

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

Form #2

Do Not Mark In This Box

FILED
2015 JUN 25 P 4: 23

OFFICE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

AGENCY: Department of Health and Human Resources/Bureau for Public Health TITLE NUMBER: 64

RULE TYPE: Legislative CITE AUTHORITY: W. Va. Code §§ 16-1-4 & 16-46-6

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

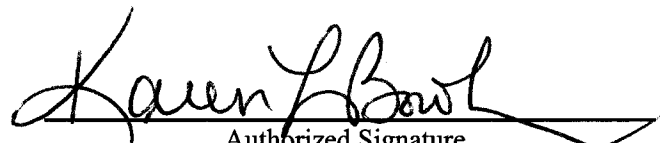
IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 104

TITLE OF RULE BEING PROPOSED: CERTIFICATION OF OPIOID OVERDOSE PREVENTION AND
~~TREATMENT TRAINING PROGRAMS~~

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, 2015 AT 5:00 PM ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Brian J. Skinner, Director, Public Health Regulations
~~West Virginia Department of Health and Human~~
Resources
Bureau for Public Health
~~350 Capitol Street Room 702~~
Charleston, WV 25301
(304) 356-4122 - O
~~brian.j.skinner@wv.gov~~

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


Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

**TITLE 64
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH**

**SERIES 104
CERTIFICATION OF OPIOID OVERDOSE PREVENTION AND
TREATMENT TRAINING PROGRAMS**

Brief Summary of Rule: This rule series establishes standards for certification and procedures for the approval of opioid overdose prevention and treatment training programs for initial responders.

Statement of Circumstances: Enacted during the 2015 Regular Legislative Session, the “Access to Opioid Antagonists Act” (S.B. 335) authorizes initial responders to possess and administer opioid antagonists in suspected opiate-related overdoses. An opioid antagonist are federal Food and Drug Administration-approved drug for the treatment of an opiate-related overdose, such as naloxone hydrochloride or other substance, that, when administered, negates or neutralizes, in whole or in part, the pharmacological effects of an opioid in the body. Initial responders must first successfully complete required training before administering an opioid antagonist, such as Naloxone.

This rule series applies to all persons and entities that intend to offer opioid overdose prevention and treatment programs for the purpose of training initial responders on the proper administration of an opioid antagonist in an emergency situation.

This rule series is intended to implement standards for certification and approval of opioid overdose prevention and treatment training programs authorized by the Access to Opioid Antagonists Act (*W. Va. Code* §§ 16-46-1 *et. seq.*).

Relevant Statutes or Regulations: *W. Va. Code* §§ 16-1-4 & 16-46-6

Drafting Note: This rule is new; therefore, underscoring and strike-through have been omitted.

Rule Title: _____

3. Explanation of above estimates (including long-range effect):

Please include any increase or decrease in fees in your estimated total revenues.

The costs incurred will be for travel (\$500 annually), staff time (the first year expenses included time to develop the training and then to deliver/provide the training. Ongoing staff time is calculated to provide monthly training sessions), training materials (\$60 per training device X 12 monthly trng sessions X 30 participants per trng session = \$21,600), etc. to carry out the training of first responders as indicated in SB 335. No fees/revenue are realized with this proposed rule. Training is provided at no cost.

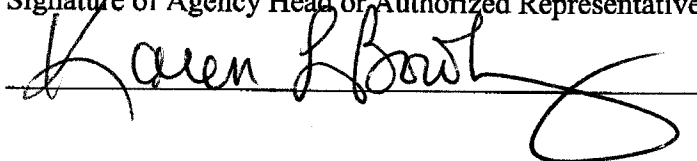
MEMORANDUM

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.

Not applicable.

Date: May 21, 2015

Signature of Agency Head or Authorized Representative



APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: CERTIFICATION OF OPIOID OVERDOSE PREVENTION AND TREATMENT TRAINING PROGRAMS +

Type of Rule: Legislative Interpretive Procedural

Agency: DHHR/BPH/Office of Emergency Medical Services

Address: 350 Capitol St. Room 425
Charleston, WV 25301

Phone Number: 304-558-3956 Email: melissa.j.kinnaird@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.

This proposed rule provides the mechanism for the certification of opioid overdose prevention and treatment training programs required of the OEMS in S.B. 335. The costs incurred will be for travel (\$500 annually), staff time, training materials (\$60 per training device X 12 monthly trng sessions X 30 participants per trng session = \$21,600), etc. to carry out the training of first responders. No fees/revenue are realized with this proposed rule. Training is provided at no cost.

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	10,059.00	25,924.00	25,924.00
Personal Services	9,559.00	3,824.00	3,824.00
Current Expenses	500.00	22,100.00	22,100.00
Repairs & Alterations			
Assets			
Other			
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: CERTIFICATION OF OPIOID OVERDOSE PREVENTION AND TREATMENT TRAINING PROGRAMS +

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: _____

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency Name, Address & Phone No.) West Virginia Department of Health and Human Resources
Bureau for Public Health
Office of the Commissioner & WV State Health Officer

350 Capitol Street Room 702
Charleston, WV 25301

(304)558-2971

LEGISLATIVE RULE TITLE: CERTIFICATION OF OPIOID OVERDOSE PREVENTION AND
TREATMENT TRAINING PROGRAMS

1. Authorizing statute(s) citation W. Va. Code §§ 16-1-4 & 16-46-6

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

b. What other notice, including advertising, did you give of the hearing?

c. Date of Public Hearing(s) *or* Public Comment Period ended:

d. Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.

Attached _____ No comments received _____

e. Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)

f. **Name, title, address and phone/fax/e-mail numbers** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

Brian J. Skinner, General Counsel and Director, Public Health Regulations
West Virginia Department of Health and Human Resources
Bureau for Public Health
350 Capitol Street Room 702
Charleston, WV 25301
(304) 356-4122 - O
brian.j.skinner@wv.gov

g. **IF DIFFERENT FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

b. Date of hearing or comment period:

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

d. Attach findings and determinations and reasons:

Attached

TITLE 64
LEGISLATIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

FILED
2015 JUN 25 P 4:23

SERIES 104
CERTIFICATION OF OPIOID OVERDOSE PREVENTION AND
TREATMENT TRAINING PROGRAMS

OFFICE WEST VIRGINIA
SECRETARY OF STATE

§64-104-1. General.

1.1. *Scope.* – This rule series establishes standards for certification and procedures for the approval of opioid overdose prevention and treatment training programs for initial responders.

1.2. *Authority.* – *W. Va. Code §§ 16-1-4 & 16-46-6*

1.3. *Filing Date.* – *June 25, 2015*

1.4. *Effective Date.* –

1.5. *Applicability.* – This rule series applies to all persons and entities that intend to offer opioid overdose prevention and treatment programs for the purpose of training initial responders on the proper administration of an opioid antagonist in an emergency situation.

1.6. *Purpose* – This rule series is intended to implement standards for certification and approval of opioid overdose prevention and treatment training programs authorized by the Access to Opioid Antagonists Act (*W. Va. Code §§ 16-46-1 et. seq.*).

1.7. *Background* - Enacted during the 2015 Regular Legislative Session, the “Access to Opioid Antagonists Act” (S.B. 335) authorizes initial responders to possess and administer opioid antagonists in suspected opiate-related overdoses. An opioid antagonist are federal Food and Drug Administration-approved drug for the treatment of an opiate-related overdose, such as naloxone hydrochloride or other substance, that, when administered, negates or neutralizes, in whole or in part, the pharmacological effects of an opioid in the body. Initial responders must first successfully complete required training before administering an opioid antagonist, such as Naloxone.

§64-104-2. Definitions.

2.1. “Curriculum” means a detailed course outline, description, or syllabus submitted to the OEMS as part of the approval process by an association, educational institution, health care facility, or emergency medical services agency sponsoring a training program.

2.2. “Initial responder” means emergency medical service personnel, as defined by W.Va. Code § 16-4c-3(g), including, but not limited to, a member of the West Virginia State Police, a sheriff, a deputy sheriff, a municipal police officer, a volunteer or paid firefighter and any other person acting under color of law who responds to emergencies.

2.3. "Office of Emergency Medical Services" or "OEMS" means the office under the Commissioner of the Bureau for Public Health pursuant to *W. Va. Code* §16-4C-4, mandated by the provisions of the "Access to Opioid Antagonists Act" to administer standards for certification and approval of opioid overdose prevention and treatment training programs authorized by the Act.

2.4. "Opiates" or "opioid drugs" means drugs that are members of the natural and synthetic opium family, including, but not limited to, heroin, morphine, codeine, methadone, oxycodone, hydrocodone, fentanyl and hydromorphone.

2.5. "Opioid antagonist" means a federal Food and Drug Administration-approved drug for the treatment of an opiate-related overdose, such as naloxone hydrochloride or other substance, that, when administered, negates or neutralizes, in whole or in part, the pharmacological effects of an opioid in the body.

2.6. "Opioid overdose prevention and treatment training program" or "training program" means any program operated or approved by the Office of Emergency Medical Services.

2.7. "Overdose" means an acute condition, including, but not limited to, life-threatening physical illness, coma, mania, hysteria or death, which is the result of the consumption or use of opioid drugs.

§64-104-3. Opioid overdose prevention and treatment training programs.

3.1. Training programs must contribute directly to the professional competence, skills, and education of initial responders and must educate participants on the following;

3.1.a. The four risk factors for overdose;

3.1.b. Recognizing three signs of an overdose;

3.1.c. Ability to perform techniques to stimulate someone who appears to have overdosed;

3.1.d. Ability to correctly perform rescue breathing; and

3.1.e.. Ability to correctly administer naloxone.

3.2. Instructors must possess the necessary practical and academic skills to conduct the courses effectively and meet all standards specified by OEMS, including:

3.2.a. Have working knowledge of opioid drugs, risk factors for overdose, signs of an overdose, use of naxolone with respect to training and naloxone prescription and furnishing;

3.2.b. Be able to communicate with potential responders in an open, non-judgmental manner using non-technical language;

3.2.c. Be familiar with and sensitive to the health and social experiences of substance users; and

3.2.d. Have mastery of the information and skills addressed in these guidelines, including naloxone administration and rescue breathing.

3.3. Training program materials shall be written and distributed to attendees at or before the time offered, whenever practical;

3.4. Training programs shall be presented in a suitable setting, including on-line or other distributive education methods, appropriate to the educational purpose of the specific course;

3.5. Individuals completing a training program must demonstrate at least the minimum acceptable proficiency in tasks or duties set forth in subsection 3.1. This minimum acceptable proficiency must be determined by the instructor for the course.

3.6. The training program instructor must document an individual's successful completion of the training program in a certificate or letter, the original of which must be given to the individual, containing the following information:

3.6.a. The individual's name;

3.6.b. The individual's date of birth;

3.6.c. The name of the individual's employer;

3.6.d. The date of successful completion of the course;

3.6.e. The course sponsor; and

3.6.f. The course instructor.

3.7. The information required by subsection 3.6. must also be submitted to the OEMS in form or letter signed by the administrator.

§64-104-4. Approval of Training Programs.

4.1. *Applications for Training Programs.* Any association, educational institution, health care facility or emergency medical services agency may apply to the OEMS for approval to conduct a training program for initial responders.

4.2. Applications for approval of a training program must be made on a form provided by the OEMS, together with the curriculum for the course as defined in section 3. The application must include the following information:

4.2.a. The title of the course;

4.2.b. The sponsor's name;

4.2.c. The name(s) of the course instructor and the instructor is certified to provide training or has received instruction on the course curriculum;

4.2.d. The names and authors of all textbooks to be used, if any, including the publisher and edition, or if no textbook is to be used, a list of written materials to be used, including the source of such materials;

4.2.e. The specific objectives for the course;

4.2.f. Time to be spent on each of the components required by subsection 3.1;

4.2.g. The method(s) of instruction for each component listed in subsection 3.1 (for example, lecture, demonstration, simulation, slide presentation, etc.);

4.2.h. A description of the practical training to be provided for each component listed in subdivision 3.1.c., 3.1.d. and 3.1.e. ;

4.2.i. The reading assignment in the text or in other materials, if any, for each unit;

4.2.j. The evaluation method for each unit (for example, written examination, student presentation or demonstration, competency check-off, etc.);

4.2.k. An explanation of when students will be evaluated (for example, after each unit, comprehensively at the end of the course); and

4.2.l. An explanation of the grading system to be used for written examinations and proficiency evaluations; and

4.3. The application and curriculum must be submitted at least 30 days prior to the date on which the course is to be given.

4.4. The application must be submitted by the administrator or operating officer for the entity conducting the course.

4.5. Only applications which are complete will be considered. In order to be considered complete, an application must include:

4.5.a. All of the information requested on the application;

4.5.b. A complete curriculum as defined in section 3; and

4.5.c.. The signature of the administrator or operating officer of the entity making application.

4.5 An applicant may submit such additional documents or information as the applicant may consider relevant to the application and compliance with the provisions of this rule series.

4.6. In the event that an application is determined to be incomplete, the OEMS will notify the applicant of the information necessary to complete the application and retain the application submitted pending receipt of the additional information.

4.7. *Continuing Approval:* Once an application for approval for a training program has been approved by the OEMS, re-approval is not required for each occasion on which the course is administered so long as the training program is not changed, or so long as the training programming requirements are not changed by law. If the training program, or any portion of a training program, is changed, reapplication must be made in accordance with subsection 4.2. In cases where only a portion of a course is changed, the applicant may submit documentation and information only as to the changes made, but must clearly indicate those portions that are unchanged by so stating on the application.

4.8. *Applications to Conduct Approved Courses Developed by Others:* Associations, educational institutions, health care facilities, emergency medical services agencies, may, with the consent of the developer(s), conduct training programs developed by others who have received approval from the OEMS. Such facilities must apply for approval in accordance with subsection 4.2, but need not submit curriculum materials required by section 3, except to the extent that the training program, will be varied in any manner from the approved training program. Applicants must indicate on the application the title of the approved training program to be used, name of the entity whose approved course will be used, and the date on which such course was approved.

4.9. Any changes in approved training program must be submitted to the OEMS for prior approval.

4.10. All training programs are subject to on-site periodic review by the OEMS. Sponsors of approved training programs must provide written notice to the OEMS of the date(s) and location that a basic course will be held at least five working days before each occasion on which an approved course is scheduled to begin.

4.11. The approved training program sponsor must maintain attendance records for such courses for a minimum of two years from the date of completion of each course.

4.12. Attendance records are subject to review by the OEMS upon request.

§64-104-5. Denial, Suspension, or Revocation of Approval.

The OEMS may deny, suspend, or revoke approval of a training program for failure to meet the requirements of *W.Va. Code* §§ 16-46-1 et. seq., as applicable, or the provisions of this rule series. If the OEMS determines to deny, suspend, or revoke approval of a training program, the OEMS will send the applicant a notice identifying the reasons for the determination. The

notice will be sent by either registered or certified mail. The denial, suspension, or revocation will become final 30 days after the mailing of the notice unless the applicant, within that 30-day period, gives written notice of a request for a hearing. Hearings will be conducted in accordance with the Administrative Procedure Act (*W. Va. Code* §§ 29A-5-1 *et. seq.*), and the Bureau for Public Health rule series, Rules of Procedure for Contested Case Hearings and Declaratory Rulings (64 CSR 1).