

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #2

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MAY 26 2 47 PM '98

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

Division of Health
AGENCY: Department of Health and Human Resources TITLE NUMBER: 64

RULE TYPE: Legislative; CITE AUTHORITY W. Va. Code §§16-50-11 & 16-1-7

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: 60

TITLE OF RULE BEING PROPOSED: _____

Medication Administration by Unlicensed Personnel

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 June 30, 1998 AT 4:30 p.m. ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS.

Regulatory Development

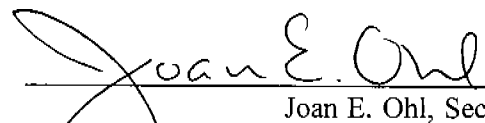
Department of Health & Human Resources

Capitol Complex - Building 3, Room 265

Charleston, WV 25305

ATTN: Marsha Dadisman, Acting Director

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


Joan E. Ohl, Secretary

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

\$6.20

Brief Summary of the Rule

The proposed rule, medication administration by unlicensed personnel, provides requirements for: staff eligibility; training, testing, and approval of unlicensed staff by a registered professional nurse, to administer medications in certain health care facilities; facility participation in this program; limitations on approved medication assistive personnel; and oversight and withdrawal of authorization, in accordance with West Virginia Code § 16-50-1 et seq.

Statement of Circumstances Which Require the Proposed Rule

The proposed rule is necessary to continue to allow the medication administration by unlicensed personnel that is provided for in W. Va. Code Article 50, Chapter 16, after the expiration of the emergency rule that the Legislature has directed to be promulgated in W. Va. Code § 16-50-11. Without the proposed rule the emergency rule would expire ending the reductions in costs that the Article allows.

FISCAL NOTE FOR PROPOSED RULES

Rule Title:

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

Agency: 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 FY98	Next FY99	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. OHFLAC 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 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. 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 ICF/MR residents. 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 cost of providing services to ICF/MR residents by providers within that health care industry. Some of these cost savings may be passed on to the consumers of these services.

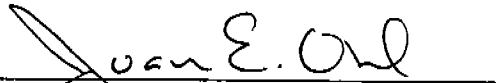
C. Economic Impact on Citizens/Public at Large.

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

Date: May 13, 1998

Representative

Signature of Agency Head or Authorized



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

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: May 22, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Department of Health and Human Resources

State Capitol Complex, Building 3, Room 265, Charleston, WV 25305

Telephone: (304) 558-3223

LEGISLATIVE RULE TITLE: Medication Administration by Unlicensed Personnel,

64 CSR 49

1. Authorizing statute(s) citation: WV Code §§ 16-50-11 & 16-1-7

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

May 26, 1998

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

Notice of availability of the proposed rule will be sent to the health care providers listed in the "facility" definition of the proposed rule, including residential board and care homes, personal care homes, behavioral health group homes, intermediate care facilities for the mentally retarded and home health agencies. The Department's Office of Social Services will be provided written notice of availability of the proposed rule for distribution to their adult family care homes as applicable.

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

June 30, 1998

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

Attached N/A No comments received N/A

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

N/A

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

Marsha Dadisman, Acting Director

Regulatory Development/Department of Health and Human Resources

Bldg. 3, Room 265, Capitol Complex, Charleston, West Virginia 25305

(304) 558-3223 FAX: (304) 558-1130 MDadisman@WVDHHR.ORG

- 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):

Kathy Beauchamp, Surveyor (304) 558-0607

Office of Health Facility Licensure & Certification

Bureau for Public Health, Department of Health and Human Resources

Building 3, Room 550, Capitol Complex, Charleston, West Virginia 25305

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 a hearing for the taking of evidence and a general

description of the issues to be decided.

N/A

b. Date of hearing or comment period:

N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

TITLE 64

LEGISLATIVE RULES

DIVISION OF HEALTH

SERIES ~~40~~ 60

MEDICATION ADMINISTRATION BY UNLICENSED PERSONNEL

For a Public Comment Period
Ending June 30, 1998

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TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH

SERIES ~~49~~ 60
MEDICATION ADMINISTRATION BY UNLICENSED PERSONNEL

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TITLE 64
LEGISLATIVE RULES
DIVISION OF HEALTH

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

MAY 26 2 48 PM '98

FILED

SERIES 60

MEDICATION ADMINISTRATION BY UNLICENSED PERSONNEL

§64-49-1. 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 §16-50-1 et seq.

1.2. Authority. -- W. Va. Code §§16-50-11 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 §16-50-2(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.

§64-49-2. Definitions.

2.1. Administration of Medications. --

2.1.a. Assisting a person in the ingestion, application or inhalation of medications, including 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 medication administered, including the time, route and amount taken: *Provided*, That

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for purposes of this article, "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 established for adults/children with similar needs, levels of independence, and ability which provides services and supervision for individuals who are developmentally disabled, behaviorally disabled or substance abusers; is licensed by the department; and complies 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 or respiratory care professional licensed under chapter thirty of this code.

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2.10. ICF/MR. -- An intermediate care facility for the mentally retarded which is certified by the department 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," 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 coordinate 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. Registered Professional Nurse. -- A person who holds a valid license pursuant to article seven, chapter thirty of the West Virginia Code.

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

2.16. 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

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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.

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

2.18. 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 prepackage 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.

2.19. 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.)

2.20. 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.

§64-49-3. State 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

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facility trainer / instructor orientation course developed by the authorizing agency.

3.2. The facility will be required to submit a fee, the amount to be determined by the authorizing agency, for participation of a registered professional nurse in the facility trainer / instructor orientation course and a fee per test for each facility staff member's competency evaluation.

§64-49-4. 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 may only be granted if the facility staff member:

4.3.a. Has been trained pursuant to the requirements of this rule;

4.3.b. Is considered by the registered professional nurse to be competent;

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

4.3.d. Is monitored or supervised by the registered professional nurse.

§64-49-5. Instruction and Training.

5.1. Curriculum.

5.1.a. The curriculum utilized to train facility staff shall be the West Virginia Department of Health and Human Resources Curriculum for Unlicensed Medication Assistive Personnel March 1998.

5.2. Competency Testing.

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5.2.a. Competency tests utilized shall be those developed and provided by the authorizing agency.

5.2.b. A competency test shall be administered to the facility staff member by the authorized registered professional nurse after completion of the required training. The completed exam shall be returned to the authorizing agency, postmarked within forty-eight (48) hours of completion.

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

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;

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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.

§64-49-6. Eligibility Requirements of Facility Staff.

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

6.1.a. The staff member has successfully completed the facility's medication administration training program and received a satisfactory competency evaluation as required by the provisions of this rule;

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

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

6.1.f. The facility staff member participates in the required retraining program at least every two (2) years.

6.2. 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.

6.3. 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 6.1.a. - f. This file shall be maintained in the facility and available to representatives of the authorizing agency on request.

§64-49-7. Facility Oversight of Medication Administration by Unlicensed Personnel.

7.1. Administrative Policy Requirements.

7.1.a. The facility 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. The authorized registered professional nurse shall participate in development 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 supervision of the approved medication assistive personnel by the registered professional nurse employed or contracted by the facility including: twenty-four (24) hour on-call coverage; 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 all approved medication assistive personnel during medication administration; 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.

7.1.d. Each facility shall have available resource information on all drugs

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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.

§64-49-8. 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.

§64-49-9. 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.

§64-49-10. Administrative Due Process.

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10.1. Administrative due process and remedies for actions taken under this rule, W. Va. Code §§16-5O-1 et seq. are as provided in this rule, in said articles of the West Virginia Code, and in the division of health procedural rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.