

**WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

FILED

2013 JUL 16 PM 2:00

SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative (Emergency Rule) CITE AUTHORITY: WV Code Section 30-5-7

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: Series 3

TITLE OF RULE BEING AMENDED: BOARD OF PHARMACY RULES FOR CONTINUING
EDUCATION FOR LICENSURE OF PHARMACISTS

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON August 21, 2013 AT 4:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy

Attn: CPE Rules
106 Capitol Street

Charleston, WV 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.

David E. Potters
Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

**BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE
THE PROPOSED LEGISLATIVE RULE**

**BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR
LICENSURE OF PHARMACISTS**

15 CSR 3

Summary and Statement of Circumstances: House Bill 4037 (2012 Regular Legislative Session) requires the Board to require certain continuing pharmacy education for the dispensing of controlled substances designed to reduce and prevent drug diversion. The other practitioner licensing boards required by the new law to provide this continuing education requirement promulgated theirs by emergency rule in the Fall of 2013, citing the ongoing drug diversion problems for the immediate need to put the rules in place. It is this same reason which the Board of Pharmacy cites for the need to do this by emergency rule. Pharmacists need to have proper notice of the requirement prior to the 2014 biennial license renewal period in order to comply. Thus, the rule seeks to implement the new training for “drug diversion training and best practice prescribing of controlled substances training” In addition, the changes implement the use of the new CPE Monitor, the service for electronic reporting of CPE hours earned. The rule then clarifies what a “live” program is. Finally, the Board sought to clean up and make minor clarifications throughout.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, David E. Potters, Executive Director and General Counsel, 106 Capitol Street, Suite 100, Charleston, West Virginia, 25301, telephone (304) 558-0558.

Note: This is a modification of the Series, such that changes are reflected by strike-throughs and underlining in the proposed rule.



EMERGENCY RULE QUESTIONNAIRE

DATE: July 16, 2013

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: *(Agency Name, Address & Phone No.)* West Virginia Board of Pharmacy
106 Capitol Street, Suite 100
Charleston, West Virginia 25301
304-558-0558

EMERGENCY RULE TITLE: Board of Pharmacy Rules For Continuing Education For Licensu

1. Date of filing July 16, 2013

2. Statutory authority for promulgating emergency rule:
WV Code 30-5-7

3. Date of filing of proposed legislative rule: July 16, 2013

4. Does the emergency rule adopt new language or does it amend or appeal a current legislative rule? Amends current legislative rule.

5. Has the same or similar emergency rule previously been filed and expired?
No

6. State, with particularity, those facts and circumstances which make the emergency rule necessary for the **immediate** preservation of public peace, health, safety or welfare.
~~The ongoing drug diversion problems caused the Legislature to require certain~~ continuing education for controlled substances dispensing. This rule change needs to go into effect immediately to provide pharmacists with sufficient notice prior to the July 1, 2014 license renewal period. The other licensing boards required to do this did so by emergency rule last fall. Due to changes in the Board's Continuing Education Committee makeup, the Board was unable to promulgate these rules until this year. However, the nature of the emergency, drug diversion, remains the same.

7. If the emergency rule was promulgated in order to comply with a time limit established by the Code or federal statute or regulation, cite the Code provision, federal statute or regulation and time limit established therein.

WV Code Section 30-1-7a, to have in place for the 2014 biennial renewal cycle.

8. State, with particularity, those facts and circumstances which make the emergency rule necessary to prevent substantial harm to the public interest.

~~Pharmacists are required by WV Code Section 30-1-7a to have continuing education~~ regarding drug diversion and dispensing of controlled substances due to the ongoing drug diversion issues plaguing the State, region, and nation. Proper notice through this rule is necessary to have the pharmacists comply with the continuing education requirement in the next licensing renewal period, July 1, 2014. This required education is designed to help prescribers and dispensers of controlled substances to have a positive effect in reducing drug diversion.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Board of Pharmacy Rules For Continuing Education For Licensure of Pharmacists

Rule Title: _____

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 106 Capitol Street, Suite 100
Charleston, West Virginia 25301

Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

None. This simply places topical requirements on continuing education for pharmacists, and clarifies methods of obtaining and reporting the continuing education.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Board of Pharmacy Rules For Continuing Education For Licensure of Pharmacists

Rule Title: _____

Rule Title: _____

3. **Explanation of above estimates (including long-range effect):**
Please include any increase or decrease in fees in your estimated total revenues.

No fiscal effects are expected. This simply places topical requirements on continuing education for pharmacists, and clarifies methods of obtaining and reporting the continuing education.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule would not have a fiscal impact, and/or any special issues not captured elsewhere on this form.

None.

Date: July 16, 2013

Signature of Agency Head or Authorized Representative

David E. Potters

FILED

2013 JUL 16 PM 2:01

**TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY**

OFFICE OF THE
SECRETARY OF STATE

**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 §30-5-3A.

1.3. Filing Date. -- April 4, 2012 _____

1.4. Effective Date. -- April 4, 2012 _____

§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.

~~2.2.3.~~ "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.

~~2.3.4.~~ "Continuing Pharmacy Education Committee" ("CPE Committee") means that committee appointed by the Board responsible for approval of the content of each CPE program, which is not otherwise automatically approved by this rule for CPE credit, offered by a provider of CPE.

~~2.4.5.~~ "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 and licensure renewal requirements.

~~2.5.6.~~ "Continuing Pharmacy Education Hour" ("CPE Hour") means one hour of participation in a Board accredited continuing pharmacy education program under responsible sponsorship, 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 hour.

~~2.62.7.~~ "Continuing Pharmacy Education Number" (Number) means either the ACPE number or ~~Board~~board-issued CPE number assigned to identify each approved program.

~~2.72.8.~~ "Continuing Pharmacy Education Provider" (Provider) means an institution, organization, agency, corporation, company, or individual approved by the ~~Board~~board for the purpose of direct provision of continuing pharmacy education programs.

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.

~~2.82.10.~~ The "Reporting Period" means the ~~two~~2-year licensure period beginning on July 1 of a given year through June 30 two years later which coincides with the licensee's renewal period.

~~2.92.11.~~ "West Virginia Pharmacists Association" (Association) means a statewide professional organization whose members are pharmacists duly licensed by the ~~Board~~board.

~~2.102.12.~~ "West Virginia Society of Health System Pharmacists" means a statewide professional organization representing the interests of pharmacists duly licensed by the ~~Board~~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. ~~Beginning July 1, 2002, a~~ 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 presence of the pharmacist at the CPE program.

4.4. Beginning July 1, 2014, 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 3 hours of drug diversion training and best practice prescribing of controlled substances training during the previous reporting period.

4.4.1. Said 3 hours of CPE shall be a part of the 30 hours of CPE required, and is not 3 additional hours.

4.4.2. For purposes of this subsection, "drug diversion training and best practice prescribing of controlled substances training" means a training course of at least 3 CPE hours which includes, at a minimum, all of the following:

(a). Drug diversion, including West Virginia statistics on prescription drug abuse and resulting deaths;

(b). Epidemiology of chronic pain and misuse of opioids;

(c). Indication for opioids in chronic pain treatment including, at a minimum, general characteristics, toxicities, and drug interactions;

(d). Patient evaluation and risk assessment and tools to assess risk and monitor benefits.

(e). 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;

(f). Case study of a patient with chronic pain;

(g). Identification of diversion and drug seeking tactics and behaviors;

(h). Best practice methods for working with patients, prescribers, law enforcement, and others as appropriate, concerning patients suspected of drug seeking behavior and diversion;

(i). Compliance with controlled substances laws and rules; and

(j). Registration with and use of 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:

5.1.1. Live Programs, 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.

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

5.1.3. 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;

5.1.4. Continuing pharmacy education programs granted credit by other states;

5.1.5. Any program approved by ACPE;

§15-3-6. Program Administration.

6.1. The Boardboard 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:

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

6.2.2. recommend to the Boardboard for its approval those providers of continuing pharmacy education programs who have been certified as meeting the criteria established for this purpose; and

6.2.3. recommend to the Boardboard for its approval those continuing pharmacy education programs 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 Boardboard 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 offered by a provider of CPE credit.

7.5. 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 Boardboard.

§15-3-8. Responsibilities of Providers.

- 8.1. CPE providers are responsible for submitting CPE programs to the Board for approval.
- 8.2. Providers shall submit an application for approval of any CPE program in writing to the Board at least ~~thirty~~ (30) days prior to their offering in order that potential participants will know whether the program is approved. The Board may approve programs submitted later provided proper cause is shown for late submission.
- 8.3. The proposed CPE program 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 will be offered, agenda, content overview, learning objectives and faculty.
- 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 shall require the provider to submit a new application for the program.
- 8.6. Providers shall retain a file of participants of each accredited program 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 presented or made available along with the names and addresses of each participant successfully completing each program within ~~thirty~~ (30) days following the presentation or completion of an approved program.
- 8.8. Providers shall provide a statement of credit of participation/~~completion~~ to each participant or report course completion to the CPE Monitor for each participant who attends and successfully completes a program. The statement of credit must shall include at a minimum, the course name, date completed, total CPE hours earned, and the provider's name, address, phone number, and CPE number.

§15-3-9. Responsibilities of Pharmacists.

- 9.1. Pharmacists shall keep valid records, receipts, and certifications of continuing pharmacy education programs 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 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 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~~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.

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 attended or completed.

§15-3-10. Approval of Providers.

10.1. The ~~Board~~board has established the policy that all CPE providers approved by the- 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~~board. Providers shall:

10.2.1. have a qualified director or coordinator of CPE program;

10.2.2. have qualified faculty to develop and present CPE programs, or shall have contracted or retained qualified people to develop and present programs;

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

10.2.4. 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

10.2.5. demonstrate their ability and willingness to provide any and all information required by the ~~Board~~board or the CPE Committee.

10.3. Providers approved in accordance with section 10.2 ~~must~~shall be reapproved as a provider every ~~four~~(4) years from the date of approval. The ~~Board~~board shall withdraw approval if a provider is found to be in violation of subsection 8.4 of this rule. The ~~Board~~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~~board at its discretion may impose a period of probation if it approves the application for re-approval.

§15-3-11. Approval of Continuing Pharmacy Programs.

11.1. Providers shall submit all CPE programs for approval by the ~~Board~~board except as provided for in subsections 11.2 and 11.3 of this section.

11.2. The ~~Board~~board has approved all programs developed and presented by ACPE approved providers.

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

11.4. All programs shall meet the criteria utilized by ACPE and additionally shall meet the following criteria:

11.4.1. The program shall be within the scope of the following subjects:

~~11.4.1.1(a)~~. Pharmaceutics: bioavailability, bioequivalence, product selection based on bioavailability and/or bioequivalence;

~~11.4.1.2(b)~~. Pharmacognosy: drugs of natural origin as related to therapeutics;

~~11.4.1.3(c)~~. Pharmacology: as related to therapeutics, dosage regimen, etc.;

~~11.4.1.4(d)~~. Pharmaceutical Chemistry: chemistry of drugs as related to therapeutics;

~~11.4.1.5(e)~~. Pharmacy Administration: as related to the managerial, behavioral, and social aspects of pharmacy practice;

~~11.4.1.6(f)~~. 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

~~11.4.1.7(g)~~. Public Health: as related to improving the pharmacist's role in public health and the health care system.;

11.4.2. The program shall be relevant, timely, and applicable to pharmacy practice;

———11.4.3. The program content shall be well organized with stated objectives, and an orderly flow of material, with appropriate examples and/or illustrations; and

11.4.4. The program shall be appropriately presented, with the mode/method of presentation appropriate to the topic; and.

§15-3-12. Program Evaluation.

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

12.2. 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.

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

§15-3-13. Credits and Records.

13.1. Credits and records of CPE shall be based on a CPE hour.

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

13.3. 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~~board, its authorized agent or Committee.

13.4. Students 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 discontinues his or her pursuit of graduate study, the prevailing CPE requirements apply for his or her continued licensure.