WEST VIRGINIA SECRETARY OF STATE BETTY IRELAND ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE OF WEST VINGINIA SECRETARY OF STATE

NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE AND FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

AGENCY: DHHR - Bureau for Public Health	TITLE NUMBER:	64
CITE AUTHORITY: WV Code §§16-3-1, 16-1-4, 16-3C-1, 16-4-1 et seq.	and 16-22-3, 16-35-4	& 16-
AMENDMENT TO AN EXISTING RULE: YES X NO		
IF YES, SERIES NUMBER OF RULE BEING AMENDED: 7		
TITLE OF RULE BEING AMENDED: Reportable Diseases, Events	and Conditions	
IF NO, SERIES NUMBER OF RULE BEING PROPOSED:		

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

Maxiha Yessex Halker
Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title:	Reportable Disease, Events and Conditions, 64CSR7				
Type of Rule:	x Legislati	ve	Interpretive	Procedural	
Agency:	WV Bureau for Public Health, Depart	ment of Health and H	luman Resources		
Address:	350 Capitol Street, Room 702				
	Charleston, West Virginia 25301				
Phone Number:	(304) 558-0035	Email:	annspaner@wvdhhr.org		

Fiscal Note Summary

Summarize in a clear and concise manner what effect this measure will have on costs and revenues of state government.

Speed is of the essence in disease reporting. Both the need for and the cost of immediate and accurate disease surveillance, laboratory analysis, outbreak investigation and rapid reporting have increased dramatically in the past few years. One need only think of the SARS outbreak to understand the global public health and safety at stake in this effort. West Virginia needs to enact this rule modification to be able to respond quickly and effectively in the event of a disease outbreak, chemical or biological attack or other threat to public health. Implementation of this rule will cost \$671,347 in 2006 and \$480,147 in 2007 and beyond. With that investment we will build the necessary infrastructure of staff, equipment and information management systems technology upgrades. In our partnerships with the Centers for Disease Control and Prevention (CDC) and the Health Resources Service Administration (HRSA) we have agreed to meet certain standards or expectations for disease reporting that are beyond our current abilities.

This rule is not expected to generate a significant amount of revenue, but it is likely that it will lead to more laboratory tests being performed at our state hygienic laboratory and it will also facilitate a faster turnaround of test results. We will be able to charge a reasonable fee based on the actual cost of such testing. Furthermore, both the CDC and HRSA expect the state to support these efforts in order to qualify for continued federal funding. For example, federal grant monies have funded the purchase of Laboratory Information Management System (LIMS) software, but the state must find the money to hire qualified staff to implement and operate it. We must also be able to use both the LIMS and the West Virginia Electronic Disease Surveillance System (WVEDSS) to rapidly and effectively exchange information with our federal government partners and our sister agencies in other states, as well as with local health departments in this state. The rule requires much more rapid reporting than has ever been possible previously. Information Technology systems and qualified operators are essential to making the electronic reporting systems established in this rule work.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

	Fiscal Year			
Effect of Proposal	2005 Increase/Decrease (use"-")	2006 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)	
1. Estimated Total Cost		671,347	480,147	
Personal Services		231,347	231,347	
Current Expenses		118,000	98,800	
Repairs and Alterations				
Equipment		152,000	0	
Other		170,000	150,000	
2. Estimated Total Revenues		0	0	

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

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

Personal Services	OEHP	OLS	Total	
1 Prog Analyst II (database responsibilities-WVEDSS & WVSIIS)	37,750			37,750
1 Prog Analyst III (LIMS administration)		43,500		43,500
1 Data Entry Operator II (LIMS support and administration)		25,000		25,000
1 Microbiologist I (Disease outbreak response and surge capacity)		27,000		27,000
1 Microbiologist II (Disease outbreak response and surge capacity)		32,000		32,000
Total	37,750	127,500		165,250
Fringe Benefits	14,280	51,817		66,097
TOTAL PERSONAL SERVICES	52,030	179,317		231,347
CURRENT EXPENSE				-
Training Support (i.e. qrtly training, drills, outreach to hospitals, etc.)	48,000			48,000
WVEDDS reporting forms	20,000			20,000
Testing reagents for disease confirmation (\$1,500/outbreak X 25/yr.)				-
Total	68,000	50,000		118,000
EQUIPMENT				-
Computer	2,000			2,000
LIMS (Hardware that will allow interface with WVEDDS)		150,000		150,000
Total	2,000	150,000		152,000
SOFTWARE				
Programs for WVEDSS export to LIMS & interface with commercial labs		\$ 170,000	\$	170,000

Memorandum

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

The proposed changes will expand the number of categories of diseases to be reported by health care providers and laboratories from 3 to 5. Many of the diseases within categories have been reexamined or relocated to other categories. Three new sections are added in response to emerging health threats from animals, bioterrorism and SARS. Since many of these diseases or events were previously unknown, the rule explains the requirements for reporting in unusual circumstances. Many time frames have been changed to require more rapid reporting. Additional reporting of immunization data for children between the ages of 6 and 18 is included. This will require more time and staff to enter the data in the West Virginia Statewide Immunization Information System (WVSIIS). The rule references the WV Electronic Disease Surveillance System (WVEDSS) as the preferred reporting mechanism once the system is fully operational. LIMS, the Laboratory Information Management System, has been purchased with federal grant money but it is staffed and made operational by the provisions of this rule. Other clean up and clarification changes have been made to the rule.

Date	Agency	Authorized Representative
	Department of Health and Human Resources	Martha Geager Walker Secretary

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.)

DAT	E: Ju	<u>ly 29, 2005</u>
ГО:	LEG	GISLATIVE RULE-MAKING REVIEW COMMITTEE
TD∩I	M·(4~	ncy Name, Address & Phone No Department of Health and Human Resources
KOI	VI.(Age	Bureau for Public Health
		350 Capitol Street, Room 702
		Charleston, WV 25301
		(304) 558-2971
LEGI	 ISLAT	IVE RULE TITLE: Reportable Diseases, Events and Conditions
l.	Aut	horizing statute(s) citation
2.	a.	Date filed in State Register with Notice of Hearing or Public Comment Period:
		June 29, 2005, rule filed for Public Comment
	b.	What other notice, including advertising, did you give of the hearing?
		The Office of Epidemiology and Health Promotion posted the proposed rule on their website to invite public review and comment.
	c.	Date of Public Hearing(s) or Public Comment Period ended:
		July 29, 2005 at noon
	d.	Attach list of persons who appeared at hearing, comments received, amendments, reasons for amendments.
		AttachedX No comments received

	e.	Date you filed in State Register the agency approved proposed Legislative Rule following public hearing: (be exact)				
		July 29, 2005				
	f.	Name, title, address and phone/fax/e-mail numbers of agency person(s) to receive all written correspondence regarding this rule: (Please type)				
		Ann A. Spaner	John D. Law			
		Bureau for Public Health	Secretary's Office, DHHR			
		350 Capitol Street, Room 702	Building 3, Room 206			
		Charleston, WV 25301	Charleston, WV 25305			
		558-0035 Phone, 558-1035 Fax	558-7899 Phone; 558-7075 Fax			
		annspaner@wvdhhr.org	johnlaw@wvdhhr.org			
	g.		P, please give Name, title, address and phone rote and/or has responsibility for the contents of this			
		Loretta Haddy, State Epidemiologis Bureau for Public Health 350 Capitol Street, Room 125 Charleston, WV 25301 558-7078 Phone; 558-1553 Fax lorettahaddy@wvdhhr.org	t			
3.		rminations to be made as a condition pre-	the submitted rules requires certain findings and cedent to their promulgation: In the State Register a notice of the time and place dence and a general description of the issues to be			

υ.	Date of hearing of confinent period.
	The comment period ran from June 29 to July 29, 2005.
c.	On what date did you file in the State Register the findings and determinations require together with the reasons therefor?
	n/a
d.	Attach findings and determinations and reasons:
	Attached n/a

Public Comments on Legislative Rule Title 64, Series 7 REPORTABLE DISEASES, EVENTS AND CONDITIONS

Name:

Sandra LeMaster, RN
Berkeley County Health Department
800 Emmett Rousch Drive
Martinsburg, WV 25401

Date received:

July 14, 2005

Comment:

Did I read this correctly? Is viral-asceptic meninghitis on the list to be REMOVED? If so I'm in favor, if not I would like to suggest that it be on the list to be removed.

Response:

Yes, you are reading this correctly, viral-asceptic meningitis is proposed to be removed.

Name:

Margaret Taylor, CDC Senior Public Health Advisor Division of Surveillance and Disease Control 350 Capitol Street, Room 125 Charleston, WV 25301

Date received:

July 15, 2005

Comment:

On page 12, 3.6a (second paragraph) Race should be added to the information since race drives many of our program functions and activities and is a mandated field on our CDC grants.

On page 20, 10.3 Race should be added here too.

On page 22, 12.3a.4 Activities should be reported to STD/HIV/TB Program

On page 24, 64-7-17 Gonorrhea (all types)

Response:

Thank you, I will ask Ann Spaner to make these changes.

Name:

Karen McClain, RN Brooke County Health Department Courthouse, 632 Main Street Wellsburg, WV 26070

Date received:

July 15, 2005

Comment:

It seems that the proposed Communicable Disease Rule to go before the 2006 Legislature has changes in the reporting of diseases for labs according to what category the disease is now listed under? Is that correct?

Response:

We really didn't make any changes from what we took to the 2005 session that was not approved due to a large fiscal note. If you didn't see that version, you probably would did not see the changes from the currently approved version.

Name:

Clarence Christian, District Sanitarian Office of Environmental Health 100 East Prince Street Beckley, WV 25801

Date received:

July 15, 2005

Comment:

This section should be updated to develop uniformity and consistency throughout the state. Food Service Worker Training or management training should be made mandatory by each county health department. Guidelines should be established to determine what is considered adequate Food Service Worker Training and/or management training.

Response:

Please review this section with appropriate OEHS staff and provide the exact wording you would like to propose in the rule, or do you just want it to read that the Food Service Worker training is mandatory?

Name:

Joseph Wyatt
Office of Environmental Health
Capitol & Washington Streets
1 Davis Square
Charleston, WV 25301

Date received:

July 28, 2005

Comment:

Clarence.

I agree with you 100%, however, I feel we should approach this change in a different manner. Many years ago local health departments sought to change what was then mandatory food service workers training to what we have now. To suddenly change back could undermine the level of trust between state and local that has been developed over the past several years. I would like to bring the issue up before the liaison committee and gradually work toward mandating this training. The reportable disease rule is updated every year or two so we will have opportunities in the near future to make changes.

Response:

Comment received and reviewed. At this point, no changes are being made.

Name:

Lloyd White Marion County Health Department 300 Second Street Fairmont, WV 26554

Date received:

July 18, 2005

Comment:

The question I have is this: Is EMS intended to be included in the definition of health care providers? It appears that they are in the very broad definition. As you know, EMS does not diagnose but treat symptoms. I don't think they should be included in the definition if indeed they are.

Response:

The definition for health care provide in 64CSR7 is - any physician, dentist, nurse, or other individual who provides to individuals medical, dental, nursing, or other health care services of any kind. If you are referring to 'other health care services of any kind', I would say you are right that could mean EMS, but it was not intended to mean EMS. This 'catch-all' phrase is to be used for infection control practitioners who report diseases for hospitals on behalf of the facility and attending physician, etc.

Name:

Linda Bennett, RN Monongalia County Health Department 453 Van Voorhis Road Morgantown, WV 26505

Date received:

July 16, 2005

Comment:

Reviewed the proposed rule and have one thought - there are several references to the health officer and their role and since we do not have a full time health officer most of what it references to the health officer, we do. Would it be possible to include "or designee" in those instances where we do the follow up? I'm sure this is how it has always been stated and may not be able to be changed but thought I'd mention it.

Response:

Comment received and reviewed. At this point, no changes are being made.

Name:

Robert Fernatt, WVEDSS IT Manager Surveillance and Disease Control 350 Capitol Street, Room 125 Charleston, WV 25301

Date received:

July 27, 2005

Comment:

I had asked about syndromic surveillance being covered in the new rule and we had talked about record retention. After looking at the rule, there is provision for syndromic surveillance and electronic reporting of syndromic data, so that looks fine to me.

As far as records retention is concerned, I asked Kay Shamblin's office for a copy of the 1995 retention schedule guidelines and talked with Diana Sears at Nicholas County. The 1995 schedule calls for "disease files" to be kept for 10 years and then shredded while rheumatic fever documents are to be kept until the patient is deceased and shredded afterwards.

While talking with Diana Sears about the HIPAA assessment that was done for LHDs and whether or not LHDs had their own schedules, it really sounds like there wasn't much supplied to them following that assessment that they are using. Nicholas is keeping disease reporting documents indefinitely and doesn't see any reason to change this. According to Diana, every LHD will probably have some variation in the way they keep and destroy records for various programs dictated to some degree by available filing manpower and storage space/costs.

In consideration of electronic systems and electronic records, Diana agreed that there are other documents (lab reports, worksheets, handwritten notes, etc.) that will not be a part of an electronic system in the near future so it would be best to continue to keep paper records. Additionally, distributed paper records are always "plan B" in the case of some catastrophic scenario where the system and backups may be destroyed (we can't afford the type of failover systems necessary to guard against those scenarios). Speaking of business continuity, providers and LHDs should have a stock of blank paper forms in the event of a disaster that affects the system.

The only part of the new rule that I can see changing, unless IDEP wants something more expansive, is the phrase "according to the record retention schedule for the local health department." This should probably be strengthened so that every county is using

the Division of Local Health record retention schedule. That way, retention changes dictated by federal law, etc. can be reflected in the Division of Local Health document and will not require a future change to the rule.

Response:

Comment received and reviewed. At this point, no changes are being made.

Name:

Kit Reed, RN, BSN, MPH, CIC Charleston Area Medical Center Clinical Epidemiology 3200 MacCorkle Ave. SE Charleston, WV 25304

Date received:

July 28, 2005

Comment:

Page	Number	Subject	Comments And Questions
1	1.5	Exposure or alleged exposure	Define alleged. Does this include patients who state they "think" they got food poisoning, etc.?
1	Section 2	Definitions	May be helpful to define Community Acquired in the rule.
1	Section 2	Definitions	Define Invasive Disease
2	2.19	Infectious Agents bacteria, parasite, virus, toxin, prion	Should fungal infections be included?
4	3.3а	Report immediately	Pre-supposes 24/7 surveillance coverage at both the reporting agency and receiving county health department. Could this be clarified? Telephone vs. WVEDSS. Manual entries will not happen immediately. Telephoning is a possibility, but the Local HD will not be open 24/7. Is there an on-call process for Local HD? How will providers access this? What if the LHD is not reachable? Who next?
	3.3a 3.4a 3.5a 3.6a 3.7a	Demographic data collection	Hospital and Lab personnel may not have routine access to all the listed demographical data. Physician address, office phone and especially fax number may not be available.
	3.3 a	Normal	We are assuming this is referring to

Page	Number	Subject	Comments And Questions
	3.4 a 3.5 a 3.6 a	value/Range	values outside of negative/positive (Negative would be the normal value for most diseases). Results/ranges that are available, often are already built into the printed lab report. Could the reason for this need be clarified. Is it for WVEDSS?
12	3.6b	Removal of Encephalitis	Note: not all practitioners send CSF / serology for arboviral testing and until they start doing this routinely, many cases will go unreported
12	3.6.b.3	Community acquired MRSA, Invasive etc	Define community acquired and invasive; see comment above for section 2
12	3.6.b.17	Streptococcal Toxic Shock Syndrome	Redundant with 3.6.b.20; why does Strept need its own category if any TSS is reportable? Or should Staphylococcus be added since Strept is there?
12	3.6.b.21	Latent TB	Suggest to further define Latent to specify only positive PPD in the absence of active disease symptoms and/or positive CXR
Starting pg 13	3.7b	Report timing confusing	Listed under 1-week reporting but many state within 24 hours in parentheses also. Maybe should have a separate category for 24 hour reporting?
14	3.7.b.11	Hepatitis C, acute or chronic	Is a report required for every visit of patients with known Hepatitis C, and / or every time the test is repeated if known to have been reported in past?
14	3.7.b.13	Influenza culture confirmed	Few places do cultures – does this include the antigen tests for Types A & B? 99% of influenzas are detected by antigen tests. This will also miss all the rapid testing by test-pack methods.
16	5.7	Rabies PEP	Is this to be reported on yellow cards or a separate form if no WVEDSS? Note: question raised by APIC member - Why can't local DOH give

Page	Number	Subject	Comments And Questions
			these shots? The hospital is the only provider with the vaccine in this county, and the hospital and patient incur substantial expense for outpatient distribution following the acute episode treatment in ER.
16	7.1	Disease Outbreaks	Specify Community outbreaks, unless internal facility outbreaks are also being required
17	7.6	Outbreak Investigation	Specify that when the commissioner requests lab tests on ill and/or well persons, that the DOH will provide the testing site, the tests, and absorb the costs
19	10.1	Syndromic Surveillance	Specify how local healthcare providers will be informed whenever this is needed
20	10.3	Addition of viruses listed in 10.3a – 10.3f	Will this only occur when automated laboratory reports via WVEDSS are operational? CAMC processes 300 specimens a day during viral season. Reporting the demographics requested for all of these virus' daily by hand would be impossible.
20	10.3a	Adenovirus by culture or PCR	This will miss the majority of adenoviruses, which are detected as antigen.
20	10.3c	Influenza, by culture, including type and subtype as available	99% of influenzas are detected by antigen tests. This will also miss all the rapid testing by test-pack methods. This statement did not include the previous requirements for numerical totals only by the week?
21	12.1.a.7	Negative laboratory tests or evaluations	Specify only when requested for indicated parameters in a specific group of people over a particular period of time.
21	12.2.b.1	Lab Submitting isolates	Requests have been made that the state provides the labs with transportation containers (prelabeled), transport media, submission forms and courier service. Labs do not have the resources (human and otherwise) to comply with this rule.
21	12.2.b.1	Lab reporting	Delete; lab personnel don't know if the

Page	Number	Subject	Comments And Questions
		and submission of isolates of CA-MRSA	MRSA is community acquired and frequently do not have access to records or have the time to figure this out. If it stays in rule, is this all CA-MRSA or just invasive?
	Diseases	Suggestion	Add alphabetic index to document; the way its written, it's too hard to tell which are additions, deletions, and some are just moved. See below to see what we think is what now.
	Conditions	Non-infectious	Why are autism, birth defects, cancer, hemophilia, lead tests in the communicable disease rule?
	Additional Comments		A lab director suggested that a meeting between the SHD and Lab supervisors be set up to discuss the rule.

Response:

Comments received and reviewed. Thank you. The following changes were made:

Pg 17 64-7-7.1 Change to: When a health care facility, health care provider or laboratory becomes aware of a community outbreak, the outbreak shall be reported to the local health officer immediately.

Pg 20 10.3.a Change to: Adenovirus, by culture, antigen or PCR

Pg 20 10.3.c. *Change to:* <u>Influenza, by culture, antigen or PCR, including type and subtype, as available</u>

Pg 21 12.1.a.7 Change to: Assist the commissioner or local health officer in ruling out previously reported cases of infectious diseases by submitting copies of negative laboratory tests of medical evaluations

Pg 21 12.2.b.1 Delete: Community acquired Staphylococcus aureus

Department of Health and Human Resources Bureau for Public Health Legislative Rule Title 64, Series 7

REPORTABLE DISEASES, EVENTS AND CONDITIONS

STATEMENT OF CIRCUMSTANCES

The rule on reportable diseases, events and conditions is in need of a major revision. There are numerous diseases to be added, deleted or reorganized as well as events and conditions that have not been contemplated prior to this rule revision. The reporting time frames for certain diseases or events have been shortened and the movement toward an electronic reporting system has been written into this rule.

BRIEF SUMMARY OF THE PROPOSED RULE

The rule expands the number of categories of diseases, which must be reported by health care providers and laboratories, from 3 to 5. Within each of the five (5) categories of diseases all of the entries have been re-examined. New diseases have been added and some diseases have been deleted. In some instances diseases have been moved to a different category for a variety of medical and epidemiological reasons.

The rule adds four entirely new sections describing other reportable events in response to the plethora of new and emerging health threats from such things as zoonotic diseases, bioterrorism and international disease outbreaks, such as SARS.

These new sections begin with section 7, Disease Outbreaks, and include; section 8, Surveillance program evaluation and special studies; section 9, Bioterrorism response; and section 10, Syndromic surveillance and electronic laboratory reporting. Since many of these diseases, events and conditions were previously unknown and unimaginable; the bureau has included an explanation of the procedure and protocol for reporting in these unusual circumstances.

Due to the complexity of emerging diseases and the potentially rapid spread of virulent new strains of diseases, some time frames for reporting have been accelerated. Frequent reference is made throughout the rule to the West Virginia Electronic Disease Surveillance System (WVEDSS) as the preferred mechanism to report diseases, events and conditions which will be necessary for our state to comply with federal requirements for threat preparedness and emergency response.

Finally, the rule includes clean up and clarification changes to facilitate use of the rule by health care providers and laboratories who must abide by its provisions.

64CSR7

TITLE 64

LEGISLATIVE RULE

BUREAU FOR PUBLIC HEALTH DEPARTMENT OF HEALTH AND HUMAN RESOURCES



SERIES 7

05 JUL 29 PM 4 06

REPORTABLE DISEASES, EVENTS AND CONDITIONS

OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

§64-7-1. General.

- 1.1. Scope -- This legislative rule establishes procedures governing the reporting of certain diseases and conditions, unusual health events, and clusters or outbreaks of diseases to the division of bureau for public health. It also establishes the responsibility of various individuals and facilities in controlling communicable diseases. The WV Code is available in public libraries and on the Legislature's web page, http://www.legis.state.wv.us/.
- 1.2. Authority. -- WV Code §§16-3-1, and 16-1-4; related 16-3C-1 et seq., and 16-4-1 et seq., 16-22-3, 16-35-4 and 16-40-7.
 - 1.3. Filing Date. --
 - 1.4. Effective Date. --
- 1.5. Applicability. -- This rule applies to physicians and other licensed health practitioners; local health officers; other public health providers; private or public laboratories; all health care facilities; the bureau; health care professional licensing boards and agencies; any individual administering immunizations; administrators of schools, camps, and vessels; administrators of health care facilities operated by the department; the State registrar of vital statistics; county humane officers, dog wardens, sheriffs, pathologists, coroners, veterinarians and other animal health care providers, and medical examiners; and any other person investigating or treating disease, health conditions, exposure or alleged exposure to infectious agents, or cause of death.
- 1.6. Enforcement. -- This rule is enforced by the commissioner of the West Virginia bureau for public health or his or her lawful designee.

§64-7-2. Definitions.

- 2.1. Animal health care providers Veterinarians or veterinary technicians or other individuals providing health care to animals.
- 2.2 Automatic reporting capability The ability of an electronic laboratory reporting system to report laboratory findings through an electronic interface such that data is automatically transferred from a laboratory database to WVEDSS without human intervention.
- 2.3 Biological toxin Toxin produced by microorganisms, including botulinium toxin or toxins of Staphylococcus aureus or Clostridium perfringens; or toxic products or byproducts of higher plants or animals, such as ricin.
- 2.4. Bioterrorism Agent Infectious agent or biological toxin deliberately introduced into the food, air, water or other part of the environment; or directly into an animal or human with the criminal intent of causing disease in animals or humans.
- 2.5. Bioterrorist event The occurrence of a case of disease or a disease outbreak due to a bioterrorism agent; or attempted exposure of one or more individuals to a bioterrorism agent.
- 2.1. 2.6. Bureau The bureau for public health of the West Virginia department of health and human resources.
- 2.7. Case An occurrence of disease in a human or animal which meets a specific case definition listed in the West Virginia Reportable Diseases Protocol Manual or a case definition approved by the commissioner. (Manual is available online at http://www.wvdhhr.org/idep)
- 2.8. Cluster An aggregation of cases of disease in time and place with or without

- exceeding the expected number of cases; frequently the expected number of cases is not known.
- 2.2. 2.9. Commissioner The commissioner of the bureau for public health of the West Virginia department of health and human resources or his or her designee.
- 2.3. 2.10. Communicable Disease A disease caused by an infectious agent or its toxic products, which is transmitted, directly or indirectly, to a susceptible host from an infected person, animal, arthropod, environmental exposure or other source.
- 2.4. 2.11. Department The West Virginia department of health and human resources.
- 2.12. Epidemic An outbreak or the occurrence of more cases of disease than expected in a given area among a specific group of people over a particular period of time.
- 2.5. 2.13. Epidemiologic Information Medical data or other information, interviews, investigative reports, other records and notes collected during the course of an epidemiologic investigation of a disease, condition, or outbreak.
- 2.14. Epidemiologic Investigation An investigation to determine the distribution, determinants and risk factors for disease in a specified population, for the purpose of prevention or control of the disease in the population; or to evaluate prevention and control efforts; or for increased understanding of the effects of the disease on the population.
- 2.15. Foodborne outbreak An incident in which two or more persons experience a similar illness after ingestion of a common food, and epidemiologic analysis implicates the food as the source of the illness.
- 2.6. 2.16. Health care provider Any physician, dentist, nurse, or other individual who provides medical, dental, nursing, or other health care services of any kind to individuals.
- 2.7. 2.17. Health care facility Any hospital, nursing home, clinic, cancer treatment center, laboratory, or other facility which provides health

- care or diagnostic services to individuals, whether public or privately owned.
- 2.8. 2.18. Hospital A facility licensed as a hospital under WV Division of Health Legislative Rule, Hospital Licensure, 64 CSR 12.
- 2.19. Infectious Agent A biological organism such as a bacteria, parasite or virus; or a bacterial toxin; or a prion capable of causing disease in animals or man when introduced into the individual through water, air, food, the environment or by the percutaneous or other route.
- 2.20. Intentional Exposure The deliberate introduction of a harmful agent into the air, water, food or environment of an individual or group of individuals with the intent of causing disease.
- 2.9. 2.21 Isolation The separation of infected persons or animals from other persons or animals, under the necessary time frame and conditions to prevent the direct or indirect transmission of the infectious agent from the infected persons or animals to other persons or animals who are susceptible or who may spread the disease to others.
- 2.10. 2.22. Laboratory Any licensed facility or place, however named, for the biologic, microbiologic, serologic, virologic, chemical, hematologic, immuno-hematologic, biophysical, cytologic, pathologic, genetic, molecular or other examination of materials for the purpose of providing medical or epidemiologic information for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings. The term "laboratory" includes both public and private laboratories, freestanding laboratories, and hospital laboratories.
- 2.23. Law Enforcement Personnel Any person who is employed by a local, county, state or federal agency with law enforcement responsibilities.
- 2.11. 2.24. Local Board of Health A board of health serving one or more counties, one or more municipalities, or a combination thereof.
- 2.12. 2.25. Local Health Department The staff of the local board of health.

- 2.13. 2.26. Local Health Officer The individual who fulfills the duties and responsibilities of the health officer for a local board of health, or his or her designee.
- 2.14. 2.27. Medical Information Data or other information regarding the history, examination, <u>radiological or lab laboratory</u> findings, diagnosis, treatment, or other clinical care for a person examined or treated for a suspected or actual disease.
- 2.15. 2.28. Nursing Home Any facility licensed as a nursing home under WV Legislative Rule, Nursing Home Licensure, 64 CSR 13, or any extended care facility operated in conjunction with a hospital.
- 2.29. Outbreak The occurrence of more cases of disease than expected in a given area among a specific group of people over a particular period of time or an epidemic.
- 2.30. OLS The office of laboratory services in the bureau.
- 2.16. 2.31. Physician An individual licensed to practice medicine by either the board of medicine or the board of osteopathy.
- 2.17. 2.32. Placarding The posting on a home, building or other structure of a sign or notice warning of the presence of a communicable disease or other health hazard and the danger of the disease or hazard within or beyond the placarded home, building or structure.
- 2.18. 2.33. Quarantine The limitation of freedom of movement of persons or animals in a time frame and manner to prevent contacts that could lead to spread of disease.
- 2.19. 2.34. Reportable Disease or Condition Any disease or condition required to be reported by this rule.
 - 2.20. 2.35. STD Sexually transmitted disease.
- 2.36. Surveillance The systematic collection, analysis, interpretation and dissemination of health data on an ongoing basis, to gain knowledge of the

- pattern of disease occurrence and potential in a community; or to understand the disease patterns in the community in order to control and prevent disease in the community, or to evaluate prevention and control efforts.
- <u>2.37. Veterinarian A doctor of veterinary</u> medicine.
- 2.38. Waterborne outbreak An incident in which two or more persons experience a similar illness after consumption or use of water and epidemiologic evidence implicates the water as the source of the illness.
- 2.39. WVEDSS West Virginia Electronic Disease Surveillance System An electronic data system for reporting and tracking cases and outbreaks of infectious diseases with simultaneous reporting of the disease to the bureau and local health departments.

§64-7-3. Selection, Categorization, and Required Reporting.

- 3.1. Selection and Categorization of Required Reportable Diseases and Conditions.
- 3.1.a. The commissioner may, by order filed with the Secretary of State, add or delete a disease or condition in any category. The commissioner shall select and categorize diseases and conditions for inclusion in this rule based on whether the disease or condition constitutes or has the potential to constitute a public health emergency, whether it requires public health follow up, or whether the collection of data or other information on the disease or condition can assist in either determining the need for or effectively implementing public health programs or other projects to protect and promote the health of the people of West Virginia.
- 3.1.b. In emergency situations, such as potential epidemics, the commissioner may require same day reporting for diseases and conditions in any of the categories listed in this rule.
 - 3.2. Reporting of Diseases and Conditions.
- 3.2.a. The commissioner shall establish specific protocols for reporting diseases and

conditions. These that may be found in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep). The protocols shall include any information to be reported beyond that listed in this rule and any additional information necessary regarding reporting or appropriate public health management.

- 3.2.b. The reports required by this rule may shall be made reported electronically to WVEDSS in a manner approved by the commissioner or on forms supplied by the commissioner.
- 3.3. Category I Reportable Diseases and Conditions.
- 3.3.a. Health care providers, health care facilities and laboratories shall report cases of Category I diseases or conditions listed in subdivisions 3.3.b and 3.3.c of this section by telephone to the local health department in serving the patient's county of residence within twentyfour (24) hours of diagnosis. immediately; and also shall immediately file an electronic report with WVEDSS. All local health departments shall report the case to the bureau immediately upon receipt of the report (toll free at 1 800 423 1271). When WVEDSS is certified as operational by the commissioner, the local health department shall use WVEDSS to file the report. The reports Reports from health care providers and health care facilities shall include the patient's name, address, telephone number, date of birth, sex, and the patient's physician's name, office address, office phone and fax numbers, and any other information requested by the commissioner relevant to the purposes of this rule. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex; and the physician's name, office address, office phone and fax numbers; name of person or agency submitting the specimen for testing, specimen source, date of specimen collection, date of result, name of the test, test result, normal value or range; and name, address, phone and fax number of the laboratory.
- 3.3.b. Category I.A diseases and conditions reportable by health care providers and health care facilities are:

3.3.b.1. Anthrax;

3.3.b.2. Bioterrorist event, suspect or confirmed;

3.3.b.2. 3.3.b.3. Botulism;

3.3.b.3 Brucellosis;

3.3.b.4. Cholera;

3.3.b.5. Dengue Fever;

3.3.b.6. Diptheria;

3.3.b.7. Enterohemorrhagie Escherichia coli (EHEC) including but not limited to E. coli O157:H7:

3.3.b.8. 3.3.b.4. Foodborne Disease outbreak, suspect or confirmed;

3.3.b.9. Haemophilus influenzae, Invasive Disease;

3.3.b.10. Hemolytic Uremic Syndrome, postdiarrheal;

3.3.b.11. Hepatitis A, acute;

3.3.b.12. Hepatitis B. acute or perinatal;

3.3.b.13. Hepatitis D:

3.3.b.5. Intentional exposure to an infectious agent or biological toxin, suspect or confirmed;

3.3.b.14. Meningococcal Disease, invasive:

3.3.b.6. Orthopox infection, including smallpox and monkeypox;

3.3.b.15. 3.3.b.7. An outbreak or cluster of any illness or condition - suspect or confirmed;

3.3.b.16. Pertussis (Whooping Cough);

3.3.b.17. 3.3.b.8. Plague;

3.3.b.18. Poliomyelitis;

3.3.b.19. Rabies in animals or in humans;

3.3.b.20. Rubella (German Measles);

3.3.b.21. 3.3.b.9. Rubeola (Measles);

3.3.b.10. SARS coronavirus infection, suspect or confirmed;

3.3.b.22. 3.3.b.11. Smallpox;

3.3.b.23. Staphylococcus aureus with glycopeptide intermediate (GISA/VISA) or glycopeptide resistant susceptibilities (GRSA/VRSA);

3.3.b.24. Tuberculosis (all forms, including antibiotic susceptibility patterns)*;

3.3.b.25. 3.3.b.12. Tularemia;

3.3.b.26. Typhoid Fever;

3.3.b.13. Viral hemorrhagic fevers, including filoviruses such as ebola and Marburg and arenaviruses such as lassa fever; and

3.3.b.27. 3.3.b.14. Waterborne disease, outbreak, suspect or confirmed.

3.3.b.28. Yellow Fever.

- 3.3.c. Reports of Category I.A diseases and conditions marked with one(1) asterisk (*) shall be made on the tuberculosis report form. Others should be submitted on standard reporting cards and supplemental forms.
- 3.3.c. Reports of Category I.A diseases and conditions should be submitted on standard reporting cards and supplemental forms or preferably by filing an electronic report with WVEDSS, in accordance with the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep).
- 3.3.d. Category I.B diseases and conditions reportable by laboratories are:

3.3.d.1. Bacillus anthracis;

3.3.d.2. Bordatella pertussis, microbiologic evidence;

3.3.d.2. Bioterrorist event, suspect or confirmed;

3.3.d.3. Brucellosis, microbiologic or serologic evidence;

3.3.d.4. 3.3.d.3. Clostridium botulinum, microbiologic or toxicologic evidence;

3.3.d.5. Corynobacterium diphtheriae, microbiologic or histopathologic evidence;

3.3.d.6. Dengue Fever, serologic evidence;

3.3.d.7.Enterohemorrhagie
Escherichia coli (EHEC) including but not limited to E. coli O157:H7 and Shiga like toxin producing E. Coli O157:NM, from any clinical specimen;

3.3.d.4. Foodborne outbreak, suspect or confirmed;

3.3.d.5. Francisella tularensis;

3.3.d.8. Haemophilus influenzae from any normally sterile body site;

3.3.d.9. Hepatitis A, positive IgM;

3.3.d.10. Hepatitis B, positive anti-HBc IgM or HBsAg;

3.3.d.11. Hepatitis D, positive serology;

3.3.d.6. Intentional exposure to an infectious agent; suspect or confirmed;

3.3.d.12. Neisseria meningitidis from a normally sterile site;

3.3.d.7. Orthopox infection, virologic, electron microscopic or molecular evidence;

3.3.d.13. 3.3.d.8. Outbreak or cluster of any illness or condition - suspect or confirmed;

3.3.d.14. Poliomyelitis, virologic or serologic evidence;

3.3.d.15. Rabies, animal or human;

3.3.d.16. Rubella, virologie or serologie evidence;

3.3.d.17. 3.3.d.9. Rubeola (measles), virologic or serologic evidence;

3.3.d.18. Salmonella typhi from any site:

3.3.d.10. SARS coronavirus infection, serologic evidence or PCR;

3.3.d.19. 3.3.d.11. Smallpox, virologic or serologic evidence;

3.3.d.20. Staphylococcus aureus with glycopeptide intermediate (GISA/VISA) or glycopeptide resistant (GRSA/VRSA) susceptibilities;

3.3.d.21. Tularemia, culture, antigen or serologic evidence;

3.3.d.22. Vibrio cholerae, microbiologic or serologic evidence;

3.3.d.23. Yellow Fever, virologic or serologic evidence;

3.3.d.12. Viral hemorrhagic fever;

3.3.d.13. Waterborne outbreak, suspect or confirmed;

3.3.d.24. 3.3.d.11. Yersinia pestis, microbiologic or serologic evidence; and

3.3.d.25. 3.3.d.12. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category I.A.

3.4. Category II Reportable Diseases and Conditions.

3.4.a. Health care providers, health care facilities and laboratories shall report cases of Category II diseases or conditions <u>listed in this section by telephone</u> to the local health department in serving the patient's county of residence within one (1) week twenty-four hours of diagnosis,

preferably by filing an electronic report with WVEDSS. When WVEDSS is certified as operational by the commissioner, the local health department shall use WVEDSS to file the report. The reports Reports from providers shall include the patient's name, address, telephone number, date of birth, sex, and the patient's physician's name, office address, office phone and fax numbers, and any other information requested by the commissioner relevant to the purposes of this rule. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex; and the physician's name, office address, office phone and fax numbers; name of person or agency submitting the specimen for testing, specimen source, date of specimen collection, date of result, name of the test, test result, normal value or range; and name, address, phone and fax number of the laboratory

3.4.b. Category ILA diseases <u>and</u> <u>conditions</u> reportable by health care providers and health care facilities are:

3.4.b.1. Amebiasis;

3.4.b.1. Animal bites;

3.4.b.2. Brucellosis;

3.4.b.2. Campylobacteriosis;

3.4.b.3. Chickenpox (numerical

totals only);

3.4.b.3. Cholera;

3.4.b.4. Cryptosporidiosis;

3.4.b.5. Cyclospora;

3.4.b.4. Dengue Fever;

3.4.b.5. Diphtheria;

3.4.b.6. Ehrlichiosis;

3.4.b.7. Encephalitis, Arboviral;

3.4.b.8. Encephalitis, other primary and unspecified;

3.4.b.6. Enterohemorrhagic

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Escherichia co	oli (EHEC) including but not limited	cough);
to E. coli O15	<u>'7:H7;</u>	3.4.b.14. Poliomyelitis;
	3.4.b.9. Giardiasis;	2.4.1.5 Ofman (apriolla
Invasive Dise	3.4.b.7. Haemophilus influenzae, ase;	3.4.b.15. Q-fever (coxiella burnetii);
	3.4.b.10. Hantavirus Disease;	3.4.b.16. Rabies; human or animal;
Syndrome, po	3.4.b.8. Hemolytic Uremic stdiarrheal;	3.4.b.20. Psittacosis;
		3.4.b.21. Rheumatic Fever;
including retransaminase	3.4.b.9. Hepatitis A, acute, esults of hepatitis serologies, levels and bilirubin;	3.4.b.22. Rocky Mountain Spotted Fever;
	3.4.b.10. Hepatitis B, acute,	3.4.b.17. Rubella;
_	rinatal, including results of hepatitis cologies, transaminase levels and	3.4.b.23. 3.4.b.18. Rubella, Congenital Syndrome;
3.4.b.11. Hepatitis D including results of hepatitis A and B seologies, transaminase levels and bilirubin;		3.4.b.24.—Salmonellosis (except Typhoid Fever);
		3.4.b.25. Shigellosis;
3.4.b.11. Influenza-like illness (numerical totals only);		3.4.b.26. Streptococcal Disease,
	3.4.b.12. Legionellosis;	invasive Group A, (Streptococcus pyogenes);
	3.4.b.13. Leptospirosis;	3.4.b.27. Streptococcal Disease, invasive Group B;
	3.4.b.14. Listeria;	3.4.b.28. Streptococcal Toxic
	3.4.b.15. Lyme Disease;	Shock Syndrome;
	3.4.b.16. Malaria;	3.4.b.29. Streptococcus pneumoniae, invasive disease, (include antibiotic susceptibility patterns);
3.4.b.17. Meningitis, Other Bacterial (cases not reported as other specific		3.4.b.19. Staphylococcus aureus
disease types)	3.4.b.12. Meningococcal Disease,	with glycopeptide-intermediate (GISA/VISA) or glycopeptide-resistant (GRSA/VRSA) susceptibilities, including results of susceptibility testing;
,	3.4.b.18. Meningitis, Viral or	3.4.b.30. Tetanus;
Aseptic;		3.4.b.31. Toxic Shock Syndrome;
	3.4.b.19. Mumps;	3.4.b.32. Trichinosis;
	3.4.b.13. Pertussis (whooping	

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3.4.b.33. 3.4.b.20. Tuberculosis; latent infection (limited to individuals with a positive Mantoux tuberculin skin test conversion in the last 2 years or any positive Mantoux tuberculin skin test in a child less than 5 years of age); and all forms, including antibiotic susceptibility patterns;

3.4.b.21. Typhoid fever (salmonella typhi);

3.4.b.22. Yellow fever; and

3.4.b.34. Any unexplained or illdefined illness, condition, or health occurrence of potential public health significance.

- 3.4.b.24. Any other unusual condition or emerging infectious disease of potential public health importance;
- 3.4.c. Reports of Category II.A diseases and conditions are reported on standard reporting cards shall be submitted on reporting cards and supplemental forms as listed in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep) or preferably by filing an electronic report with WVEDSS.
- 3.4.d. Category II.B <u>diseases and</u> conditions reportable by laboratories are:
- 3.4.d.1. Borrelia burgdorferi from culture, or diagnostic levels of IgG or IgM, (preferably followed by a Western blot);
- 3.4.d.1. Bordatella pertussis, microbiologic or molecular evidence;
- 3.4.d.2. Brucellosis, microbiologic or serologic evidence;

3.4.d.2. Campylobacter;

3.4.d.3. Cryptosporidium;

3.4.d.4. Cyclospora;

3.4.d.3. Corynebacterium diphtheriae, microbiologic or histopathologic evidence;

3.4.d.4. Coxiella burnetii;

- 3.4.d.5. Dengue Fever, serologic evidence;
- 3.4.d.5. Ehrlichiosis, serologie, microbiologic or other evidence;
- 3.4.d.6. Encephalitis, virologic, serologic, or other evidence of arboviral or other encephalitides;

3.4.d.7. Entamoeba histolytica;

- 3.4.d.6. Enterohemorrhagic Escherichia coli (EHEC) including but not limited to E. coli O157:H7 and Shiga-like toxin-producing E. Coli O157:NM, from any clinical specimen;
- 3.4.d.8. Giardia lamblia, microscopic or immunodiagnostic evidence;
- 3.4.d.7. *Haemophilus influenzae* from any normally sterile body site, including results of susceptibility testing;
- 3.4.d.9. Hantavirus infection, serologic, PCR, immunohistochemistry, or other evidence;
- 3.4.d.8. Hepatitis A, positive IgM, including transaminase and bilirubin levels;
- 3.4.d.9. Hepatitis B, positive anti-HBc IgM or HBsAg, including hepatitis A serologies and transaminase and bilirubin levels;
- 3.4.d.10. Hepatitis D, positive serology, including hepatitis A and B serologies and transaminase and bilirubin levels;
- 3.4.d.10. Influenza, culture confirmed, (numerical totals only, by type and subtype as available):
- 3.4.d.11. Legionnella, bacteriologic or serologic evidence;
- 3.4.d.12. Leptospirosis, virologic or serologic evidence;

3.4.d.13. Listeria monocytogenes;

3.4.d.14. Malaria organisms on smear

of blood;

3.4.d.15. Meningitis, as indicated by bacterium in spinal fluid;

3.4.d.16. Meningitis, Viral, virologic or serologic evidence;

3.4.d.17. Mumps, virologic or serologic evidence;

3.4.d.11 Mycobacerium tuberculosis from any site (include drug susceptibility patterns);

3.4.d.12. Neisseria meningitidis from a normally sterile site;

3.4.d.18. Psittacosis, microbiologic or serologic evidence;

3.4.d.19. Rocky Mountain Spotted Fever, serologic evidence;

3.4.d.20. Salmonella (any species, excluding Salmonella typhi);

3.4.d.21. Shigella (any species);

3.4.d.22. Streptococcus pyogenes (Group A Streptococcus) from a normally sterile site:

3.4.d.23. Streptococcus, Group B, from a normally sterile site;

3.4.d.24. Streptococcus pneumoniae, from a normally sterile site (include antibiotic susceptibility patterns on all isolates);

3.4.d.25. Trichinosis, demonstration of cysts or serologic evidence;

3.4.d.26. Unexplained or ill-defined illness, condition, or health-occurrence of potential public health significance; and

3.4.d.27. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category II.A.

3.4.d.13. Poliomyelitis, virologic or

serologic evidence;

3.4.d.15. Rabies, animal or human;

3.4.d.16. Rubella, virologic or serologic evidence;

3.4.d.17. Salmonella typhi from any site;

3.4.d.18. Staphylococcus aureus with glycopeptide-intermediate (GISA/VISA) or glycopeptide-resistant (GRSA/VRSA) susceptibilities, including the results of susceptibility testing;

3.4.d.19. Vibrio cholerae, microbiologic or serologic evidence;

3.4.d.20. Yellow Fever, virologic or serologic evidence;

3.4.d.21. Any other unusual condition or emerging infectious disease of public health importance; and

3.4.d.27. 3.4.d.22. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category IIA.

3.5. Category III Reportable Diseases and Conditions.

3.5.a. Health care providers, health care facilities and laboratories shall report cases of Category III diseases and conditions to the division within one (1) week of diagnosis unless otherwise indicated, the local health department serving the patient's county of residence within seventy-two hours of diagnosis, preferably by filing an electronic record in WVEDSS. The local health department shall report the case to the bureau within seventy-two hours of receiving the report. When WVEDSS is certified as operational by the commissioner, the local health department shall use WVEDSS to file the report and when electronic laboratory reporting is certified as operational, laboratories with automatic reporting capability shall report Category III diseases and Reports from health care conditions daily. providers and health care facilities shall include the patient's name, address, telephone number, date of birth, sex, and the patient's physician's name, office address, and office phone and fax numbers, and any other information requested by the commissioner relevant to the purposes of this rule. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex; and the physician's name, office address, office phone and fax numbers; name of person or agency submitting the specimen for testing, specimen source, date of specimen collection, date of result, name of the test, test result, normal value or range; and name, address, phone and fax number of the laboratory.

3.5.b. Category III.A diseases and conditions reportable by health care providers and health care facilities are:

3.5.b.1. AIDS diagnosed from the presence of AIDS defining diseases or conditions (including previously reported HIV positive individuals), according to the time frame in, the Bureau for Public Health rule, AAIDS Related Medical Testing and Confidentiality,@ 64CSR64.

3.5.b.1. Amebiasis;

3.5.b.2. Autism Spectrum Disorder; not reported to the Bureau according to the protocol in the West Virginia Reportable Diseases Protocol Manual.

3.5.b.3. Birth Defects, including Down=s Syndrome;

3.5.b.2. Campylobacteriosis;

3.5.b.4.—Cancer, including non-malignant intra cranial and central nervous system tumors, in time frame noted in Bureau for Public Health rule, ACancer Registry,@ 64CSR68;

3.5.b.5. Chancroid**:

3.5.b.6. Chlamydia trachomatis**;

3.5.b.3. Cryptosporidiosis;

3.5.b.4. Cyclospora;

3.5.b.5. Giardiasis;

3.5.b.7. Gonococcal Disease**
conjunctivitis in the newborn, drug resistant
disease, or pelvic inflammatory disease (within 24
hours);

3.5.b.8. Gonorrhea (all other)**;

3.5.b.9. Hemophilia;

3.5.b.10. Hepatitis C/Other non-A or non-B, acute or chronic;

3.5.b.11. Herpes, genital**;

3.5.b.12. HIV (Human Immunodeficiency Virus) according to the time frame in the Bureau for Public Health rule, AAIDS Related Medical Testing and Confidentiality, A 64CSR64;

3.5.b.13. Lead, all blood lead test results:

3.5.b.6. Listeria;

3.5.b.14. Occupational illnesses;

3.5.b.7. Salmonellosis (except Typhoid Fever), including results of susceptibility testing;

3.5.b.8. Shigellosis, including the results of susceptibility testing;

3.5.b.15. Syphilis (late latent, late symptomatic, or neurosyphilis)**;

3.5.b.16. Syphilis** — primary, secondary, early latent (less than one (1) year), or congenital (all within 24 hours); and

3.5.b.17. Traumatic Brain Injury, not reported to the Bureau according to the protocol in the West Virginia Reportable Diseases Protocol Manual.

3.5.b.9. Trichinosis; and

3.5.b.10. Yersiniosis.

3.5.c. Reports of Category III.A diseases and conditions marked with two asteriska (**) are

made on the sexually transmitted disease report eard (VD-91). are reported on reporting cards and supplemental forms as listed in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep). When WVEDSS is certified as operational by the commissioner, all reporters shall use WVEDSS to file their reports.

3.5.d. Category III.B diseases and conditions reportable by laboratories are:

3.5.d.1. CD4+ T-lymphocyte counts of two hundred or less per cubic millimeter (200/mm³) or a percentage less than fourteen (14) percent according to the time frame in the Bureau for Public Health rule, AAIDS Related Medical Testing and Confidentiality,@ 64CSR64.

3.5.d.1. Campylobacter species;

3.5.d.2. Chlamydia trachomatis by culture, antigen, DNA probe methods, or other procedures declared reportable by the commissioner**;

3.5.d.2. Cryptosporidium;

3.5.d.3. Cyclospora;

3.5.d.3. Down's Syndrome chromosomal anomaly;

3.5.d.4. Haemophius ducrevi**:

3.5.d.5. Hepatitis C / Other non-A or non-B, virologic or serologic evidence;

3.5.d.4. Entamoeba histolytica;

3.5.d.5. Giardia lamblia, microscopic or immunodiagnostic evidence;

3.5.d.6. Herpes simplex virus**, isolation of herpes simplex virus from cervix, urethra or anogenital lesion, or demonstration of virus by antigen detection technique in clinical specimens from cervix, urethra or anogenital lesion, or demonstration of multinucleated giant cells on a Tzanck smear of scrapings from an anogenital lesion;

3.5.d.7. HIV (Human Immunodeficiency Virus) Type 1 or 2, confirmed antibody or virus detection test (serology, culture, antigen, PCR, DNA, RNA probe, etc.), according to the time frame in the Bureau for Public Health rule, AAIDS Related Medical Testing and Confidentiality,@ 64CSR64.

3.5.d.8. Lead, all blood lead test results:

3.5.d.6. Listeria monocytogenes;

3.5.d.9. Mycobacterium tuberculosis from any site (include drug susceptibility patterns) (within 24 hours);

3.5.d.10. Neisseria gonorrheae (drug resistant) from any site** (within 24 hours);

3.5.d.11. Neisseria gonorrheae from female upper genital tract** (within 24 hours);

3.5.d.12. Neisseria gonorrheae from the eye of a newborn** (within 24 hours);

3.5.d.13. Neisseria gonorrheae**, culture or other positive laboratory evidence, (all other);

3.5.d.7. Salmonella (any species, excluding Salmonella typhi), including the results of susceptibility testing;

3.5.d.8. Shigella (any species), including the results of susceptibility testing;

3.5.d.14. Syphilis**, serologic evidence:

3.5.d.15. Treponema pallidum, positive dark field examination** (within 24 hours); and

3.5.d.9. Trichinosis, demonstration of cysts or serologic evidence;

3.5.d.10. Yersinia enterocolitica, microbiologic evidence; and

3.5.d.16. 3.5.d.11. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category III.A.

3.5.e. Reports of Category III.B diseases and conditions marked with two asterisks (**) are made on the appropriate sexually transmitted disease report forms provided by the division.

3.6. Category IV Reportable Diseases and Conditions.

3.6.a. Health care providers, health care facilities and laboratories shall report cases of Category IV diseases or conditions to the local health department serving the patient's county of residence within one week of diagnosis, preferably by filing an electronic report with WVEDSS. The local health department shall report the case to the bureau within one week of receiving the report. When WVEDSS is certified as operational by the commissioner, the local health department shall use WVEDSS to file the report.

Reports from health care providers and health care facilities shall include the patient's name, address, telephone number, date of birth, sex, race, and the patient's physician's name, office address and office phone and fax, and any other information requested by the commissioner relevant to the purposes of this rule.

Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex, race, and the physician's name, office address, office phone and fax numbers; name of person or agency submitting the specimen for testing, specimen source, date of specimen collection, date of result, name of the test, test result, normal value or range; and name, address, phone and fax number of the laboratory. When electronic laboratory reporting is certified as operational by the commissioner, laboratories with automatic reporting capability shall report Category IV diseases on a daily basis.

3.6.b. Category IV.A diseases reportable by health care providers and health care facilities are:

3.6.b.1. Arboviral infection:

3.6.b.2. Chickenpox (numerical

totals only);

3.6.b.3 Community-acquired

methicillin-resistant Staphylococcus aureus, invasive, include susceptibility patterns;

3.6.b.4. Erlichiosis;

3.6.b.5. Hantavirus Pulmonary

Syndrome;

3.6.b.6. Influenza-like illness (numerical totals only);

3.6.b.7. Influenza-related death in an individual less than 18 years of age;

3.6.b.8. Legionellosis;

3.6.b.9. Leptospirosis;

3.6.b.10. Lyme Disease;

3.6.b.11. Malaria;

3.6.b.12. Mumps;

3.6.b.13. Psittacosis;

3.6.b.14. Rocky Mountain Spotted

Fever;

3.6.b.15. Streptococcal Disease, invasive Group A, (Streptococcus pyogenes), including results of susceptibility testing;

3.6.b.16. Streptococcal Disease, invasive Group B;

3.6.b.17. Streptococcal Toxic Shock Syndrome;

<u>3.6.b.18.</u> Streptococcus pneumoniae, invasive disease, (include antibiotic susceptibility patterns);

3.6.b.19. Tetanus;

3.6.b.20. Toxic Shock Syndrome;

and

3.6.b.21. Tuberculosis, latent infection (limited to individuals with a positive Mantoux tuberculin skin test conversion in the last two years or any positive Mantoux tuberculin skin test in a child less than five years of age).

- 3.6.c. Reports of Category IV.A diseases and conditions are reported on reporting cards and supplemental forms as listed in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep). When WVEDSS is certified as operational by the commissioner, all reporters shall use WVEDSS to file their reports.
- 3.6.d. Category IV.B conditions reportable by laboratories are:
- 3.6.d.1. Arboviral infection, virologic, serologic, or other evidence;
- 3.6.d.2. Borrelia burgdorferi from culture, or diagnostic levels of IgG or IgM, (with Western blot confirmation);
- <u>3.6.d.3.</u> Ehrlichiosis, serologic, microbiologic or other evidence;
- 3.6.d.4. Hantavirus infection, serologic, PCR, immunohistochemistry, or other evidence;
- <u>3.6.d.5. Legionella, bacteriologic</u> or serologic evidence;
- 3.6.d.6. Leptospirosis, virologic or serologic evidence;
- 3.6.d.7. Malaria organisms on smear of blood;
- 3.6.d.8. Mumps, virologic or serologic evidence;
- 3.6.d.9. Psittacosis, microbiologic or serologic evidence;
- 3.6.d.10. Rocky Mountain Spotted Fever, serologic evidence;
- 3.6.d.11. Streptococcus pyogenes (Group A Streptococcus) from a normally sterile site;
- 3.6.d.12. Streptococcus, Group B, from a normally sterile site;

- <u>3.6.d.13.</u> Streptococcus pneumoniae, from a normally sterile site (include antibiotic susceptibility patterns on all isolates); and
- 3.6.d.14. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category IV.A.
- 3.7. Category V Reportable Diseases and Conditions.
- 3.7.a. Health care providers, health care facilities and laboratories shall report Category V diseases and conditions, preferably by WVEDSS to the bureau within one week of diagnosis unless otherwise indicated. Reports shall include the patient's name, address, telephone number, date of birth, sex, the patient's physician's name, office address, and office phone and fax, and any other information requested by the commissioner relevant to the purposes of this rule.
- 3.7.b. <u>Category V.A diseases and conditions reportable by health care providers and health care facilities are:</u>
- 3.7.b.1. AIDS diagnosed from the presence of AIDS defining diseases or conditions (including previously reported HIV positive individuals), according to the time frame in the bureau rule, "AIDS Related Medical Testing and Confidentiality", 64CSR64 **.
- <u>3.7.b.2. Autism Spectrum</u> <u>Disorder; reportable to researchers at</u> http://www.marshall.edu/wvasdr/
- 3.7.b.3. Birth Defects, including Down's Syndrome;
- 3.7.b.4. Cancer, including non-malignant intra cranial and central nervous system tumors, in time frame noted in the bureau rule, "Cancer Registry," 64CSR68;
 - 3.7.b.5. Chancroid; **
 - 3.7.b.6. Chlamydia;**
 - 3.7.b.7. Enterovirus (non-polio),

culture confirmed, (numerical totals only, by serotype as available, and including echovirus, coxsackievirus, and parechovirus):

3.7.b.8. Gonococcal Disease**--conjunctivitis in the newborn or drug-resistant disease (within 24 hours);

3.7.b.9. Gonorrhea (all other sites);**

3.7.b.10. Hemophilia;

3.7.b.11. Hepatitis C / Other non-A or non-B, acute or chronic, including results of hepatitis A and B serologies and transaminase and bilirubin levels;

3.7.b.12. HIV (Human Immunodeficiency Virus) according to the time frame in the bureau rule, "AIDS Related Medical Testing and Confidentiality", 64CSR64;**

3.7.b.13. Influenza, culture confirmed, (numerical totals only, by type and subtype, as available);

3.7.b.14. Lead, all blood lead test results;

3.7.b.15. Occupational illnesses;

3.7.b.16. Pelvic inflammatory

disease;**

3.7.b.17. Syphilis (late latent, late symptomatic, or neurosyphilis);**

3.7.b.18. Syphilis** -- primary, secondary, early latent (less than one (1) year), or congenital (all within 24 hours); and

3.7.b.19. Traumatic Brain Injury, reportable to researchers at the WV Department of Vocational Rehabilitation through the bureau's website at http://www.wvdhhr.org/idep.

3.7.c. Reports of Category V.A. diseases and conditions are submitted on forms as specified in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep).

3.7.d. Category V.B. diseases and conditions reportable by laboratories are:

3.7.d.1. All CD4+ T-lymphocyte or percentages according to the time frame in the bureau rule, "AIDS Related Medical Testing and Confidentiality", 64CSR64.

3.7.d.2. Chlamydia trachomatis by culture, antigen, DNA probe methods, or other positive laboratory evidence:*;

3.7.d.3. Down's Syndrome chromosomal anomaly;

3.7.d.4. Haemophilus ducreyi;**

3.7.d.5. Hepatitis C / Other non-A or non-B, virologic or serologic evidence, including results of hepatitis A and B serologies and transaminase and bilirubin levels;

3.7.d.6. HIV (Human Immunodeficiency Virus) Type 1 or 2, confirmed antibody or virus detection test (serology, culture, antigen, PCR, DNA, RNA probe, etc.), according to the time frame in the bureau rule, "AIDS Related Medical Testing and Confidentiality", 64CSR64;**

3.7.d.7. Lead, all blood lead test

results;

3.7.d.8. Mycobacterium tuberculosis from any site** (include drug susceptibility patterns) (within 24 hours);

3.7.d.9. Neisseria gonorrheae (drug resistant) from any site** (within 24 hours);

<u>3.7.d.10. Neisseria gonorrheae</u> from female upper genital tract** (within 24 hours);

3.7.d.11. Neisseria gonorrheae from the eye of a newborn** (within 24 hours);

3.7.d.12. Neisseria gonorrheae**, culture or other positive laboratory evidence, (all other);

3.7.d.13. Syphilis**, serologic

evidence;

3.7.d.14. Treponema pallidum, positive dark-field examination** (within 24 hours); and

3.7.d.15. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category V.A.

3.7.e. Reports of Category V diseases and conditions marked with two (2) asterisks (**) shall be made on the appropriate STD/HIV/AIDS and TB report forms provided by the bureau, until such time as these diseases can be reported electronically using the WVEDSS.

§64-7-4. Other Reportable Events: Birth Defects.

4.1. The commissioner shall arrange for the reporting of birth defects as soon as detected by pediatric health care providers or human genetic services providers. Birth defects are also identified from birth certificates and health care facility medical records. After case review, evaluation and referrals, reports are consolidated in the Maternal and Child Health database. The division bureau shall provide appropriate report forms for this reporting.

§64-7-5. Other Reportable Events: Potentially Rabid Animal Bites, Rabid Animals, Rabies Pre-Exposure Vaccinations and Post-Exposure Prophylaxis.

- 5.1. If a person is bitten, scratched, or otherwise exposed (gets saliva, neural tissue, or other potentially infectious fluid into an open cut, wound, or mucous membrane) to an animal which has or is suspected of having rabies, then the incident, including the person's full name, date of birth, and address, shall be reported to the local health officer within twenty-four hours, by phone, or preferably by WVEDSS, by the following individuals:
- 5.1.a. The physician or other health care provider caring for or observing the person;

- 5.1.b. The veterinarian or animal health care provider;
- 5.1.b. 5.1.c. The person bitten, scratched, or otherwise exposed, if no physician or other health care provider is in attendance and the person bitten, scratched or otherwise exposed is an adult;
- 5.1.e. 5.1.d. Whoever is caring for the person, if no physician or other health care provider is in attendance and the person bitten, scratched, or otherwise exposed is incapacitated; or
- 5.1.d. 5.1.e. The parent or guardian, if no physician or other health care provider is in attendance and the person bitten, scratched or otherwise exposed is a child.
- 5.2. The local health officer shall report <u>within</u> <u>twenty-four hours</u> to the commissioner the name, date of birth, address, circumstances of the exposure, and action taken for every person bitten, scratched, or otherwise exposed to an animal which has or is suspected of having rabies.
- 5.3. If the animal is a domestic dog, or cat or ferret, the local health officer shall make a reasonable attempt to determine the animal's owner, and, if successful, shall direct the owner to confine the animal for a period of ten days. The owner of the dog, or cat or ferret, county humane officer, dog warden or sheriff shall notify the local health officer immediately if the animal shows symptoms compatible with rabies or dies, and the local health officer, county humane officer, dog warden or sheriff shall arrange for appropriate examination of the animal's brain at the office of laboratory services.
- 5.4. If the local health officer cannot determine the owner of the domestic dog, of cat or ferret, he or she shall direct the county humane officer, dog warden or sheriff to pick up the suspect dog, of cat or ferret, that has bitten a person and confine it in isolation for a period of ten days. If the animal shows symptoms compatible with rabies, including if the animal bit someone without provocation, or if the animal demonstrates aggressive behavior toward human beings such that the animal may pose a continuing risk to other people, the local health officer shall direct the county humane

officer, dog warden, sheriff, or other designee to humanely destroy the animal and arrange for appropriate examination of the animal's brain. If the animal dies, the local health officer shall arrange for appropriate examination of the animal's brain at the office of laboratory services.

- 5.5. If a person is reported bitten by any animal having or suspected of having rabies other than a domestic dog, or cat or ferret, especially a wild mammal or hybrid, the local health officer, if necessary, shall may direct the county humane officer, dog warden, sheriff, or other designee to have the animal humanely destroyed immediately and to arrange for appropriate examination of the animal's brain at the office of laboratory services.
- 5.6. Any person who becomes aware of the existence of an animal apparently afflicted with rabies shall report the existence of the animal, the place where it was last seen, the owner's name, if known, and the symptoms suggesting rabies to the local health officer immediately.
- 5.7. Health care providers, health care facilities, local health officers and other facilities administering rabies pre-exposure vaccination or post-exposure prophylaxis shall report vaccinations and treatment administered to WVEDSS.

§64-7-6. Other Reportable Events: Administration of Immunizations.

- 6.1. The commissioner shall establish and maintain a centralized registry for tracking compliance with nationally recommended immunization schedules and for monitoring vaccine use.
- 6.2. Health care providers, health care facilities, local health officers, and any other provider or facility administering immunizations shall report immunizations administered to the centralized immunization registry as required by this rule. Administration of immunization against the following diseases are reportable: diphtheria, whooping cough, tetanus, polio, measles, mumps, rubella, hepatitis-B, Haemophilus influenzae type b disease, chickenpox, peumococcal diseases, meningococcal diseases and any additional immunizations required by the commissioner for public health purposes as published by an order

filed with the secretary of state.

- 6.3. All immunizations administered to children of ages six (6) persons eighteen years of age and under shall be reported to the immunization registry within two weeks of the administration of the immunization. Immunizations of adults may also be reported to maintain an accurate and useful database of all immunization information.
- 6.4. Immunization reports shall contain the name of the <u>ehild person</u> receiving the immunization, his or her address, date of birth, mother's maiden name, information on the immunization administered, and any other information required by the commissioner for development, maintenance, and use of the immunization registry and vaccine tracking system.
- 6.5. Immunization data that must be reported to the department is confidential, except it may be shared with other health care providers, or other entities with a legally defined access to the data, who are enrolled in the system, without the specific consent of the parent or patient. The data shall only be used for the ongoing care of the patient to assess immunization status, to determine immunization coverage rates, to assist in outbreak investigations or for other purposes determined by the commissioner.
- 6.6 Local health officers and other health care providers identified by the state health officer as smallpox vaccination clinics and charged with the responsibility of providing and administering smallpox vaccinations shall report smallpox vaccine administration information to the state health officer through the first responder immunization tracking system within twenty-four hours.
- 6.7 In the event of an influenza or other pandemic or a bioterroist event or intentional exposure to an infectious agent, local health departments or other health care providers charged with administering prophylactic medication or vaccinations shall report administration to the commissioner via an electronic database within 24 hours of the administration of the prophylactic medication or vaccination.

§64-7-7. Other Reportable Events: Disease Outbreaks.

- 7.1. When a health care facility, health care provider or laboratory becomes aware of a community outbreak, the outbreak shall be reported to the local health officer immediately.
- 7.2. When the local health officer becomes aware of an outbreak in his or her jurisdiction, he or she shall notify the bureau immediately.
- 7.3. As appropriate, the local health officer shall collaborate in investigation of the outbreak with:
- 7.3.a. Other local health officers if cases from other local health jurisdictions are identified;
- 7.3.b. Public health officials from other states if cases from those states are identified;
 - 7.3.c. The department; and
 - 7.3.d. Federal public health officials.
- 7.4. An appropriate investigation generally includes:
- 7.4.a. Establishment of the existence of the outbreak;
- 7.4.b. Confirmation of the diagnosis, including obtaining appropriate laboratory examinations of cases;
- 7.4.c. Formulation of an appropriate case definition;
- 7.4.d. Notification of laboratories and providers in the jurisdiction to identify and report additional cases;
- 7.4.e. Systematic collection of demographic and epidemiological information on the cases;
- 7.4.f. Formulation and implementation of control measures to stem the spread of the outbreak;
 - 7.4.g. Formulation and implementation of

- special studies to determine the source of the outbreak; and
- 7.4.h. Summarization of the findings of the outbreak investigation in written form.
- 7.5. In the process of outbreak investigation, the commissioner, in collaboration with the local health officer, may perform epidemiological studies, including case-control, cross-sectional and cohort studies which involve interviews and evaluations of ill persons and well persons. Interviews and evaluations of ill and well persons are confidential and not discoverable under the state freedom of information act, WV Code §29B-1-1, et seq. Information may only be released in aggregate for the purpose of informing the public of the conclusions of the investigation.
- 7.6. In the process of outbreak investigation, the commissioner, in collaboration with the local health officer, may request laboratory studies on ill persons and/or well persons. Laboratory results obtained on ill and well persons are confidential and not discoverable under the state freedom of information act, WV Code 29B-1-1 et seq. Information may only be released in aggregate for the purposes of informing the public of the conclusions of the investigation.

§64-7-8. Other Reportable Events: Surveillance program evaluation and special studies.

- 8.1. As necessary, the commissioner may conduct special studies to evaluate the completeness, timeliness and accuracy of the surveillance and epidemiological information reported under this rule. In the process of conducting program evaluation, the commissioner may request any of the following information from providers, facilities, laboratories, or other individuals named in this rule:
- 8.1.a. Computerized or paper reports of cases diagnosed during a limited timeframe, usually during a one year interval, but not more than five years;
- 8.1.b. Specified laboratory results collected over a limited timeframe, usually during a one year interval, but not more than five years;

- 8.1.c. Access to records to perform audits for completeness, accuracy and timeliness of reporting, or
- 8.1.d. Any other information required to verify the completeness and accuracy of reporting.
- 8.2. In addition, the commissioner may conduct special studies on the health of the population for the purposes of quantifying the risk to the population or access to appropriate prevention and control services or validating information collected through surveillance data. Studies may include cross-sectional studies, casecontrol studies, cohort studies or other similar study designs where ill and well persons are evaluated or interviewed or information is collected on these individuals. All information collected in these studies, whether on ill or well persons is confidential and not discoverable under the state freedom of information act, WV Code 29B-1-1, et seq. Information may be released in aggregate for the purposes of informing the public about the health risk or the quality of the surveillance system.

§64-7-9. Other Reportable Events: Bioterrorism response.

- 9.1. All health care providers, health care facilities, animal health care providers, laboratories and law enforcement personnel shall report suspected or confirmed disease due to a bioterrorism agent immediately by telephone with follow up by other rapid means of notification (fax or WVEDSS) to the local health department in the jurisdiction where the bioterrorist event is identified.
- 9.2. Suspect disease due to bioterrorism agents may be identified by the following epidemiological findings:
- 9.2.a. Unusual temporal or geographic clustering of illness. This might include persons who attended the same public event or gathering, or patients presenting with clinical signs and symptoms that suggest an infectious disease outbreak. More than two persons presenting with an unexplained febrile illness associated with sepsis, pneumonia, respiratory failure, rash or a

- botulism-like syndrome with flaccid paralysis, especially if occurring in otherwise healthy persons;
- 9.2.b. An unusual age distribution for common diseases, such as an increase in what appears to be a chickenpox like illness among adult patients, but which might be smallpox;
- 9.2.c. A large number of cases of acute flaccid paralysis with prominent bulbar palsies, suggestive of a release of botulinum toxin;
- 9.2.d. A laboratory finding characteristic of one of the known bioterrorism agents;
- 9.2.e. An unusually high number of laboratory samples, particularly from the same biologic medium, such as blood or stool cultures;
- 9.2.f. Unusual requests for testing or culturing; or
- 9.2.g. Any other unusual medical, laboratory or epidemiological findings not consistent with known patterns of transmission of naturally-occurring infectious agents.
- 9.3. Bioterrorism agents may include, but are not limited to:
 - 9.3.a. Anthrax (Bacillis anthracis);
- 9.3.b. Botulism (Clostridium botulinum toxin);
 - 9.3.c. Brucellosis (Brucella species);
- 9.3.d. Epsilon toxin of Clostridium perfringens;
- 9.3.e. Food safety threats (e.g., Salmonella species, Escherichia coli O157:H7, Shigella);
 - 9.3.f. Glanders (Burkholderia mallei);
- 9.3.g. Melioidosis (Burkholderia pseudomallei);
 - 9.3.h. Plague (Yersinia pestis);
 - 9.3.i. Psittacosis (Chlamydia psittaci);

- 9.3.j. O fever (Coxiella burnetii);
- 9.3.k. Ricin toxin from Riccinus communis (castor beans);
 - 9.3.1. Smallpox (variola major);
 - 9.3.m. Staphylococcal enterotoxin B;
 - 9.3.n. Tularemia (Francisella tularensis);
- 9.3.o. Typhus fever (Rickettsia prowazekii);
- 9.3.p. Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis];
- 9.3.q. Viral hemorhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo]); and
- 9.3.r. Water safety threats, such as Vibrio cholerae, Cryptosporidium parvum.
- 9.4. In the event of a suspected or confirmed bioterrorist event, the commissioner may designate a disease or condition as immediately reportable by direct notification of local health departments and/or health care providers by any rapid means available. In that situation, the commissioner may request the reporting of cases by phone or by filing an electronic report with WVEDSS.
- 9.5. The local health officer, on notification of a suspected or confirmed bioterrorist event shall immediately notify the bureau by phone 1-800-423-1271 or (304) 558-5358. When WVEDSS is certified as operational by the commissioner, reports shall also be filed with WVEDSS.
- 9.6. As appropriate, the local health officer shall collaborate in an investigation of the bioterrorist event with:
- 9.6.a. Other local health officers if cases from other local health jurisdictions are identified;
- 9.6.b. Public health officials from other states if cases from those states are identified;

- 9.6.c. The department;
- 9.6.d. Federal public health officials; and
- 9.6.e. Law enforcement personnel.
- 9.7. The local health officer shall collaborate in an epidemiological investigation of the bioterrorist event, usually to include a complete outbreak investigation as described in section seven (7) of this rule.
- 9.8 The commissioner shall collaborate with the Federal Bureau of Investigation and other federal, state and local law enforcement, emergency responders and other public safety representatives to develop and use a protocol for sharing information on an investigation.
- 9.8.a. Information may only be shared if the commissioner determines that sharing such information is critical to protecting the public's health.
- 9.8.b. Any information shared shall be protected from further disclosure in a manner consistent with state and federal law and regulations and in accordance with the protocol agreed upon by all parties.

§64-7-10. Syndromic surveillance and electronic laboratory reporting.

10.1 As a part of outbreak and bioterrorism surveillance, the commissioner may establish syndromic surveillance under this rule. The commissioner may create a list of clinical syndromes to be reported by publishing the list in the West Virginia Protocol Manual (available online at www.wvdhhr.org/idep). established, health care facilities may be requested to submit daily reports on the total number of new patients with each syndrome identified within the last 24 hours. The commissioner may request reporting of syndromes from health care facilities, either on an ongoing basis; or for a limited time frame such as during a period of heightened awareness of possible disease outbreaks. Reports may be made by fax, telephone or electronic means. Reports from health care facilities shall include the timeframe of report, the name of the

facility reporting, the number of new admissions during that timeframe, the number of new admissions with each clinical syndrome and any other information requested by the commissioner. Reports from emergency rooms shall include the timeframe of the report, the name of the facility reporting, the number of patient visits during the timeframe, the number of patients with each clinical syndrome, and any other information requested by the commissioner.

- <u>10.2 Clinical syndromes reportable may</u> include:
 - 10.2.a. Acute neurological illness;
 - 10.2.b. Acute vomiting and/or diarrhea;
 - 10.2.c. Death in the emergency room;
- 10.2.d. Febrile illness with flu-like symptoms;
- 10.2.e. Febrile illness with flu-like symptoms and rash;
 - 10.2.f. Pneumonia;
- 10.2.g. Septicemia of unknown etiology; or
- 10.2.h. Other syndromes defined by the commissioner.
- 10.3 When electronic laboratory reporting is certified as operational by the commissioner, laboratories with automatic reporting capability shall report the conditions listed below on a daily basis. These conditions are in addition to conditions reportable in this rule. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex and race; name of person or agency submitting the specimen for testing, specimen source, date of specimen collection, date of result, name of the test, test result, normal value or range; and name, address, phone and fax number of the laboratory. Conditions to be reported include:
- 10.3.a. Adenovirus, by culture, antigen or PCR;

- 10.3.b Enterovirus (non-polio), by culture or PCR; by serotype;
- 10.3.c. Influenza, by culture, antigen or PCR, including type and subtype, as available;
- <u>10.3.d. Parainfluenza virus, by antigen</u> detection or culture;
- 10.3.e. Respiratory syncitial virus, by antigen detection or viral isolation; or
- 10.3.f. Rotavirus, by antigen detection or electron microscopy.

§64-7-7. §64-7-11. Deaths from Reportable Diseases and Conditions; Reportable Diseases and Conditions Diagnosed After Death.

- 7.1. 11.1. Upon receipt of any death certificate showing a reportable disease or condition, except a Category III disease or condition, the State registrar of vital statistics shall send a copy of the death certificate to WVEDSS. to the local health officer for the county in which the death occurred and to the county in which the decedent resided. The State registrar shall report Category III all deaths due to diseases listed in this rule to the division bureau.
- 7.2. 11.2. If a pathologist, coroner, medical examiner, physician, other health care provider, or other individual investigating the cause of death determines from the examination of a corpse or from a history of the events leading to death, that at the time of death, the decedent had a disease or condition required to be reported by this rule, he or she shall report the case promptly as required by this rule as if the diagnosis had been established prior to death.

§64-7-8 §64-7-12. Persons, Facilities, and Laboratories Required to Report; Other Related Responsibilities.

- 8.1. 12.1 Health Care Providers and health care facilities.
- 8.1.a. 12.1.a. Any health care provider who or health care facility who which suspects, diagnoses, or cares for a patient with a disease or condition listed in Subdivisions 3.3.b., 3.4.b.,

3.5.b., or elsewhere in this rule shall:

8.1.a.1. 12.1.a.1. Report the disease or condition as required by this rule;

8.1.a.2. 12.1.a.2. Assist public health officials in appropriate case and outbreak investigation and management and in any necessary contact investigation and management;

8.1.a.3. 12.1.a.3. Make every effort to submit the specimens identified in protocols specified by the commissioner to establish an accurate diagnosis of the disease or condition to a laboratory approved by the commissioner;

8.1.a.4. 12.1.a.4. If the disease or condition is communicable, advise, in consultation with State and local public health officials, the patient, and as necessary, members of the patient's household and other patient contacts regarding the precautions to be taken to prevent further spread of the disease. In cases of sexually transmitted diseases, HIV, and tuberculosis, the division bureau recommends that health care providers and health care facilities refer contact notification activities to the division for STD and HIV STD/HIV/TB program and local health departments for tuberculosis rather than attempt to accomplish the notification themselves;

8.1.a.5. 12.1.a.5. Follow a method of control specified by the commissioner in established protocols in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep), or by methods developed in consultation with the commissioner; and

8.1.a.6. 12.1.a.6. Assist the commissioner or the local health officer by promoting implementation of the control method for the disease or condition specified in the protocol with the patient, and, as applicable, members of the patient's household, facility staff, and other involved individuals; and

12.1.a.7. Assist the commissioner or local health officer in ruling out previously reported cases of infectious diseases by submitting copies of negative laboratory tests of medical evaluations.

8.2. 12.2. Laboratories.

8.2.a. 12.2.a. All laboratories, whether public, private or hospital-based, shall report evidence of current infection with the diseases or conditions listed in Subdivisions 3.3.d., 3.4.d., and 3.5.d. of this rule and shall otherwise comply with the requirements of this rule.

8.2.b. 12.2.b. A laboratory which receives a specimen yielding Mycobacterium tuberculosis shall submit the first isolate to the office of laboratory services, bureau for public health. Additionally, any isolate of M. tuberculosis from a patient collected ninety or more days after the initial specimen shall also be forwarded to the office of laboratory services. The laboratory shall perform or arrange for drug susceptibility testing on the initial isolate from each patient from whom M. tuberculosis was isolated and report the results of that drug susceptibility testing to the local health department in the county where the patient resides, within one working day from the time the person or agency who submitted the specimen is notified. If any subsequent culture of M. tuberculosis is found to have developed new patterns of resistance, an additional culture or subculture of the resistant isolate shall be submitted to the office of laboratory services. Clinical laboratories that identify acid fast bacillus (AFB) on a smear from a patient shall culture and identify the AFB, or refer these to another laboratory for those purposes.

8.2.b.1. 12.2.b.1. Clinical laboratories that isolate Bacillis anthracis, Clostridium botulinum, Corynebacterium diphtheriae, Tularemia. Salmonella, Shigella, Campylobacter, Listeria monocytogenes, or suspect or confirmed E. coli O157:H7 or Yersinia pestis from any patient specimen or Neisseria meningitidis, Streptococcus pneumoniae, or Haemophilus influenzae from a sterile site should submit the first isolate or a subculture of that isolate to the office of laboratory services. In addition, the commissioner may request routine submission of other bacterial isolates by inclusion in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep) and by written notification of laboratories of the specific requirement. During outbreak or other special investigations, the commissioner may request submission of isolates from persons with disease during a timeframe specified by the commissioner.

8.2.b.2. 12.2.b.2. Information that shall be included in any of the specimens listed in this section includes:

8.2.b.2.A. 12.2.b.2.A. The name, address, and date of birth of the patient;

8.2.b.2.B. 12.b.2.B. The specimen accession number or other unique identifier;

8.2.b.2.C. 12.2.b.2.C. The date the specimen was obtained from the patient;

8.2.b.2.D. 12.2.b.2.D. The source of the specimen;

8.2.b.2.E. 12.2.b.2.E. The type of test performed;

8.2.b.2.F. 12.2.b.2.F. The name, address, and telephone and fax number of the submitting laboratory; and

8.2.b.2.G. 12.2.b.2.G. The name, office address, and office telephone and fax number of the physician or health care provider for whom the examination or test was performed.

12.2.b.3. Clinical laboratories that identify virological, serological, electron microscopic or molecular evidence of acute infection with LaCrosse, West Nile, Eastern Equine or St Louis encephalitis; orthopox virus (including smallpox and monkeypox); poliomyelitis; rabies; rubella; rubeola; or SARS coronavirus shall submit an acute specimen to the office of laboratory services for confirmation. In addition, the commissioner may request routine submission of laboratory specimens for confirmation of other diseases by documentation of the request in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep) and by written notification of laboratory directors. During an outbreak or other special investigations, the commissioner may request submission of isolates from persons with disease during a timeframe specified by the commissioner.

- 12.2.b.4. In addition, the laboratory shall assist the commissioner or local health officer in ruling out reported suspect cases of infectious diseases by submitting copies of negative laboratory tests for the condition under evaluation.
- 8.3. 12.3. Administrators of schools, camps, vessels, and department-operated health care facilities.
- 8.3.a. 12.3.a. When no physician or other responsible health care provider is in attendance, the administrator of any school, camp, vessel or department-operated health care facility shall:
- 8.3.a.1. 12.3.a.1. Report any reportable disease or condition occurring in the school, camp, vessel or department-operated health care facility as required by this rule;
- 8.3.a.2. 12.3.a.2. Assist public health officials in appropriate case and outbreak investigation or management and in any necessary contact investigation and management;
- 8.3.a.3. 12.3.a.3. Follow a method of control specified by the commissioner in established protocols in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep) or by recommendations developed in consultation with the commissioner;
- 8.3.a.4. 12.3.a.4. If the disease or condition is communicable, advise, in consultation with state and local public health officials, the patient, and as necessary, members of the patient's household and other patient contacts regarding the precautions to be taken to prevent further spread of the disease. In cases of sexually transmitted diseases, HIV, and tuberculosis the division bureau recommends that health care providers and health care facilities refer contact notification activities to the division for STD and HIV STD/HIV/TB Program and local health departments for tuberculosis rather than attempt to accomplish the notification themselves; and
- 8.3.a.5. 12.3.a.5. Assist the local health officer by promoting implementation of the control method for the disease or condition specified in the protocol with the patient, and, as

applicable, members of the patient's household, facility staff, and other involved individuals.

§64-7-9 §64-7-13. Distribution of Rule.

9.1. The division bureau and health care professional licensing boards and agencies may distribute this rule to licensed health care professionals who have a duty under this rule. Local health departments may copy and distribute this rule to local health care providers at no cost. The rule is also available online from the Secretary of State's office at www.wvsos.com.

§64-7-10 §64-7-14. Responsibilities of Local Health Officers.

- 10.1. 14.1. Local health officers shall comply with the requirements of this rule.
- 10.2. 14.2. Local health officers shall maintain a record of the information they collect and the reports they make pursuant to this rule according to the record retention schedule for the local health department. They shall give the information and reports to their successor.
- 10.3. 14.3. Upon receipt of a reportable disease or condition report, a local health officer shall:
- 10.3.a. 14.3.a. As circumstances require, investigate the source of the disease or condition, identify contacts, look for undetected and unreported cases, and implement the prevention and control methods specified by the protocols in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep), or developed in consultation with the commissioner;
- 10.3.b. 14.3.b. Act in accordance with the protocols established by the commissioner in the West Virginia Reportable Diseases Protocol Manual (available online at http://www.wvdhhr.org/idep), or recommendations developed in consultation with the commissioner;
- 10.3.e. 14.3.c. Determine if required specimens have been collected and submitted; and if not, arrange for collection and submission of the necessary specimens to investigate the case,

determine the source of the infection, and identify infection of contacts, as necessary. Local health officers shall submit specimens to the bureau laboratory or other laboratory approved by the commissioner:

- 10.3.d. 14.3.d. Give the patient, those persons caring for the patient, household members, and other contacts instructions and advice necessary to prevent the spread of the disease or condition; and
- 10.3.e. 14.3.e. Report any disease or condition listed in Subsections 3.3, 3.4, 3.5, or elsewhere in this rule to the division bureau within the time frame specified in each category.
- 10.4. 14.4. If the report received is a death certificate listing a reportable disease or condition, the local health officer shall ascertain whether the disease or condition was reported according to the requirements of this rule prior to the individual's death. As with any other report, the local health officer shall investigate the source of the disease or condition, identify contacts, and look for undetected and unreported cases and implement prevention and control measures as circumstances require.
- 10.5. 14.5. Whenever a local health officer knows of or suspects the existence of any reportable disease or condition, and either no health care provider is in attendance, or the health care provider has failed or refused to comply with this rule, the local health officer shall investigate the alleged reportable disease or condition. If the investigation establishes the existence of a reportable disease or condition, the local health officer shall further investigate, manage, and report the disease or condition as required by this rule.
- 10.6. 14.6. If the local health officer determines that a health care provider, health care facility, laboratory, or other individual named in this rule as responsible for reporting failed to report a reportable disease or condition, the local health officer shall notify the responsible individual or facility and shall request an explanation for the failure to report the disease as required by this rule.
 - 10.7. 14.7. The local health officer shall report

to the commissioner the name and address of the health care provider, health care facility, laboratory, or other responsible individual named in this rule and his or her reason for failure to comply with the requirements of this rule.

§64-7-11. §64-7-15. Management of Undiagnosed Diseases or Conditions Suggesting a Reportable Disease or Condition.

11.1. When presenting symptoms of an undiagnosed disease or condition suggest a reportable disease or condition, the local health officer may initiate and enforce control methods appropriate for the reportable suggested disease or condition until a definitive diagnosis is established. If the disease diagnosed does not require the control measures initiated, then these measures shall be terminated at once immediately.

§64-7-12. §64-7-16. Disputed Diagnoses of Reportable Diseases or Conditions.

12.1. When doubt exists as to the diagnosis of a submitted reportable disease or condition, the local health officer may enforce the protocol and methods of control established by the commissioner for the suspected disease or condition and shall simultaneously notify the commissioner of the case. If the commissioner judges it necessary, he or she shall consult or assist with any investigation needed to make a final decision.

§64-7-13. §64-7-17. Designation of Diseases as Sexually Transmittable.

13.1. As allowed under WV Code §16-4-1 and for the purposes of treatment under WV Code §16-4-10, the following diseases are designated as potentially sexually transmittable: chlamydia trachomatis, gonorrhea (all types), herpes simplex virus type 2, syphilis (all stages), chancroid, lymphogranuloma venereum, human immunodeficiency virus, hepatitis B virus, and any other diseases the commissioner determines sexually transmittable, by order filed with the Secretary of State. The commissioner may, by order filed with the Secretary of State, also remove the designation of diseases he or she has, by order, previously designated.

§64-7-14. §64-7-18. Confidentiality.

- 14.1. 18.1. Any epidemiologic information collected and maintained pursuant to this rule by local health officers or the commissioner which identifies an individual or facility as having or suspected of having a reportable disease or condition, or as having been identified in an epidemiologic investigation is confidential and exempt from disclosure as provided in WV Code §29B-1-1 et seq., the freedom of information act.
- 14.2. 18.2. In the case of an individual, the commissioner or a local health officer may release confidential information identified in Subsection 14.1. 18.1. of this rule to the following:

14.2.a. 18.2.a. The patient;

- 14.2.b. 18.2.b. The patient's legal representative whose authority encompasses the authority to access the patient's confidential information;
- 14.2.e. 18.2.c. Individuals who maintain and operate the data and medical record systems used for the purposes of this rule, if the systems are protected from access by persons not otherwise authorized to receive the information;
- 14.2.d. 18.2.d. The patient's physician or other medical care provider when the request is for information concerning the patient's medical records and is, in the determination of the commissioner or the local health officer, to be used solely for the purpose of medical evaluation or treatment of the patient;
- 14.2.e. 18.2.e. Any individual with the written consent of the patient and of all other individuals identified, if applicable, in the information requested;
- 14.2.f. 18.2.f. Staff of a federal, State, or local health department or other local agency agencies with the responsibility for the control and treatment of disease, to the extent necessary for the agency to enforce specific relevant provisions of federal, State and local law, rules and regulations concerning the control and treatment of disease;

14.2.g. 18.2.g. Medical personnel caring

for a potentially exposed individual to the extent necessary to protect the health or life of the exposed individual;

14.2.h. 18.2.h. The manager of a licensed facility employing the case or suspected case if determined absolutely necessary by the commissioner for protection of the public's health under the following provisions:

14.2.h.1. <u>18.2.h.1.</u> Disclosed information is limited to the name of the individual, the name of the disease, laboratory test results associated with the reportable disease and steps the manager shall take to assure protection of the health of the public; and

14.2.h.2. 18.2.h.2. The personal identity of the employee shall be kept confidential by the manager of the licensed facility to whom a disclosure was made; and

14.2.i. 18.2.i. The persons to whom reports are required to be filed under WV Code §49-6A-1 et seq. regarding children suspected to be abused or neglected, subject to the confidentiality protections of WV Code §§16-4-10, 16-29-1, 16-3C-3, or any other applicable confidentiality code section.

14.3. 18.3. In the case of a licensed facility, the commissioner or a local health officer may release confidential information to the public when there is a clear and convincing need to protect the public's health as determined necessary by the commissioner.

§64-7-15. §64-7-19. Isolation, Quarantine and Placarding.

15.1. 19.1. The authority to implement and terminate quarantine or placarding to prevent spread of a communicable disease or to protect the public from other health hazards rests with the commissioner. This authority extends to local health officers when they are following protocols established by the commissioner for management of reportable diseases and conditions, or established following consultation with the commissioner for these or other health risks.

15.2. 19.2. When an individual or a group of

individuals is suffering from a communicable disease for which isolation is required for the control of the disease, the local health officer may initiate and terminate the necessary isolation, unless the person is in a hospital, nursing home, or other institution. In these cases, the attending physician or other responsible health care provider within the institution shall assume responsibility for isolation and its termination.

15.3. 19.3. No person shall interfere with or obstruct any local health officer in the posting of any placard used to prevent transmission of a communicable disease or exposure to another health hazard. In addition, no person shall conceal, mutilate or remove any placard, except by permission of the local health officer.

15.4. 19.4. In the event a placard is concealed, mutilated or torn down, the occupant or, if there is no occupant, the owner of the premises where the placard was posted shall notify the local health officer of the fact immediately upon discovery.

§64-7-16. §64-7-20. Exclusion from School Due to a Communicable Disease; Readmission.

16.1. 20.1. When a pupil or school personnel member suffers from a communicable disease potentially placing other students or school personnel at risk of disease, the individual may be excluded from school by the local health officer, the individual's physician, or the school administrator acting in accordance with jointly developed the Department of Education rule, "Communicable Disease Control Policy", 126CSR51. and Department rules and communicable disease policies.

16.2. 20.2 When a pupil or school personnel member has been excluded from school due to a communicable disease, the individual may return upon presentation of a certificate of health to school officials from a physician, local health officer or his or her authorized representative stating that the individual is no longer liable to transmit the disease to others. The return is subject to compliance with jointly developed the Department and Department of Education rule, "Communicable Disease Control Policy", 126CSR51 rules and policies governing those eases.

§64-7-17. §64-7-21. Examination and Training of Food Service Workers.

17.1. 21.1. Food service management training or workers' training may be provided by the local health departments at the discretion of the local health officer.

17.2. 21.2. Food service management training courses shall satisfy the local health officer that the training of management personnel will result in suitable training for the other food service workers within that particular food service establishment.

17.3. 21.3. For the protection of the public, the local health officer may advise a medical examination of a food service worker by a physician approved by the local health officer. In addition, the local health officer may exclude the individual from specific work activities until the exam is completed and the individual no longer presents a threat to public health.

17.4. 21.4. The local health officer may require any laboratory examinations necessary to detect any condition in the food service worker or in the food service facility in which the worker is working, whether or not for compensation, which might constitute a hazard to the public's health.

§64-7-18. §64-7-22. Penalties.

18.1. 22.1. Any person listed in Subsection 1.6. of this rule who is subject to the provisions of this rule who fails to report a disease or condition as required by this rule or otherwise fails to act in accordance with this rule is guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than five hundred dollars (\$500), as provided under WV Code §16-1-18. Each violation is considered a separate offense.

18.2. 22.2. Any local health officer who fails or neglects to appropriately investigate cases or suspected cases of reportable diseases or other public health threats reported to him or her by any physician, health care provider or other person, within a reasonable period of time after the receipt of the report, is guilty of neglect of duty and may, at the discretion of the commissioner, be removed from office in accordance with WV Code §§16-2-4

or 16-2A-8.

18.3. 22.3. A local health officer who fails to make the immediate or weekly reports required by this rule in the manner specified by the commissioner is guilty of neglect of duty and may at the discretion of the commissioner, be removed from his or her office according to the provisions of W. Va. Code §§16-2-4 or 16-2A-8. WV Code §16-2-12.

§64-7-19. §64-7-23. Administrative Due Process.

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 bureau for Public Health procedural rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.