

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

Form #2

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OFFICE OF THE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative Rule CITE AUTHORITY: W.Va. Code §30-5-3A

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 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 July 25, 2011 AT 4:00 P.M., Eastern Time ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

West Virginia Board of Pharmacy

C/O Public Comment on Series 2
232 Capitol Street

Charleston, West Virginia 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



Board Members
George Karos, Pres.
Lydia Main, Vice Pres.
Charles Woolcock, Sec.
Martin Castleberry
Rebekah E. Hott
Carl K. Hedrick, Jr.
Sam Kapourales

David E. Potters,
Executive Director &
General Counsel

Betty Jo Payne,
Asst. Exec. Director

Office

232 Capital Street

Charleston, West Virginia 25301

Board of Pharmacy

Phone (304) 558-0558

Fax (304) 558-0572

APPROVAL OF FILING OF RULES

BE IT HEREBY KNOWN that the West Virginia Board of Pharmacy approves the filing of the following modified rules with the Secretary of State and the Legislative Rulemaking and Review Committee, each of which were considered and approved for filing by the Board at its regular meeting held on June 17, 2011:

- (1) Title 15, Series 2, "RULES OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT", with modification regarding electronic prescribing (per SB 1001, 2007 1st Special Session and subsequent changes in federal law), limiting early refills, and clarifying other provisions;
- (2) Title 15, Series 3, "BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR LICENSURE OF PHARMACISTS", modernizing certain language and updating requirements to match national standards; and
- (3) Title 15, Series 5, "LICENSURE OF WHOLESALE DRUG DISTRIBUTORS", to update language as required by federal law, and clarify requirements for licensing of distributors who maintain title, ownership, or control over their product which is brought into this State by another entity on their behalf.

Signed this 23th day of June, 2011,

BY:



 George Karos, President



Board of Pharmacy

Phone (304) 558-0558
Fax (304) 558-0572

Office
232 Capitol Street
Charleston, West Virginia 25301

APPROVAL OF FILING OF RULES

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- (3) Title 15, Series 5, "LICENSURE OF WHOLESALE DRUG DISTRIBUTORS", to update language as required by federal law, and clarify requirements for licensing of distributors who maintain title, ownership, or control over their product which is brought into this State by another entity on their behalf.

Signed this 23th day of June, 2011,

BY: David E. Potters
David E. Potters
Executive Director & General Counsel

**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: The Board last modified this Series in 2002. Since that time, certain terminology has changed, and the manner in which continuing pharmacy education (CPE) has evolved. Therefore, the Board determined that it needed to modify the rule to update definitions and references to match modern terminology, such as the proper name for the national accreditation organization for CPE, and the use of “continuing pharmacy education” in place of “continuing pharmaceutical education”. Further, the Board sought to bring our rule into compliance with standards used by the national accreditation organization, including the methods by which CPE is provided and what constitutes a credit hour (60 minutes of instruction per credit). Next, the Board sought to clarify the process for approval of course offerings by providers. 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, 232 Capitol Street, 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.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Title 15, Series 3, "BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR LICENSURE OF PHARMACISTS"

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street
Charleston, WV 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.

No impact. These are just rule modifications to update language and requirements on pharmacists, and will not impact the functions of the Board. It will not raise revenue, or impact current ongoing activities of the Board.

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

Rule Title: Title 15, Series 3, "BOARD OF PHARMACY RULES FOR CONTINUING EDUCATION FOR LICENSURE OF PHARMACISTS"

Rule Title: _____

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

These are just rule modifications to update language and requirements on pharmacists, and will not impact the functions of the Board. It will not raise revenue, or impact current ongoing activities of the Board.

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.

Date: June 23, 2011

Signature of Agency Head or Authorized Representative

David E. Potters

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2011 JUN 23 PM 2:59

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. -- ~~June 25, 2002~~, _____

1.4. Effective Date. -- ~~June 30, 2002~~, _____

§15-3-2. Definitions.

2.1. ~~American Council on Pharmaceutical Education~~ "Accreditation Council for Pharmacy Education" ("ACPE") means the national accreditation organization for continuing pharmaceutical pharmacy education.

~~2.2. Continuing Education 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 fifty (50) minutes of participation and represents 1.0 continuing education hour.~~

2.32. "Continuing Pharmaceutical-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.

2.43. "Continuing Pharmaceutical-Pharmacy Education Committee" ("CPE Committee") means that committee appointed by the Board responsible for approval of the content of each continuing pharmaceutical education CPE program offered by a provider of continuing pharmaceutical education CPE.

2.54. "Continuing Pharmaceutical-Pharmacy Education Coordinator" ("CPE Coordinator") means that individual or organization who may be retained by the Board for the purpose of coordinating continuing pharmaceutical education CPE programming and licensure renewal requirements.

2.5. "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.

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

2.67. “Continuing Pharmaceutical-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 pharmaceutical-pharmacy education programs to pharmacists.

2.7. — Continuing Pharmaceutical Education Sponsor (Sponsor) means an institution, organization, agency, corporation, company, or individual approved by the Board for the purpose of administering a continuing pharmaceutical education program.

2.8. The “Reporting Period” means the two 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.

2.9. “West Virginia Pharmacists Association” (Association) means a statewide professional organization whose members are pharmacists duly licensed by the Board.

2.10. “West Virginia Society of Health System Pharmacists” means a statewide professional organization representing the interests of 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 Pharmaceutical-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 Pharmaceutical-Pharmacy Education Requirements.

4.1. Beginning July 1, 2002, a licensed pharmacist shall complete a minimum of: thirty (30) continuing education CPE hours every two years in order to renew his or her license to practice pharmacy in West Virginia, and each reporting period thereafter. ~~Provided, that a pharmacist that only receives a license valid for one year, from July 1, 2002 to June 30, 2003, shall submit only fifteen (15) continuing education hours for his or her subsequent renewal and thirty (30) continuing education hours for each reporting period thereafter.~~

4.2. 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 of CPE for licensure.

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

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

5.1. Continuing pharmacy education hours of credit may be earned by licensed pharmacists in the following manner if the ~~sponsor or provider~~ grants the pharmacist a ~~certificate of completion of~~ statement of credit:

5.1.1. Live Programs

~~5.1.42. Cassette~~ Home study by print, webinar, computer-based training, video, or other non-live approved programs or audio-visual presentations;

~~5.1.2. In-company professional seminars;~~

~~5.1.3. Accredited school of pharmacy continuing education programs;~~

~~5.1.43. Credit earned from a United States accredited college/school or university for p~~Post-graduate courses in pharmaceutical sciences or other courses applicable to pharmacy practice;

~~5.1.5. Correspondence courses;~~

~~5.1.64. Programs granting e~~Continuing pharmacy education programs granted credit by other states;

~~5.1.75. Any P~~programs approved by the American Council of Pharmaceutical Education ACPE;

~~5.1.8. Continuing education television series;~~

~~5.1.9. Programs sponsored by professional health care organizations approved by the Board as providers or sponsors; and~~

~~5.1.10. Programs sponsored by or approved by the West Virginia Pharmacists Association.~~

§15-3-6. Program Administration.

6.1. The Board has the ~~statutory~~ 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 Board for its approval those providers ~~and sponsors~~ of continuing pharmacy education programs who have been certified as meeting the criteria established for this purpose; and

6.2.3. recommend to the Board 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, ~~the West Virginia University School of Pharmacy, and 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 ~~the content of each~~ program offered by a provider of ~~Continuing Education~~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 Board.

§15-3-8. Responsibilities of Providers and Sponsors.

8.1. ~~Continuing Pharmaceutical Education~~CPE providers and sponsors are responsible for submitting continuing education CPE programs to the Board for approval.

8.2. ~~Potential applicants~~Providers shall submit an application for approval of any CPE programs in writing to the Board at least ~~sixty~~thirty (~~60~~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 under certain circumstances but in no event may any program be submitted for approval less than ten (10) days prior to offering provided proper cause is shown for late submission.

8.3. ~~Providers and sponsors requesting approval of continuing pharmaceutical education~~The proposed CPE programs shall ~~submit an application containing any~~ contain all required information the Board required 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 or sponsors for submission of fraudulent information statements or certificates concerning continuing pharmaceutical education CPE.

8.5. ~~Providers or sponsors of continuing pharmaceutical education programs shall submit changes in approved programs in writing to the Board and the changes must be approved by the Board or the Board shall revoke or suspend approval of the program~~Changes to the content of an ongoing approved program shall require the provider to submit a new application for the program.

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

8.7. Providers and sponsors shall advise the Board in writing of the date, location, and continuing education 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 and sponsors shall provide a ~~certificate~~ statement of credit of participation/completion to each participant who attends and successfully completes a program. The statement of credit must include at a minimum, the course name, date completed, total CPE hours earned, provider name 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.

9.2. The Board may take disciplinary action against a pharmacist for submission of fraudulent statements or certificates concerning ~~continuing pharmaceutical education~~ CPE.

9.3. A Pharmacist shall submit, on forms provided by the Board, a list of accredited ~~continuing pharmaceutical education~~ 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 ~~continuing pharmaceutical education 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 ~~continuing education~~ CPE requirements.

9.5. A pharmacist may request a waiver from the Board for ~~continuing pharmaceutical education 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 ~~continuing education~~ CPE hours from another state to West Virginia if the other state accepts the transfer of West Virginia ~~continuing education~~ CPE hours.

9.8. A West Virginia licensed pharmacist who resides ~~in another state requiring continuing pharmaceutical education~~ CPE and who does not practice in West Virginia may renew his or her West Virginia license by certifying on his or her ~~Continuing Pharmaceutical Education~~ 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."

Signed:

Date:

Notarized:

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

§15-3-10. Approval of Providers and Sponsors.

10.1. The Board has established the policy that all ~~continuing pharmaceutical education~~CPE providers approved by the ~~American Council on Pharmaceutical Education (ACPE)~~ACPE are approved as providers of ~~Continuing Pharmaceutical Education (CPE)~~CPE in West Virginia ~~unless experience with a particular provider proves to be unsatisfactory.~~

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

10.2.1. ~~Shall~~ have a qualified director or coordinator of ~~continuing pharmaceutical education~~CPE program;

10.2.2. ~~Shall~~ have qualified faculty to develop and present ~~continuing pharmaceutical education~~CPE programs, or shall have contracted or retained qualified people to develop and present programs;

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

10.2.4. ~~Shall~~ 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. ~~Shall~~ demonstrate their ability and willingness to provide any and all information required by the Board or the Committee.

~~10.3. All sponsors who are not providers shall make application for approval as a sponsor on the form provided by the Board. Sponsors shall satisfy the provisions prescribed in subdivisions 10.2.1, 10.2.4, and 10.2.5 of this section.~~

~~10.4. Providers approved in accordance with section 10.2 must be reapproved as a provider every four (4) years from the date of approval. Providers and sponsors need to be approved one time only. The Board shall withdraw approval if a provider or sponsor 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 or sponsor 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 or sponsor 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. Approval of Continuing Pharmaceutical Pharmacy Programs.

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

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

11.3. Approval of a ~~continuing pharmaceutical education~~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. ~~Pharmaceutics: bioavailability, bioequivalency~~bioequivalence, product selection based on bioavailability and/or ~~bioequivalency~~bioequivalence;

11.4.1.2. Pharmacognosy: drugs of natural origin as related to therapeutics;

11.4.1.3. Pharmacology: as related to therapeutics, dosage regimen, etc.;

11.4.1.4. Pharmaceutical Chemistry: chemistry of drugs as related to therapeutics;

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

11.4.1.6. 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

11.4.1.7. 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 ~~suited~~applicable to pharmacy practice;

~~11.4.3. The program shall be Practical, i.e., may be applied to practice in one setting or another;~~

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

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

~~11.4.6. A certificate of participation and completion shall be awarded each participant by the provider.~~

§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 ~~continuing education~~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 upon request.

§15-3-13. Credits and Records.

13.1. Credits and records of ~~continuing pharmaceutical education~~CPE shall be based on a continuing educationCPE hour.

13.2. A pharmacist who develops and/or presents an approved ~~continuing pharmaceutical pharmacy education~~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, ~~sponsors,~~ 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.

13.4. Students ~~enrolled providing documentation of enrollment in~~ graduate programs of health related fields or ~~participating 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.