

**WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION**

Form #2

Do Not Mark In This Box

FILED

2001 JUN 28 A 11: 34

OFFICE 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 CITE AUTHORITY: WV Code 30-5-9a(b)- HB 3051

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 28, 2001 AT 4:00 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

WV Board of Pharmacy

232 Capitol Street

Charleston, WV 25301

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

William T. Douglas Jr.
Authorized Signature

William T. Douglas Jr.

558-0558

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

\$5.00



Board of Pharmacy

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

Office
232 Capital Street
Charleston, West Virginia 25301

June 27, 2001

Joe Manchin III, Secretary of State
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

Dear Mr. Manchin:

I am writing to approve the filing of two sets of proposed rules being amended by the Board of Pharmacy. The first proposed rule is 15 CSR 1, Rules and Regulations of the Board of Pharmacy; the other proposed rule is 15 CSR 3, Board of Pharmacy Rules for Continuing Education for Licensure of Pharmacists. Thank you for your cooperation in this matter.

Sincerely,

William T. Douglass, Jr.
Executive Director and
General Counsel

SUMMARY OF PROPOSED RULE

Title 15

Legislative Rules

Series 3

Board of Pharmacy Rules for Continuing Education for Licensure of Pharmacists

This rule is being amended to reflect the change to a biennial renewal of a license. The rule changes the reporting period to two years and requires 30 hours of continuing pharmaceutical education during that 2 year period, instead of 15 hours annually as is required currently.

Statement of Circumstances

Title 15

Legislative Rules

Series 3

**Board of Pharmacy Rules for Continuing Education for Licensure of
Pharmacists**

This rule amends the current Series 3, entitled “ Board of Pharmacy Rules for Continuing Education for Licensure of Pharmacists.” Series 1 is being amended to provide for biennial renewal of the licenses of pharmacists and registrations of technicians pursuant to HB 3051 passed during the 2001 Legislative Session. This rule is necessary to change the reporting period for continuing education to 2 years to match the licensure period.

□
APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Rules and Regulations of the Board of Pharmacy

Type of Rule: Legislative Interpretive Procedural

Agency: West Virginia Board of Pharmacy

Address: 232 Capitol Street

Charleston, WV 25301

1. Effect of Proposed rule:

| | ANNUAL FISCAL YEAR | | | | |
|----------------------------------|--------------------|----------|---------|------|------------|
| | INCREASE | DECREASE | CURRENT | NEXT | THEREAFTER |
| ESTIMATED TOTAL COST | n/a | n/a | n/a | n/a | n/a |
| PERSONAL SERVICES | n/a | n/a | n/a | n/a | n/a |
| CURRENT EXPENSE | n/a | n/a | n/a | n/a | n/a |
| REPAIRS & ALTERATIONS | n/a | n/a | n/a | n/a | n/a |
| EQUIPMENT | n/a | n/a | n/a | n/a | n/a |
| OTHER | n/a | n/a | n/a | n/a | n/a |

2. Explanation of Above Estimates:

The Rule changes the reporting period for continuing pharmaceutical education to a two year reporting period to match the change in 15 CSR 1 to a biennial renewal period for licensure.

3. Objectives of These Rules:

Change reporting period for continuing education by pharmacists to two years.

Rule Title: Board of Pharmacy Rules for Continuing Education for Licensure of Pharmacists

4. Explanation of Overall Economic Impact of Proposed Rule:

A. Economic Impact on State Government:
N/A

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens:
N/A

C. Economic Impact on Citizens/Public at Large.
N/A

Date: 07-05-2001

Signature of Agency Head or Authorized Representative:

William T. Douglas Jr.
William T. Douglas Jr. 558-0558

1 **ENROLLED**

2 COMMITTEE SUBSTITUTE

3 FOR

4 **H. B. 3051**

5 (By Delegates Border and Perdue)

6
7 [Passed April 14, 2001; in effect July 1, 2001.]
8
9

10 AN ACT to amend and reenact section nine-a, article five, chapter
11 thirty of the code of West Virginia, one thousand nine hundred
12 thirty-one, as amended, relating to authorizing the board of
13 pharmacy to amend its licensing procedure through legislative
14 rulemaking to include biennial licenses.

15 *Be it enacted by the Legislature of West Virginia:*

16 That section nine-a, article five, chapter thirty of the code
17 of West Virginia, one thousand nine hundred thirty-one, as amended,
18 be amended and reenacted to read as follows:

19 **§30-5-9a. Authorization for future fee modifications to be made by**
20 **rule and authorizing biennial licenses by rule.**

21 (a) Notwithstanding any other provision of this code to the
22 contrary, beginning on the first day of July, one thousand nine
23 hundred ninety-nine, the board may set any fee authorized under this
24 article by legislative rule, in accordance with article three,
25 chapter twenty-nine-a of this code.

1 (b) The board may, by legislative rule, in accordance with
2 article three, chapter twenty-nine-a of this code, amend its
3 licensing procedure to include biennial licensing with a staggered
4 implementation schedule and a fee structure.

TITLE 15
LEGISLATIVE RULES
BOARD OF PHARMACY

FILED

2001 JUN 28 A 11: 34

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

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§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. -- These legislative rules are issued under the authority of W. Va. Code §30-5-3A.

1.3. Filing Date. --

1.4. Effective Date. --

§15-3-2. Definitions.

2.1. American Council on Pharmaceutical Education (ACPE) means the national accreditation organization for continuing pharmaceutical education.

2.2. The year reporting period means the two year licensure period beginning on from July 1 of a given year through June 30 of the immediate following two years later.

2.3. Continuing Pharmaceutical 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.

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

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

2.6. Continuing Pharmaceutical Education Provider (Provider) means an institution, organization, agency, corporation, company, or individual approved by the West Virginia Board of Pharmacy for the purpose of direct provision of continuing pharmaceutical education programs to pharmacists.

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

2.8. Continuing Education ~~Unit (CEU)~~ Hour means ~~ten (10)~~ one hours of participation in a West Virginia Board of Pharmacy 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 ~~0.1~~ 1.0 continuing education hours unit (CEU).

~~2.9.~~ Unit means a measurement of value applied to particular continuing pharmacy education activity and is the estimate by the West Virginia Board of Pharmacy of the benefit it may contribute to competence in the practice of pharmacy.

~~2.910.~~ West Virginia Board of Pharmacy (Board) means that state agency, created under Chapter 30 of the Code of West Virginia, responsible for the licensure and discipline of pharmacists in the State of West Virginia.

~~2.1011.~~ West Virginia Pharmacists Association (Association) means a statewide professional organization whose members are pharmacists duly licensed by the West Virginia Board of Pharmacy.

§15-3-3. Purpose.

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

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

4.1. After June 30, 2002, all licensed pharmacists shall complete a minimum of: .5 CEU (five [5] thirty (30) hours) of CPE in order to renew his or her license to practice pharmacy in West Virginia by the year ending June 30, 1990; 1.0 CEU (ten [10] hours) of CPE in order to renew his or her license to practice pharmacy in West Virginia by the year ending June 30, 1991; and 1.5 CEU (fifteen [15] hours) of CPE in order to renew his or her license to practice pharmacy in West Virginia by the year ending June 30, 1992, and each subsequent year reporting period thereafter; Provided, that those pharmacists that only receive a license valid for one year, from July 1, 2002 to June 30, 2003, shall submit only fifteen (15) hours of CPE for their subsequent renewal and thirty (30) hours for each reporting period thereafter.

4.2. ~~CEU's or Hours~~ in excess of the number required at the end of each year reporting period shall not be transferred or applied to future years reporting periods to satisfy a future year or future years' requirements of CPE for licensure.

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

5.1. Continuing pharmaceutical 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;

- 5.1.1. Cassette or audio-visual presentations;
- 5.1.2. In-company professional seminars;
- 5.1.3. Accredited school of pharmacy continuing education programs;
- 5.1.4. Post-graduate courses in pharmaceutical sciences;
- 5.1.5. Correspondence courses;
- 5.1.6. Programs granting continuing education credit by other states;

5.1.7. Programs approved by the American Council of Pharmaceutical Education;

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 responsibility for the oversight of CPE as required for licensure renewal and to appoint a Continuing Education Committee.

6.2. The 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 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 education programs which have met the criteria established for that purpose.

§15-3-7. Continuing Education Committee.

7.1. The Continuing Education Committee shall be composed of equal representation from the West Virginia Board of Pharmacy, the West Virginia University School of Pharmacy, and the West Virginia Pharmacists Association.

7.2. The members of the Committee shall be selected by the Board and shall serve for a period of three (3) years.

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

7.4. The Committee is responsible for approval of the content of each program offered by a provider of Continuing Education Credit.

7.5. In all other matters concerning the approval of Continuing Education providers. The role of the Committee is to advise and submit its recommendations to the Board.

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

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

8.2. Programs shall be submitted in writing to the Board at least sixty (60) 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.

8.3. Providers and sponsors requesting approval of continuing pharmaceutical education programs shall submit an application containing such information as the Board may require on forms provided by the Board.

8.4. Submission of fraudulent statements or certificates concerning continuing pharmaceutical education by providers or sponsors will subject such providers or sponsors to revocation or suspension of their approval by the Board.

8.5. Changes in approved programs shall be submitted in writing to the Board and such changes must be approved by the Board or such program shall be null and void.

8.6. Providers and sponsors shall retain a file of participants of each accredited program for three (3) years.

8.7. Providers and sponsors shall advise the Board in writing of the date, location, and continuing education ~~unit~~ 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 of participation/completion to each participant who attends and successfully completes a program.

§15-3-9. Responsibilities of Pharmacists.

9.1. Pharmacists must keep valid records, receipts, and certifications of continuing pharmacy education programs completed for ~~three (3)~~ four (4) years and submit certifications of participation/completion to the Board upon request.

9.2. Submission of fraudulent statements or certificates concerning continuing pharmaceutical education will subject the pharmacist to disciplinary action by the Board as provided in W. Va. Code §30-5-1, et seq.

9.3. Pharmacists are responsible to submit on form provided by the Board a list of accredited continuing pharmaceutical education programs completed in the preceding year reporting period with their ~~annual~~ renewal license application.

9.4. In the event a pharmacist fails to submit a list of continuing pharmaceutical education programs ~~by the 31st day of July of each year with their 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 requirements.

9.5. A pharmacist may request a waiver from the Board for continuing pharmaceutical education for reasons of illness, injury, incapacity, retirement, or other extenuating circumstances.

~~9.6. A pharmacist first licensed by the Board within twelve (12) months immediately preceding the annual renewal date of their license is exempt, for the purpose of the first license renewal only, from the continuing pharmaceutical education requirements.~~

~~9.67.~~ All pharmacists shall keep the Board informed of their current mailing address.

~~9.78.~~ A pharmacist may transfer CEUs continuing education hours from another state to West Virginia if the ~~transfer other~~ state accepts the transfer of West Virginia CEUs continuing education hours.

~~9.89.~~ West Virginia licensed pharmacists who reside in states requiring continuing pharmaceutical education and who do not practice in West Virginia may renew their West Virginia license by certifying on their Continuing Pharmaceutical Education report form that they have a current and valid license to practice in the state in which they are residing. The following statement must be placed on the form, the form signed, notarized and returned to the West Virginia Board of Pharmacy with 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: _____

~~9.910.~~ A pharmacist may request continuing education credit only once in a year-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 providers approved by the American Council on Pharmaceutical Education (ACPE) shall be approved as providers of Continuing Pharmaceutical Education (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;

10.2.1. Must have a qualified director or coordinator of continuing pharmaceutical education program;

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

10.2.3. Must 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. Must 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;

10.2.5. Must 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 sections 10.2.1, 10.2.4, and 10.2.5.

10.4. Providers and sponsors need to be approved one time only. If a provider or sponsor is found to be in violation of section 8.4 of this rule, after having been approved, the provider or sponsor shall lose approval. The provider or sponsor may apply for re-approval if all applicable criteria are met. The application for re-approval must be made within thirty (30) days after the notice of disapproval and the provider or sponsor must comply with the original procedure as prescribed in Section 8.2 of this rule. The Board at its discretion may impose a period of probation if it approves the application for re-approval.

10.5. Sponsors of an ACPE approved provider program must submit the program to the Board for approval. Upon receipt of the program, the Board shall verify that the provider is approved by the ACPE. Upon verification, the Board shall approve the program.

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

11.1. All continuing pharmaceutical education programs shall be submitted for approval by the Board except as noted in Sections 11.2 and 11.3.

11.2. Programs developed and presented by ACPE approved providers and Board approved providers shall be approved by the Board.

11.3. Once a continuing pharmaceutical education program has been approved by the Board, it need not be approved within 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 subject;

11.4.1.1. Pharmaceutics: bioavailability, bioequivalency, product selection based on bioavailability and/or bioequivalency;

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 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. Relevancy, i.e., timely, suited to practice.

11.4.3. Practical, i.e., may be applied to practice in one setting or another.

11.4.4. Content is well organized with stated objectives, orderly flow of material, with appropriate examples and/or illustrations.

11.4.5. Appropriately presented, with the mode/method of presentation appropriate to the topic.

11.4.6. Certificate of participation/completion shall be awarded each participant by the provider.

§15-3-12. Program Evaluation.

12.1. An evaluation mechanism shall be provided for the purpose of allowing the participant to assess achievement of personal objectives.

12.2. The provider/sponsor shall develop and employ evaluation techniques that will assess the effectiveness of the continuing education activities and the level of fulfillment of the stated objectives, with the goal of continual provider/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 shall be based on a continuing education ~~unit (CEU)~~ hour.

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

13.3. All records shall be retained for ~~three (3)~~ four (4) years in a manner that will enable their ready retrieval upon request of the Board, its authorized agent or Committee. This applies to all providers, sponsors and pharmacists.

13.4. Students enrolled in graduate programs of health related fields or participating in a residency program in a health related field are not required to provide additional documentation of participation in CPE. Should a student discontinue his or her pursuit of graduate study, the prevailing CPE requirements will apply for his or her continued licensure.