

**WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION**

Form #4

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OFFICE OF THE WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Division of Health, Department of Health & Human Resources TITLE NUMBER: 64

CITE AUTHORITY W. Va. Code §§16-1-7 and 16-50-11

AMENDMENT TO AN EXISTING RULE: YES NO

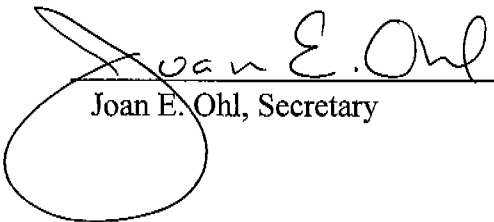
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 60

TITLE OF RULE BEING PROPOSED: Medication Administration by Unlicensed Personnel

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.


Joan E. Ohl, Secretary

\$5.40

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Medication Administration by Unlicensed Personnel, 64CSR60

Type of Rule: **Legislative** **Interpretive** **Procedural**

Agency: Bureau for Public Health (For the Division of Health)
Department of Health and Human Resources

Address: Building 3, Capitol Complex
Charleston, W. Va. 25305

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$ 101,362	\$ 149,834	\$ 157,534
Personal Services			82,446	80,752	84,352
Current Expense			17,920	63,790	68,182
Repairs & Alterations				0	0
Equipment				5,292	5,000
Other			996	0	0
Revenue					

2. Explanation of above estimates.

The above next year expenditures have been appropriated by the legislature from General Revenue Funds for the Medication Administration's budget for State fiscal year ending June 30, 1999. The Office of Health Facility Licensure and Certification will receive no additional funding to cover the cost of this program as a result of the implementation of these rules. These expenditures are based on costs projected and attached as a fiscal note to the Bill that was passed into law as § 16-50-1 et seq. during the 1997 legislative session. The original estimated expenditures are further herein refined and based on the current fiscal year's actual start-up expenditures during this first year of the project.

3. Objectives of this rule:

To fulfill the Department's requirements to promulgate rules as contained in § 16-50-1 et seq. Medication Administration by Unlicensed Personnel. This rule allows the dissemination of medications by unlicensed personnel trained and supervised in accordance with the proposed regulations.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

These rules will lower the cost of providing services to intermediate care facilities for persons with mental retardation. As a result the Bureau of Medical Services may reduce its Medicaid expenditures for payment to the providers of these services.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific Groups of Citizens.

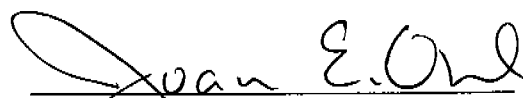
The implementation of this rule will lower the costs of providing services to intermediate care facilities for persons with mental retardation by providers within that health care industry. Some of these costs savings may be passed on to the consumers of these services.

C. Economic Impact on Citizens/Public at Large.

Payment sources for the consumers of these services may experience reductions in charges to the extent providers pass the savings back to the purchaser.

Date: 12 / 98

Signature of Agency Head or Authorized Representative


Joan E. Ohl, Secretary
Department of Health and Human Resources

**TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 60
MEDICATION ADMINISTRATION BY UNLICENSED PERSONNEL**

**MODIFIED PROPOSED RULE
AFTER REVIEW BY THE
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

64CSR60

**TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES**

**SERIES 60
MEDICATION ADMINISTRATION BY UNLICENSED PERSONNEL**

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TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

FILED
JUN 20 3 12 PM '99
OFFICE OF THE SECRETARY OF STATE

SERIES 60
MEDICATION ADMINISTRATION BY UNLICENSED PERSONNEL

§64-60-1. General.

1.1. Scope. --This legislative rule prescribes specific standards and procedures to provide for training, competency testing, and approval of unlicensed personnel for limited administration of medications in specified health care facilities. This rule must be read in conjunction with W. Va. Code §16-5O-1 et seq.

1.2. Authority. -- W. Va. Code §§16-5O-11 and 16-1-7.

1.3. Filing date. --

1.4. Effective date. --

1.5. Applicability. -- This rule applies to any person, and every form of organization, whether incorporated or unincorporated, including any partnership, corporation, trust association or political subdivision of this State establishing maintaining or operating a facility as defined in this rule and W. Va. Code §16-5O-2(d).

1.6. Enforcement. -- This rule is enforced by the secretary of the West Virginia department of health and human resources or his or her lawful designee.

§64-60-2. Definitions.

2.1. Administration of medications. --

2.1.a. Assisting a person in the ingestion, application or inhalation of medications, including both prescription drugs and non-prescription drugs, or using universal precautions for rectal or vaginal insertion of medication, according to the legibly written or printed directions of the attending physician or authorized practitioner, or as written on the prescription label; and

2.1.b. Making a written record of such assistance with regard to each

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medication administered, including the time, route and amount taken: *Provided*, That “administration” does not include judgement, evaluation, assessments, injections of medication, monitoring of medication or self-administration of medications, including prescription drugs and self-injection of medication by the resident.

2.2. Adult family care home. -- A residence where room, board and supervision are provided, with the approval of the department’s office of social services, for one (1) to three (3) adults who are ambulatory and not in need of nursing care.

2.3. Approved medication assistive personnel. -- The unlicensed facility staff member, who meets eligibility requirements, has successfully completed the required training and competency testing, and is considered competent by the registered nurse to administer medications to residents of the facility in accordance with article five-o, chapter sixteen of the West Virginia Code.

2.4. Authorizing agency. -- The department’s office of health facility licensure and certification.

2.5. Behavioral health group home. -- A community-based type of housing that is established for adults/children with similar needs, levels of independence and ability which provides services and supervision for people with developmental disabilities, behavioral disorders or substance addictions; is licensed by the department; and is in compliance with the state fire commission for residential facilities.

2.6. Department. -- The department of health and human resources.

2.7. Facility. -- An intermediate care facility for the mentally retarded (ICF/MR), a personal care home, residential board and care home, behavioral health group home, private residence in which health care services are provided under the supervision of a registered nurse or an adult family care home that is licensed by or approved by the department.

2.8. Facility staff member. -- An individual employed by a facility but does not include a health care professional acting within the scope of a professional license or certificate.

2.9. Health care professional. -- A medical doctor or doctor of osteopathy, a podiatrist, registered nurse, practical nurse, registered nurse practitioner, physician’s assistant, dentist, optometrist, pharmacist, physical therapist or respiratory care professional licensed under chapter thirty of the West Virginia code.

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2.10. ICF/MR. -- An intermediate care facility for people with mental retardation which is certified by the health care financing administration of the United States department of health and human services to provide health or rehabilitation services to persons with mental retardation or persons with related conditions who are receiving active treatment.

2.11. Medication. -- A drug, as defined in section one hundred one, article one, chapter sixty-a of the West Virginia Code, which has been prescribed by a duly authorized health care professional to be ingested through the mouth, applied to the outer skin, eye or ear, or applied through nose drops, vaginal or rectal suppositories.

2.12. Medication error. -- Any deviation from the "six rights of medication administration," (as defined in section 2.19) that occurs during medication administration: *Provided*, That resident refusal is not considered a medication error.

2.13. Personal care home. -- Any institution, residence or place, or any part or unit thereof, however named, in this State which is advertised, offered, maintained or operated by the ownership or management, whether for consideration or not, for the express or implied purpose of providing accommodations and personal assistance and supervision, for a period of more than twenty-four (24) hours, to four (4) or more persons who are dependent upon the services of others by reason of physical or mental impairment who may require limited and intermittent nursing care, including those individuals who qualify for and are receiving services coordinated by a licensed hospice: *Provided*, That services utilizing equipment which requires auxiliary electrical power in the event of a power failure shall not be used unless the personal care home has a backup power generator.

2.14. Private residence in which health care services are provided under the supervision of a registered nurse. —

2.14.a. An unlicensed home in which one or more residents receive home health agency services; and

2.14.b. An unlicensed home that has twenty-four (24) hour staffing based on the nursing care needs of one or more residents in which the registered professional nurse makes the decision as part of the treatment plan to delegate medication administration to staff members.

2.15. Registered professional nurse. -- A person who holds a valid license pursuant to article seven, chapter thirty of the West Virginia Code.

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2.16. Resident. -- A resident of a facility.

2.17. Residential board and care home. -- Any residence or any part or unit thereof, however named, in this State which is advertised, offered, maintained, or operated by the owners or management, whether for consideration or not, for the express or implied purpose of providing accommodations, personal assistance and supervision, for a period of more than twenty-four (24) hours, to four (4) or more persons who are not related to the owner or manager by blood or marriage within the degree of consanguinity of second cousin and are dependent upon the services of others by reason of physical or mental impairment or who may require limited and intermittent nursing care, including those individuals who qualify for and are receiving services coordinated by a licensed hospice: *Provided*, That services utilizing equipment which requires auxiliary electrical power in the event of a power failure shall not be used unless the residential board and care home has a backup power generator.

2.18. Secretary. -- The secretary of the department of health and human resources or his or her designee.

2.19. Self-administration of medication. -- The act of a resident, who is independently capable of reading and understanding the labels of drugs ordered by a physician, in opening and accessing prepackaged drug containers, accurately identifying and taking the correct dosage of the drugs as ordered by the physician, at the correct time and under the correct circumstances.

2.20. Single specific agency. -- A person or entity operating two or more facilities.

2.21. Six rights of medication administration. -- The criteria used to assure that each resident receives the specific medication, prescribed for the person, in the ordered amount, at the scheduled time, by the designated route - both as prescribed and prepared, which is accurately recorded in the resident's record: (1. The right resident; 2. The right drug; 3. The right dosage; 4. The right time; 5. The right route; and 6. The right record / documentation.)

2.22. Supervision of self-administration of medications. — A personal service which includes reminding residents to take medications, opening medication containers for residents, reading the medication label to residents, observing residents while they take medication, checking the self administered dosage against the label on the container and reassuring residents that they have obtained and are taking the dosage as prescribed.

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§64-60-3. Facility Administrative Procedures.

3.1. Any facility may offer the training and competency evaluation program developed by the department to its facility staff members. The training and competency program shall be provided by the facility through a registered professional nurse.

3.1.a. Prior to initiating a training program, the facility shall submit, to the authorizing agency, written notification of the intent to participate in this program, documentation of the credentials of the registered professional nurse who will provide the training, and the facility policies and procedures required by this rule.

3.1.b. Participation in the program shall only be permitted after review and approval of the nurse's credentials and the facility policies and procedures by the authorizing agency, and after the registered professional nurse has completed the facility trainer / instructor orientation course developed by the authorizing agency.

3.1.c. Approved medication assistive personnel who have successfully trained and tested in one facility type shall, prior to being approved to administer medications in another type of facility, be re-evaluated for competency by the registered professional nurse. This re-evaluation of competency shall be determined by using the tasks in the curriculum adopted in policy by the authorizing agency.

3.2. During such time as the authorizing agency contracts for an entity to provide the facility trainer / instructor orientation training for registered professional nurses and to provide the testing of each facility staff member's competency, facilities utilizing the training and testing shall pay the contract entity its fees for the training and testing.

§64-60-4. Administration of Medications in Facilities.

4.1. Administration of medication pursuant to this rule shall be performed by: registered professional nurses; other licensed health care professionals subject to the provisions of their respective licensing laws; or approved medication assistive personnel.

4.2. Subsequent to assessing the health status of an individual resident, a registered professional nurse, in collaboration with the resident's attending physician and the facility staff member, may recommend that the facility authorize the facility staff member to administer medications to the resident.

4.3. Authorization to administer medications may only be granted and continued if the facility staff member:

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4.3.a. Has successfully completed the approved medication administration training program and received a satisfactory competency evaluation as required by the provisions of this rule;

4.3.b. Is considered by the registered professional nurse to be competent, including satisfactory completion of the training program and competency evaluation and possession of the ability to perform the required tasks to administer medications;

4.3.c. Consults with the registered professional nurse or the attending physician on a regular basis;

4.3.d. Is monitored or supervised by the registered professional nurse (as defined in section 7.1.c.5); and

4.3.e. Participates in the required retraining program at least every two (2) years.

4.4. Any facility which authorizes unlicensed staff members to administer medications pursuant to the provisions of this rule shall make available to the authorizing agency a list of the approved medication assistive personnel.

4.5. The authorized registered professional nurse shall initiate and keep current, a file for all approved medication assistive personnel which contains proof of compliance with eligibility requirements required in subdivisions 6.1.a. -f. This file shall be maintained in the facility and available to representatives of the authorizing agency on request.

4.6. Exclusions from this rule for administration of medications in facilities.

4.6.a. Nothing in this rule may be construed to prohibit any facility staff member from administering medications or providing any other prudent emergency assistance to aid any person who is in acute physical distress or requires emergency assistance.

4.6.b. Supervision of self-administration of medication by facility staff members who are not licensed health care professionals may be permitted in certain circumstances, when the substantial purpose of the setting is other than the provision of health care.

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§64-60-5. Instruction and Training.

5.1. Curriculum.

5.1.a. The curriculum adopted in policy by the authorizing agency utilized to train facility staff shall be the West Virginia Department of Health and Human Resources Curriculum for Unlicensed Medication Assistive Personnel. The curriculum may be obtained from the authorizing agency.

5.2. Competency evaluation.

5.2.a. Competency evaluation includes the facility staff member's:

5.2.a.1. Satisfactory completion and demonstration of all tasks in the curriculum; and

5.2.b.2. Satisfactory completion of a competency test approved by the authorizing agency.

5.2.b. The administration of the competency test to the facility staff member shall be by the authorized registered professional nurse. The registered professional nurse shall handle competency tests in accordance with the instructions of the authorizing agency.

5.2.c. The facility staff member shall be allowed three opportunities to satisfactorily complete a competency test, utilizing a different test for each opportunity. A fourth and final competency test may only be given if the staff member repeats the training program. The decision to repeat the training course will be at the discretion of the authorized registered professional nurse.

5.3. Retraining program.

5.3.a. Retraining of the approved medication administration personnel shall be conducted every two years by the authorized registered professional nurse.

5.3.b. The content of this training shall be an overview of the original curriculum, and shall include observation, by the authorized registered professional nurse, of medication administration by the approved medication assistive personnel.

5.4. Authorization requirements of the registered professional nurse

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5.4.a. The registered professional nurse authorized to train facility staff to administer medications shall:

5.4.a.1. Possess a current active West Virginia license in good standing to practice as a registered professional nurse;

5.4.a.2. Have practiced as a registered professional nurse in a position or capacity requiring knowledge of medications for the immediate two years prior to being authorized to train facility staff;

5.4.a.3. Be familiar with the nursing care needs of the residents of the facility;

5.4.a.4. Have completed the facility trainer / instructor orientation course developed by the authorizing agency;

5.4.a.5. Have knowledge of all facility policies and procedures pertaining to medication administration; and

5.4.a.6. Have knowledge of this rule.

§64-60-6. Eligibility Requirements of Facility Staff in order to be Trained.

6.1. A facility may permit a facility staff member to be trained to administer medications in a single specific agency only after compliance with all of the following:

6.1.a. The facility determines there is no statement on the state administered nurse aide registry indicating that the staff member has been the subject of a finding of abuse or neglect of a long-term care facility resident or convicted of the misappropriation of such a resident's property;

6.1.b. The facility staff member has had a criminal background check or if applicable, a check of the state police abuse registry, establishing that the individual has not been convicted of any crimes against persons or drug related crimes;

6.1.c. The facility staff member holds a high school diploma or a general education diploma; and

6.1.d. The facility staff member is certified in cardiopulmonary resuscitation and first aid.

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§64-60-7. Facility Oversight of Medication Administration by Unlicensed Personnel.

7.1. Administrative policy requirements.

7.1.a. The facility or single specific agency must submit policies and procedures pertaining to medication administration to the authorizing agency for approval, prior to receiving authorization to train facility staff members.

7.1.b. An authorized registered professional nurse shall participate in development and revision of these policies and procedures.

7.1.c. The policies and procedures shall include at least the following:

7.1.c.1. Eligibility requirements for the registered professional nurse and facility staff members participating in medication administration;

7.1.c.2. Limitations on the functions of the approved medication assistive personnel;

7.1.c.3. Requirements for documentation in personnel records;

7.1.c.4. Requirements for documentation in resident medical records, including;

7.1.c.4.A. Each facility shall maintain a medication administration record for each resident, to be maintained as a part of the permanent medical record. This record shall be available for review by the registered professional nurse, representatives of the authorizing agency, and other authorized persons. This record shall include: the name of the resident to receive the medication; the name of the medication, the dosage to be administered and the route of administration; the time or intervals at which the medication is to be administered; the date the medication is to begin and cease; the printed name, initials and signature of the individual who administered the medication; and any special instructions for handling or administering the medication, including instructions for maintaining aseptic conditions and appropriate storage.

7.1.c.4.B. Written, signed and dated physician orders shall be present in the medical record of each resident, for each medication to be administered, including over-the-counter medications. Verbal orders may only be taken by the registered professional nurse and must be countersigned by the physician.

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7.1.c.4.C. Written, signed and dated verification of physician collaboration in the decision to allow medication administration by unlicensed personnel shall be present in the medical record of each resident.

7.1.c.5. Requirements for monitoring and supervising of the approved medication assistive personnel by the registered professional nurse employed or contracted by the facility including: registered professional nurse coverage to respond to questions related to any aspect of medication administration by unlicensed personnel; the number of approved medication assistive personnel, residents, and sites the registered professional nurse will supervise; the number of residents and sites for which the approved medication assistive personnel will administer medications; the furthest distance the registered professional nurse will be expected to travel to a site and between sites; periodic and ongoing observation and supervision, not less than quarterly, of the medication administration process including selected administration of medications; the training and approval process for an approved medication assistive personnel to administer medications at different sites within a specific agency; ongoing review of physician's orders, medication administration records and medication labels by the registered professional nurse for consistency and documentation of such, ongoing review of medication error reports and medication related incident reports by the registered professional nurse and the attending physician; and withdrawal of approval for a facility staff member to administer medication;

7.1.c.6. Requirements for communication between the approved medication assistive personnel and the supervising registered professional nurse, including: any change in a resident's condition; any discrepancy between the pharmacy label and the medication administration record; any deviation from the six rights of medication administration; any doubt or question about the medication administration process; resident refusal of medication; any question about a medication ordered to be given "as needed"; any question about a medication looking different or unusual; receipt of any change in physician's orders, and the need for disposal of medications;

7.1.c.7. The medication delivery system to be utilized by the facility including: the type of medication packaging required; medication storage; how the six rights of medication administration are assured; disposal of medications; and special procedures for controlled substances;

7.1.c.8. Infection control, including: universal precautions, use of personal protective equipment, and medical aseptic practices;

7.1.c.9. The process for resident identification.

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7.1.d. Each facility shall have available resource information on all drugs being administered in the facility, including the risks and possible side effects.

7.1.e. The authorizing agency may require alterations to facility policy if the determination is made that medication is not being administered in accordance with the six rights of medication administration or if potentially unsafe conditions exist.

7.1.f. Failure by the facility to provide oversight of medication administration as required by this rule or by facility policies may result in denial of participation in this program.

§64-60-8. Withdrawal of Authorization.

8.1. The registered professional nurse, who monitors or supervises the approved medication assistive personnel, may withdraw the approval to administer medications if the nurse determines that the approved medication assistive personnel is not performing medication administration in accordance with the training and written instructions.

8.2. The withdrawal of approval shall be documented and shall be relayed to the facility and the authorizing agency.

§64-60-9. Limitations on Medication Administration by Unlicensed Personnel.

9.1. The medication to be administered shall be received and maintained in the original container in which it was dispensed by a pharmacist or the prescribing health care professional until such time as it is administered to the resident.

9.2. No injections nor any parenteral medications shall be administered.

9.3. No irrigations nor debriding agents used in the treatment of a skin condition or minor abrasions shall be administered.

9.4. No verbal medication orders shall be accepted, no new medication orders shall be transcribed and no drug dosages shall be converted and calculated.

9.5. Medications ordered by the physician or a health care professional with legal prescriptive authority to be given "as needed" (PRN) shall be administered only if the order is written with specific parameters which preclude independent judgement.

§64-60-10. Administrative Due Process.

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10.1. Those persons adversely affected by the enforcement of this rule desiring a contested case hearing to determine any rights, duties, interests or privileges shall do so in a manner prescribed in the division of health rule 64CSR1 "Rules of Procedure for Contested Case Hearings and Declaratory Rulings."

ANALYSIS OF PROPOSED LEGISLATIVE RULES

Staff Counsel: Rita A. Pauley
Date: November 23, 1998
Agency: Division of Health
Subject: Medication Administration by Unlicensed Personnel,
64CSR60

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PERTINENT DATES

Filed for public comment: May 26, 1998
Public comment period ended: June 30, 1998
Filed following public comment period: August 3, 1998
Filed LRMRC: August 3, 1998
Filed as emergency: May 26, 1998; approved by Secretary of State
July 6, 1998

Fiscal Impact: The agency estimates the cost of implementing this rule will be \$101,362 for FY98, \$149,834 for FY99 and \$157,534 thereafter. Expenditures through the fiscal year ending June 30, 1999 have been appropriated by the Legislature.

ABSTRACT

The proposed rule prescribes the specific standards and procedures to provide for training, competency testing and approval of unlicensed personnel for the limited administration of medications in specified health care facilities. Persons who are trained to administer medication in accordance with the provisions of this rule must be monitored or supervised by a registered professional nurse. The nurse must first be trained to teach staff members to properly administer medication. He or she may then instruct staff on the administration of medication through the training and competency evaluation program developed by the agency.

It is anticipated that the implementation of the rule will lower providers costs for services to mentally retarded people living in intermediate care facilities which in turn may result in cost savings to the residents and the State.

The proposed rule is new, however, it is in effect as an emergency rule. The following is a section by section synopsis of the proposed rule.

Section 1 is the standard general section, setting forth the scope, authority, filing date and effective date of the proposed rule.

Section 2 is the definition section.

Section 3, entitled "State Administrative Procedures", sets forth the requirements that facilities must meet before they may allow unlicensed staff to administer medication. The facility must submit a written notice of intent to participate in the program to the office of health facility licensure and certification (OHFLAC). The nurses who will train and supervise facility staff must be approved by the OHFLAC and complete the facility trainer/instructor orientation course.

Subsection 3.2 requires each facility to remit an as yet undetermined fee to OHFLAC for the cost of training the nurses and an undetermined per test fee for facility staff members. West Virginia Code §16-50-9 authorizes the agency to set and collect fees through rulemaking. Counsel has suggested to the agency that it is required to set the actual fees in the rule.

Section 4 provides that medications may be administered by registered nurses, other licensed health care professionals or "approved medication assistive personnel" (staff trained pursuant to this rule). Facility staff may administer medication under this rule only after they have been trained; they must be considered competent by the supervising nurse; they must consult with the nurse or attending physician on a regular basis and they must be monitored or supervised by the nurse.

Section 5 discusses instruction and training for facility staff and the requirements for nurses who train and supervise them. The only authorized curriculum for facility staff training and evaluation is the one developed and provided by the agency. Staff members may take a competency test up to 3 times after completion of the training. If they do not pass the test they may take the training over and attempt the test one more time. The nurse instructor has the discretion to determine whether or not a staff member may take the training a second time.

Every two years each staff member authorized to administer medication must be retrained. Retraining consists of an overview of the original training and observation of the person administering medication.

Section 6 provides the eligibility requirements for facility staff member to administer medication. Not only must the employee take the required training and pass the evaluation, they must not have been guilty of abusing or neglecting residents or misappropriating resident's property. A criminal background check, and a check of the state police abuse registry must be preformed and show that the employee has a clean record. The employee must have a high school diploma and be certified in CPR and first aid and complete the retraining program every 2 years. The facility must maintain a list of the staff who have been approved to administer medication under this rule. In addition, the supervision nurse must maintain a file on these employees which contains proof of compliance with the requirements of this section.

Section 7 deals with the facilities oversight of unlicensed staff's administration of medication. The facility must develop policies and procedures on the administration of medications under this rule and they must be approved by the agency. The policy and procedures must provide for such things as maintenance of resident medication records; written verification that physician has authorized administration of medication by trained staff; monitoring and supervision requirements for trained staff by the nurse; and requirements for medication delivery system.

Section 8 provides for the withdrawal by the supervising nurse of authorization for trained staff to administer medication.

Section 9 limits the type and manner in which medication may be administered by trained staff. For example, medication must be maintained in the original container; no treatments which require skill and special training such as injections or irrigation or debridement may be preformed by these employees.

Section 10 attempts to provide for administrative due process, however, the sentence is unclear.

AUTHORITY

Statutory authority: W.Va. Code, §16-50-11, which provides, in part, as follows:

The department shall promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code as may be necessary to implement the provisions of this article. Subsequently, the department may propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code.

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

No.

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

Yes.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

No.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

No, the rule as a whole is merely a reprint of the statute. The agency has failed to specifically set fees which they are required to do by rule.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

Yes.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

No.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISION OF THE CODE?

Yes.

VIII. OTHER.

Counsel has suggested technical modifications.

ANALYSIS OF PROPOSED LEGISLATIVE RULES

FILED

Dec 3 10 22 AM '98

Counsel: Rita A. Pauley
Date: November 23, 1998
Agency: Division of Health
Subject: Medication Administration by Unlicensed Personnel,
64 CSR 60

OFFICE OF THE CLERK OF THE VIRGINIA
SECRETARIAT OF STATE

PERTINENT DATES

Filed for public comment: May 26, 1998
Public comment period ended: June 30, 1998
Filed following public comment period: August 3, 1998
Filed LRMRC: August 3, 1998
Filed as emergency: May 26, 1998; approved by Secretary of State
July 6, 1998

Fiscal Impact: The agency estimates the cost of implementing this rule will be \$101,362 for FY98, \$149,834 for FY99 and \$157,534 thereafter. Expenditures through the fiscal year ending June 30, 1999 have been appropriated by the Legislature.

ABSTRACT

The proposed rule prescribes the specific standards and procedures to provide for training, competency testing and approval of unlicensed personnel for the limited administration of medications in specified health care facilities. Persons who are trained to administer medication in accordance with the provisions of this rule must be monitored or supervised by a registered professional nurse. The nurse must first be trained to teach staff members to properly administer medication. He or she may then instruct staff on the administration of medication through the training and competency evaluation program developed by the agency.

It is anticipated that the implementation of the rule will lower providers costs for services to mentally retarded people living in intermediate care facilities which in turn may result in cost savings to the residents and the State.

The proposed rule is new, however, it is in effect as an emergency rule. The following is a section by section synopsis of the proposed rule.

Section 1 is the standard general section, setting forth the scope, authority, filing date and effective date of the proposed rule.

Section 2 is the definition section.

Section 3, entitled "State Administrative Procedures", sets forth the requirements that facilities must meet before they may allow unlicensed staff to administer medication. The facility must submit a written notice of intent to participate in the program to the office of health facility licensure and certification (OHFLAC). The nurses who will train and supervise facility staff must be approved by the OHFLAC and complete the facility trainer/instructor orientation course.

Subsection 3.2 requires each facility to remit an as yet undetermined fee to OHFLAC for the cost of training the nurses and an undetermined per test fee for facility staff members. West Virginia Code §16-50-9 authorizes the agency to set and collect fees through rulemaking. Counsel has suggested to the agency that it is required to set the actual fees in the rule.

Section 4 provides that medications may be administered by registered nurses, other licensed health care professionals or "approved medication assistive personnel" (staff trained pursuant to this rule). Facility staff may administer medication under this rule only after they have been trained; they must be considered competent by the supervising nurse; they must consult with the nurse or attending physician on a regular basis and they must be monitored or supervised by the nurse.

Section 5 discusses instruction and training for facility staff and the requirements for nurses who train and supervise them. The only authorized curriculum for facility staff training and evaluation is the one developed and provided by the agency. Staff members may take a competency test up to 3 times after completion of the training. If they do not pass the test they may take the training over and attempt the test one more time. The nurse instructor has the discretion to determine whether or not a staff member may take the training a second time.

Every two years each staff member authorized to administer medication must be retrained. Retraining consists of an overview of the original training and observation of the person administering medication.

Section 6 provides the eligibility requirements for facility staff member to administer medication. Not only must the employee take the required training and pass the evaluation, they must not have been guilty of abusing or neglecting residents or misappropriating resident's property. A criminal background check, and a check of the state police abuse registry must be preformed and show that the employee has a clean record. The employee must have a high school diploma and be certified in CPR and first aid and complete the retraining program every 2 years. The facility must maintain a list of the staff who have been approved to administer medication under this rule. In addition, the supervision nurse must maintain a file on these employees which contains proof of compliance with the requirements of this section.

Section 7 deals with the facilities oversight of unlicensed staff's administration of medication. The facility must develop policies and procedures on the administration of medications under this rule and they must be approved by the agency. The policy and procedures must provide for such things as maintenance of resident medication records; written verification that physician has authorized administration of medication by trained staff; monitoring and supervision requirements for trained staff by the nurse; and requirements for medication delivery system.

Section 8 provides for the withdrawal by the supervising nurse of authorization for trained staff to administer medication.

Section 9 limits the type and manner in which medication may be administered by trained staff. For example, medication must be maintained in the original container; no treatments which require skill and special training such as injections or irrigation or debridement may be preformed by these employees.

Section 10 attempts to provide for administrative due process, however, the sentence is unclear.

AUTHORITY

Statutory authority: W.Va. Code, §16-50-11, which provides, in part, as follows:

The department shall promulgate emergency rules pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code as may be necessary to implement the provisions of this article. Subsequently, the department may propose rules for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code.

ANALYSIS

I. HAS THE AGENCY EXCEEDED THE SCOPE OF ITS STATUTORY AUTHORITY IN APPROVING THE PROPOSED LEGISLATIVE RULE?

No.

II. IS THE PROPOSED LEGISLATIVE RULE IN CONFORMITY WITH THE INTENT OF THE STATUTE WHICH THE RULE IS INTENDED TO IMPLEMENT, EXTEND, APPLY, INTERPRET OR MAKE SPECIFIC?

Yes.

III. DOES THE PROPOSED LEGISLATIVE RULE CONFLICT WITH OTHER CODE PROVISIONS OR WITH ANY OTHER RULE ADOPTED BY THE SAME OR A DIFFERENT AGENCY?

No.

IV. IS THE PROPOSED LEGISLATIVE RULE NECESSARY TO FULLY ACCOMPLISH THE OBJECTIVES OF THE STATUTE UNDER WHICH THE PROPOSED RULE WAS PROMULGATED?

No, the rule as a whole is merely a reprint of the statute. The agency has failed to specifically set fees which they

are required to do by rule.

V. IS THE PROPOSED LEGISLATIVE RULE REASONABLE, ESPECIALLY AS IT AFFECTS THE CONVENIENCE OF THE GENERAL PUBLIC OR OF PERSONS AFFECTED BY IT?

Yes.

VI. CAN THE PROPOSED LEGISLATIVE RULE BE MADE LESS COMPLEX OR MORE READILY UNDERSTANDABLE BY THE GENERAL PUBLIC?

No.

VII. WAS THE PROPOSED LEGISLATIVE RULE PROMULGATED IN COMPLIANCE WITH THE REQUIREMENTS OF CHAPTER 29A, ARTICLE 3 AND WITH ANY REQUIREMENTS IMPOSED BY ANY OTHER PROVISION OF THE CODE?

Yes.

VIII. OTHER.

Counsel has suggested technical modifications.



FILED

JAN 15 9 30 AM '99

WEST VIRGINIA LEGISLATURE
Legislative Rule-Making Review Committee

OFFICE OF THE WEST VIRGINIA
SECRETARY OF STATE

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Delegate Mark Hunt, Co-Chairman
Debra A. Graham, Counsel

Joseph A. Altizer, Associate Counsel
Rita Pauley, Associate Counsel
Teri Anderson, Administrative Assistant

January 12, 1999

NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

TO: Ken Hechler, Secretary of State, State Register

TO: Marsha Dadisman
Health & Human Resources
Capitol Complex
Building 3, Room 265

FROM: Legislative Rule-Making Review Committee

Proposed Rule: **Medication Administration by Unlicensed Personnel, 64CSR60**

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule
 - (a) as originally filed
 - (b) as modified by the agency✓
2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached. _____
3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached. _____
4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached. _____