responsible ~~sponsorship~~

providership, capable direction and qualified instruction. For the purposes of this definition, an hour equals sixty (60) minutes of participation and represents 1.0 continuing pharmacy education contact hour, but Continuing Pharmacy Education activities of less than one hour may be approved as Continuing Pharmacy Education activities in fifteen (15) minute increments worth one quarter (.25) contact hour per fifteen (15) minute period.

2.7. “Continuing Pharmacy Education Number” (Number) means either the ACPE number or board-issued CPE number assigned to identify each approved program activity.

2.8. “Continuing Pharmacy Education Provider” (Provider) means an institution, organization, agency, corporation, company, or individual approved by the board for the purpose of direct provision of continuing pharmacy education programs activities.

2.9. “CPE Monitor” means the electronic CPE monitor created and maintained through the collaborative efforts of National Association of Boards of Pharmacy the Accreditation Council for Pharmacy Education (ACPE) to permit CPE providers, pharmacists, and pharmacy technicians to electronically keep track of CPE credits earned from CPE providers, by acting as a repository of this information maintained on licensees’ behalf and reported by NABP to state boards of pharmacy which request verification of CPE.

2.10. “Reporting Period” means the two (2) year licensure period beginning on July 1 of a given year through June 30 two (2) years later which coincides with the licensee’s renewal period.

2.11. “West Virginia Pharmacists Association” (Association) means a statewide professional organization whose members are current or former pharmacists duly licensed by the board.

2.12. “West Virginia Society of Health System Pharmacists” means a statewide professional organization representing the interests of current and former pharmacists duly licensed by the board who practice in hospitals, health maintenance organizations, long-term care facilities, home care, and other components of health care systems.

§15-3-3. Purpose.

3.1. The purpose of Continuing Pharmacy Education (CPE) is to maintain and enhance the professional proficiency of pharmacists licensed to practice in West Virginia for the benefit and health, safety and welfare of the people served by pharmacists in the State of West Virginia.

§15-3-4. Continuing Pharmacy Education Requirements.

4.1. 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, in order to renew his or her license to practice pharmacy in West Virginia, and each reporting period thereafter.

4.2. Hours earned may only be used to meet the requirements for one reporting period. Hours in excess of the number required at the end of each reporting period shall not be transferred or applied to future reporting periods to satisfy future CPE requirements. Hours earned in a new reporting period but used to meet the requirements of a prior reporting period may only be used for the prior reporting period.

4.3. Six (6) hours of the thirty (30) CPE hours required every two (2) years shall be obtained through a live presentation requiring the ~~physical~~ direct presence of the pharmacist at the CPE ~~program activity~~.

4.4. ~~Beginning July 1, 2014, u~~Unless a pharmacist has completed and timely provided to the board on the form to be provided by the board a waiver request attesting that he or she has not administered or dispensed a controlled substance during the entire previous reporting period, every pharmacist shall, as a prerequisite to license renewal, complete a minimum of ~~three~~ two (32) hours of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period.

4.4.a. Said ~~three~~ two (32) hours of CPE shall be a part of the 30 hours of CPE required, and is not ~~three~~ two (32) additional hours.

4.4.b. For purposes of this subsection, “drug diversion training and best practice prescribing of controlled substances training” means a training course of at least ~~three~~ two (32) CPE hours which includes, ~~at a minimum, all of the following: drug diversion training, best-practice prescribing of controlled substances training, and training on prescribing and administration of an opioid antagonist that has been approved by the Board.~~

~~———— 4.4.b.1. Drug diversion, including West Virginia statistics on prescription drug abuse and resulting deaths;~~

~~———— 4.4.b.2. Epidemiology of chronic pain and misuse of opioids;~~

~~———— 4.4.b.3. Indication for opioids in chronic pain treatment including, at a minimum, general characteristics, toxicities, and drug interactions;~~

~~———— 4.4.b.4. Patient evaluation and risk assessment and tools to assess risk and monitor benefits.~~

~~———— 4.4.b.5. Initiation and ongoing management of chronic pain in patients treated with opioid based therapies, including, at a minimum: treatment objectives; medication therapy management and collaborative practice; prescription of controlled substance agreements; urine screens and pill counts; patient education on safe use, storage and disposal of opioids; discontinuation of opioids; and documentation and medical records;~~

~~———— 4.4.b.6. Case study of a patient with chronic pain;~~

~~———— 4.4.b.7. Identification of diversion and drug seeking tactics and behaviors;~~

~~———— 4.4.b.8. Best practice methods for working with patients, prescribers, law enforcement, and others as appropriate, concerning patients suspected of drug seeking behavior and diversion;~~

~~———— 4.4.b.9. Compliance with controlled substances laws and rules; and~~

~~———— 4.4.b.10. How to Register with and use the West Virginia Controlled Substances Monitoring Program established in West Virginia Code § 60A-9-1, et seq.~~

§15-3-5. Methods of Acquiring Continuing Pharmacy Education.

5.1. Continuing pharmacy education hours of credit may be earned by licensed pharmacists in the following manner ~~if the provider grants the pharmacist a statement of credit or reports the credit to the CPE Monitor:~~

5.1.a. Live ~~Programs~~ Activities, which means CPE activities that provide for a direct interaction between faculty and learners, and may include lectures, symposia, live teleconferences, live webinars, workshops, and other similar venues;

5.1.b. Home study by print, webinar, computer-based training, video, or other non-live approved ~~programs~~ activities or audio-visual presentations;

5.1.c. Credit earned from a United States accredited college/school or university for post-graduate courses in pharmaceutical sciences or other courses applicable to pharmacy practice;

5.1.d. Continuing pharmacy education ~~programs~~ activities granted credit by other states; and

5.1.e. Any ~~program~~ activity approved by ACPE;

5.2. ACPE approved providers do not have to give a statement of credit to pharmacists. Non-ACPE approved providers shall provide the pharmacist a statement of credit or statement of attendance.

§15-3-6. ~~Program~~Activity Administration.

6.1. The board has the statutory responsibility for the oversight of CPE as required for licensure renewal and to appoint a Continuing Pharmacy Education Committee.

~~— 6.2. The CPE Committee shall:~~

~~—— 6.2.a. perform necessary correspondence and communication with professional groups, organizations and individuals who have interest in CPE;~~

~~—— 6.2.b. recommend to the board for its approval those providers of continuing pharmacy education programs activities who have been certified as meeting the criteria established for this purpose; and~~

~~—— 6.2.c. recommend to the board for its approval those continuing pharmacy education programs activities which have met the criteria established for that purpose.~~

§15-3-7. Continuing Pharmacy Education Committee.

7.1. The Continuing Pharmacy Education Committee shall be composed of equal representation from the West Virginia Board of Pharmacy, each accredited school of pharmacy located in the State of West Virginia, the West Virginia Pharmacists Association, and the West Virginia Society of Health System Pharmacy Pharmacists.

7.2. The members of the CPE Committee shall be selected by the board and shall serve for a period of three (3) years, and may be reappointed.

7.3. The chairman of the CPE Committee shall be selected by the members of the committee.

7.4. The CPE Committee is responsible for approval of each ~~program~~ activity offered by a non-accredited ACPE provider of CPE credit.

7.5. The CPE Committee shall:

7.5.a. perform necessary correspondence and communication with professional groups, organizations, and individuals who have interest in CPE; and

7.5.b. recommend to the board for its approval those providers of continuing pharmacy education activities who have been certified as meeting the criteria established for this purpose.

~~7.5. 7.6~~ In all other matters concerning the approval of Continuing Pharmacy Education providers, the role of the CPE Committee is to advise and submit its recommendations to the board.

§15-3-8. Responsibilities of Providers.

8.1. CPE providers are responsible for submitting CPE ~~programs~~ activities to the board for approval.

8.2. Providers shall submit an application for approval of any CPE ~~program-activity~~ in writing to the board at least thirty (30) days prior to their offering in order that potential participants will know whether the ~~program~~ activity is approved. The board may approve ~~programs~~ activities submitted later provided proper cause is shown for late submission.

8.3. The proposed CPE ~~program-activity~~ shall contain all required information on forms provided by the board, including, but not limited to, the course name, provider name, proposed dates the ~~program~~ activity will be offered, agenda, content overview, learning objectives and faculty name with biography.

8.4. The board may revoke or suspend approval of providers for submission of fraudulent information concerning CPE.

8.5. Changes to the content of an ongoing approved ~~program~~ activity shall require the provider to submit a new application for the ~~program~~ activity.

8.6. Providers shall retain a file of participants of each accredited ~~program~~ activity for four (4) years.

~~8.7. Providers shall advise the board in writing of the date, location, and number of CPE hours of each program activity presented or made available along with the names and addresses~~

~~of each participant successfully completing each program activity within thirty (30) days following the presentation or completion of an approved program activity.~~

8.87. Providers not accredited by ACPE shall provide a statement of credit of participation to each participant or report course completion to the CPE Monitor for each participant who attends and successfully completes a program activity. The statement of credit shall include at a minimum, the course name, date completed, total CPE hours earned, and the provider's name, address, phone number, and board CPE number.

§15-3-9. Responsibilities of Pharmacists.

9.1. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education programs activities completed for four (4) years and submit certifications of participation and completion to the board upon request. The records may be kept in whole or in part in the pharmacist's personal account in the CPE Monitor.

9.2. The board may take disciplinary action against a pharmacist for submission of fraudulent statements or certificates concerning CPE.

9.3. A Pharmacist shall submit, on forms provided by the board, a list of accredited CPE programs activities completed in the preceding reporting period with their renewal license application.

9.4. In the event a pharmacist fails to submit a list of completed CPE programs activities with his or her renewal application, the board shall notify the pharmacist at his or her last known address that disciplinary action shall be taken for failure to comply with CPE requirements.

9.5. A pharmacist may request a waiver from the board from the CPE requirements for reasons of illness, injury, incapacity, retirement, or other extenuating circumstances.

9.6. A pharmacist shall keep the board informed of his or her current mailing address.

~~9.7. A pharmacist may transfer CPE hours from another state to West Virginia if the other state accepts the transfer of West Virginia CPE hours.~~ A pharmacist may only transfer CPE hours from another state if that state accepts the transfer of West Virginia CPE hours to its state.

9.8. A West Virginia licensed pharmacist who resides in another state requiring CPE and who does not practice in West Virginia may renew his or her West Virginia license by certifying on his or her CPE report form that he or she has a current and valid license to practice in the state in which he or she is residing. The following statement shall be placed on the form, and the form signed, dated, notarized, and returned to the West Virginia Board of Pharmacy with the renewal application and fee:

"I declare under penalties of falsification that I hold a current and valid pharmacist license, No. [] in the State of [], and that I do not presently practice pharmacy in the State of West Virginia. I hereby agree to notify the West Virginia Board of Pharmacy if I return and commence practice in West Virginia."

9.9. A pharmacist may request CPE credit only once in a reporting period for each ~~program~~ activity attended or completed.

~~§15-3-10. Approval of Providers.~~

~~—10.1. The board has established the policy that all CPE providers approved by ACPE are approved as providers of CPE in West Virginia.~~

~~—10.2. All other providers shall make application for approval as a provider on the form provided by the board. Providers shall:~~

~~——10.2.a. have a qualified director or coordinator of CPE program;~~

~~——10.2.b. have qualified faculty to develop and present CPE programs, or shall have contracted or retained qualified people to develop and present programs;~~

~~——10.2.c. have access to appropriate resources and materials, such as printing, projectors, and other suitable hardware and software for the development and presentation of programs;~~

~~——10.2.d. have appropriate facilities and/or mechanisms to record, store, and retrieve data concerning attendance, credit, and other relevant data for individuals participating in the programs; and~~

~~——10.2.e. demonstrate their ability and willingness to provide any and all information required by the board or the CPE Committee.~~

~~—10.3. Providers approved in accordance with section 10.2 shall be reapproved as a provider every four (4) years from the date of approval. The board shall withdraw approval if a provider is found to be in violation of subsection 8.4 of this rule. The board may withdraw approval if a provider becomes unable to meet the requirements of section 10.2 at any time during the approval period. The provider may apply for re-approval if all applicable criteria are met. The application for re-approval shall be made within thirty (30) days after the notice of disapproval and the provider shall comply with the original procedure as prescribed in subsection 8.2 of this rule. The board at its discretion may impose a period of probation if it approves the application for re-approval.~~

~~§15-3-11.10. Approval of Continuing Pharmacy Programs~~ Activities.

~~11-10.1.~~ Providers shall submit all CPE ~~programs~~ activities for approval by the board except as provided for in subsections ~~11-10.2~~ and ~~11-10.3~~ of this section.

~~11-10.2.~~ The board has approved all ~~programs~~ activities developed and presented by ACPE ~~approved~~ accredited providers.

~~11-10.3.~~ Approval of a CPE ~~program~~ activity is valid for a three (3) year period if the content remains the same.

~~11-10.4.~~ All ~~programs~~ activities shall meet the criteria utilized by ACPE and additionally shall meet the following criteria:

~~11.4.a. The program activity shall be within the scope of the following subjects:~~

~~11.4.a.1. Pharmaceutics: bioavailability, bioequivalence, product selection based on bioavailability and/or bioequivalence;~~

~~11.4.a.2. Pharmacognosy: drugs of natural origin as related to therapeutics;~~

~~11.4.a.3. Pharmacology: as related to therapeutics, dosage regimen, etc.;~~

~~11.4.a.4. Pharmaceutical Chemistry: chemistry of drugs as related to therapeutics;~~

~~11.4.a.5. Pharmacy Administration: as related to the managerial, behavioral, and social aspects of pharmacy practice;~~

~~11.4.a.6. Pharmacy Practice: as related to patient compliance, patient use and utilization of drugs, drug incompatibilities, proper selection and use of nonprescription drugs, and related topics; or~~

~~11.4.a.7. Public Health: as related to improving the pharmacist's role in public health and the health care system.;~~

~~11.10.4.b.a. The program activity shall be relevant, timely, and applicable to pharmacy practice;~~

~~11.10.4.c.b. The program activity content shall be well organized with stated objectives, and an orderly flow of material, with appropriate examples and/or illustrations; and~~

~~11.10.4.d.c. The program activity shall be appropriately presented, with the mode/method of presentation appropriate to the topic.~~

§15-3-~~12~~11. Program Activity Evaluation.

~~12.11.1. The provider or sponsor shall have an evaluation mechanism for the purpose of allowing the participant to assess achievement of personal objectives.~~

~~12.11.2. The provider or sponsor shall develop and employ evaluation techniques that will assess the effectiveness of the CPE activities and the level of fulfillment of the stated objectives, with the goal of continual provided or sponsor and CPE improvement CPE improvement by the provider or sponsor.~~

~~12.11.3. The provider or sponsor shall compile the results of participants' evaluations and submit them to the board upon request.~~

§15-3-~~13~~12. Credits and Records.

~~13.12.1. Credits and records of CPE shall be based on a CPE hour or approved fifteen minute increments.~~

~~13.12.2.~~ A pharmacist who develops and/or presents an approved CPE ~~program activity~~ shall receive credit for the number of continuing pharmacy education hours of that ~~program activity~~ for his or her initial presentation.

~~13.12.3.~~ All providers and pharmacists shall retain their records for four (4) years in a manner that will enable their ready retrieval upon request of the board, its authorized agent or Committee.

~~13.12.4.~~ ~~Students~~ Graduates providing documentation of enrollment in graduate programs of health related fields or participation in a residency program in a health related field are not required to provide additional documentation of participation in CPE. If a ~~student-graduate~~ discontinues his or her pursuit of graduate study, the prevailing CPE requirements apply for his or her continued licensure.