

Secretary of State's Office
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

State of West Virginia
Joe Manchin, III
Secretary of State

Telephone: (304) 558-6000
Toll Free: 1-866-SOS-VOTE
Corporations: (304) 558-8000
FAX: (304) 558-0900
www.wvsos.com

July 15, 2003

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Bureau for Public Health

RULE: Amendments, 64CSR51, Fees for Services

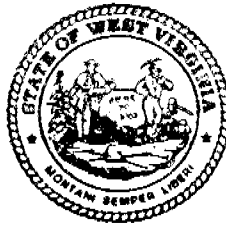
DATE FILED AS AN EMERGENCY RULE: June 26, 2003

FILED
2003 JUL 16 A 9:00
OFFICE WEST VIRGINIA
SECRETARY OF STATE

DECISION NO. 8-03

Following review under W. Va. Code §29A-3-15a, it is the decision of the Secretary of State that the above emergency rule is **approved**. A copy of the complete decision with required findings is available from this office.


JOE MANCHIN, III
Secretary of State



Secretary of State's Office
Building 1, Suite 157-K
1900 Kanawha Blvd., East
Charleston, WV 25305-0770

State of West Virginia
Joe Manchin, III
Secretary of State

Telephone: (304) 558-6000
Toll Free: 1-866-SOS-VOTE
Corporations: (304) 558-8000
FAX: (304) 558-0900
www.wvsos.com

EMERGENCY RULE DECISION
(ERD 8-03)

AGENCY: Bureau for Public Health
RULE: Amendments, 64CSR51, Fees for Services
FILED AS AN EMERGENCY RULE: June 26, 2003

- par. 1 The Bureau for Public Health (DHHR) has filed the above amendments to an existing rule as an emergency rule.
- par. 2 W. Va. Code 29A-3-15a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [§29A-3-15a].
- par. 4 (A) Procedural Compliance: W. Va. Code §29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The DHHR filed this emergency rule with supporting documents with the Secretary of State June 26, 2003 and with the LRMRC June 26, 2003.

par. 7 It is the determination of the Secretary of State that the DHHR has complied with the procedural requirements of W. Va. Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- W. Va. Code §16-1-4 reads in part:

§16-1-4. Proposal of rules by the secretary.

The secretary may propose rules, in accordance with the provisions of article three, chapter twenty-nine-a of the code, that are necessary and proper to effectuate the purposes of this chapter. The secretary may appoint or designate advisory councils of professionals in the areas of hospitals, nursing homes, barbers and beauticians, postmortem examinations, mental health and mental retardation centers and any other areas necessary to advise the secretary on rules.

The rules may include, but are not limited to, the regulation of:

(h) Fees for services provided by the bureau for public health including, but not limited to, laboratory service fees, environmental health service fees, health facility fees and permit fees;

par. 9 It is the determination of the Secretary of State that the DHHR has not exceeded its statutory authority in promulgating this emergency rule.

par. 10 (C) Emergency -- W. Va. Code §29A-3-15(f) defines "emergency" as follows:

(f) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the DHHR are as follows:

On September 11, 2001 our world changed. On that tragic day emergency services personnel & public health workers at every level at all 3 disaster sites faced challenges that had never before been seen. Their struggle to deal with the aftermath of the attacks spurred Congress to act to protect the homeland and reinforce the public health infrastructure through threat preparedness planning at the local, state and national levels and enacting new transportation security procedures.

Shortly after 9/11 we experienced another public health crisis when anthrax spores were sent through the mail and a number of people became ill or died. In November of 2001 the US Postal Service contacted the West Virginia State Hygienic Laboratory Director to request that we enter into a contract with the USPS for the purposes of conducting investigations and testing for anthrax and other agents at postal facilities in our state that might be part of a terrorist attack. We learned to our dismay that we were not authorized to enter into such a contract due to the limitations of this Fees for Service rule, Appendix A, section 5, has been added to specifically authorize our agency to enter into contracts for the testing of specimens in the conduct of public health investigations, public health interventions and public health risk assessments. This language will give us the latitude and flexibility to contract with other agencies of local, state or federal government and others for a wide range of activities related to treat preparedness and homeland security. Furthermore, we added section 6 to specifically allow us to charge a fee for any future testing related to bioterrorism or chemical terrorism.

The ongoing and unknown threat of terrorism demands that we be prepared to do the appropriate chemical and biological testing in a timely manner. Also, this rule will assist us in our efforts to comply with new state law & rules governing health facility licensure & certification, radiological machine registration & inspection, safe drinking water standards and permit requirements & it will help facilitate the agencies' ability to do mandated functions and provide essential services with reasonable & appropriate compensation.

W. Va. Code §16-5D-1 et seq enacted in 2003 requires changes to the rule, as does the Radiological Health Rule, effective in July 2001. Federal regs governing facilities that use x-ray machinery require that these devices be registered and inspected by an appropriate government agency.

We never know when the next terrorist attack may come, or where. We have to prepare to handle any event with rapid and accurate public health responses, including laboratory testing of biological and chemical agents.

par. 13

It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(f). . . "immediate preservation of public peace, health, safety or welfare" & "prevent substantial harm to the public interest"

par. 14

This decision shall be cited as Emergency Rule Decision 8-03 or ERD 8-03 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Bureau of Public Health, the Attorney General and the Legislative Rule Making Review Committee.



JOE MANCHIN, III
Secretary of State

Entered _____

FILED
2003 JUL 16 A 9:00
OFFICE WEST VIRGINIA
SECRETARY OF STATE

STATEMENT OF NEED FOR EMERGENCY RULES

Pursuant to West Virginia Code Section 29A-3-15(f), the Department of Health and Human Resources finds an emergency exists requiring the promulgation of an emergency rule. A statement of the facts and circumstances constituting this emergency follows.

The Bureau for Public Health is the state agency charged with the responsibility, "to promote the physical and mental health of all its citizens and to prevent disease, injury and disability whenever possible.¹ Protecting the public health from threats of disease or disaster has become vastly more difficult and expensive in the past few years. The powers and duties of the Commissioner of the Bureau for Public Health are set forth in WV Code §16-1-6 and they include "...investigations and inquires respecting the cause of disease, especially of epidemics and endemic conditions, and the means of prevention, suppression or control of those conditions;". All such activities have increased exponentially in the past two years.

On September 11, 2001 our world changed. On that tragic day emergency services personnel and public health workers at every level at all three disaster sites faced challenges that had never before been seen. Their struggle to deal with the aftermath of the attacks spurred Congress to act to protect the homeland and reinforce the public health infrastructure through threat preparedness planning at the local, state and national levels and enacting new transportation security procedures.

Shortly after 9/11 we experienced another public health crisis when anthrax spores were sent through the mail and a number of people became ill or died. In November of 2001 the United States Postal Service contacted the West Virginia State Hygienic Laboratory Director to

¹WV Code, §16-1-1 .

request that we enter into a contract with the USPS for the purposes of conducting investigations and testing for anthrax or other agents at postal facilities in our state that might be part of a terrorist attack. We learned to our dismay that we were not authorized to enter into such a contract due to the limitations of this Fees For Service rule. The state Laboratory had no way of billing for such testing. In this proposed emergency rule, Appendix A, section 5, has been added to specifically authorize our agency to enter into contracts for the testing of specimens in the conduct of public health investigations, public health interventions and public health risk assessments. This language will give us the latitude and flexibility to contract with other agencies of local, state or federal government and others for a wide range of activities related to treat preparedness and homeland security. Furthermore, we added section 6 to specifically allow us to charge a fee for any future testing related to bioterrorism or chemical terrorism.

Although we were not able to take advantage of the contract with the USPS to receive \$250 per test, we did, nevertheless receive and process approximately 500 samples of white or other colored powder that the public found suspicious. Many of those samples were tested in our lab, and many were sent to CDC. Laboratory personnel, including the Director, worked almost around the clock for at least a month to treat these specimens seriously and quickly. Fortunately, none were found to be anthrax. This type of testing is very expensive. It creates an undue hardship on this agency to, on the one hand, demand or require that we do the appropriate laboratory testing to investigate diseases or unforeseeable terrorist threats and then, on the other hand, not provide the necessary funds to buy the equipment, hire, train or retain qualified staff and operate in a building that is safe in which to conduct such intricate and sensitive experiments.

The State Hygienic Laboratory has very limited general revenue funding. New and emerging diseases are making the headlines everyday. These new challenges require new technology and machinery, supplies, new staff or advanced training for existing staff.

The existing fees in this rule are costing us money. Most of the tests that we are authorized to charge for end up costing more than we collect. Additionally, we are being asked to do many new and complicated tests. The requesters who send samples and specimens to our facility are generally willing to pay for this valuable service. It benefits all citizens to have a state hygienic laboratory able to do this important component of public health research, investigation and surveillance.

We have made some significant progress in updating our lab facilities to allow for the safe and accurate testing of biological and chemical agents, as well as testing for emerging epidemiological threats such as West Nile virus, La Crosse encephalitis, Monkeypox and SARS to name a few. These new tests will also require sophisticated machinery and well trained staff. The increase in fees for lab work reflected in this rule will allow our State Hygienic Laboratory to continue to function and to recoup some of the costs of the many new demands and challenges placed on us.

Being prepared to do this testing in a timely manner requires that these fees be instituted as soon as possible, and the preservation of the public health and safety of the citizens of West Virginia demands that we file this emergency rule to become effective as soon as the law allows.

The existing Fees For Service rule was last amended in 1991. Since that time a variety of state and federal laws that impact the activities covered by the rule have been enacted.

In the 2003 regular session SB 405 was passed. This new law changed the definitions of

two types of care facilities from “Personal Care Home” and “Residential Board and Care Home” to a single category called “Assisted Living Residences”. In order to bring this rule into compliance with this new statute, we need to revise the definitions and to change the fee structure to match the new statutory terminology. The new law is WV Code §16-5D-1 et seq.

The Office of Health Facility Licensure and Certification (OHFLAC) within the Bureau for Public Health also has the responsibility to inspect and license a number of facilities not covered by the 1991 rule, including, “residential care community”, “end stage renal disease”, “hospice” and “birthing center” facilities. Since the staff of OHFLAC must inspect and certify such facilities, it is imperative that they be able to charge for their professional services to maintain a high standard of oversight for the care at these specialized facilities.

Another situation which justifies this rule being filed as an emergency concerns the Office of Environmental Health Services (OEHS) requirements to comply with 64 CFR 23, the Radiological Health Rule. This massive new rule (350 pages) imposes a wide spectrum of new responsibilities on the Division of Radiological Health which is in the OEHS. A significant majority of the new definitions and a large number of the new fees sought by this rule are proposed to meet the demands of the Radiological Health Rule. That rule requires registration and inspection of all x-ray machines and any other sources of ionizing radiation, whether used in medical, dental, veterinary, industrial or security settings. Hospitals, Doctor’s offices, and all others that use such machinery must register it with this agency and the equipment must be inspected at regular intervals. It is a costly but important new activity that has no dedicated source of funding. Since the Radiological Health Rule came into effect in July of 2001, the OEHS has been doing their best to meet the requirements of this rule. However, the program is

operating in a deficit that just keeps growing without the ability to charge for the registration and inspection of the many machines added by the rule. The cost of registering and inspecting these machines should be borne by the owners of the machines. The businesses themselves are required, in many cases by their liability insurance carriers, to have their machines inspected for proper functioning by an independent governmental agency. We do them a service, for which they should pay a fair fee. Failure to file this rule immediately jeopardizes the program.

Another factor contributing to the need for filing this rule is to simplify the procedures for local health departments to establish their own fee structure. This rule will aid local health departments in their efforts to plan and budget for appropriate fees for their services. These revisions will be a welcome help for many struggling local health departments.

Lastly, the Safe Drinking Water program, which is also operated out of the Office of Environmental Health Services, is seeking a modest monthly service connection fee in this rule. The proceeds from this fee would go toward the establishment of an Operating Permit program for public water supply systems. The operating permit would be used as public health enforcement tool and it would also help fund an emergency response program to help small water systems, both publicly and privately owned, to fix broken pipes, repair or replace pumps and other parts and to generally keep water systems running and serving their customers with safe and healthy drinking water.

The proposed rule contains many other fees that have not been specifically mentioned. Many of the fees are for services that are mandated by state law. We want to remain in compliance with all such mandates that are for the protection and promotion of the public health, but, it is increasingly difficult to do the service without compensation and using ever-shrinking

general revenue dollars.

The “emergency” nature of this proposed legislative rule is cumulative. While the threat of a terrorist attack is, unfortunately, an ever-present risk, the financial difficulties being experienced at every level in public health are huge and growing. The need to have this rule revised has existed for some time. The postponement of promulgating this rule over time for a variety of reasons, some political, some practical, has placed the agency in the position of seeking emergency promulgation at this time. While it can be said that the need for this rule was an emergency last month or last year, the lack of the rule, with its new and increased fees, is a matter of urgent need right now. Without this emergency authority, new programs cannot begin to operate as they are intended to and existing programs are hamstrung by a lack of resources. We need this rule to give immediate financial relief for ongoing public health services that our agency provides and to benefit the general public with improved and expanded public health services.