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

Form #3

Do Not Mark In This Box

2012 AUG 31 P 12:24

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

AGENCY: HEALTH - BUREAU FOR PUBLIC HEALTH TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code §§16-3-1, 16-1-4, 16-3C-1,et seq., 16-4-1, et seq., 16-35-4 and 16-40-7.

AMENDMENT TO AN EXISTING RULE: YES X NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 07

TITLE OF RULE BEING AMENDED: REPORTABLE DISEASES, EVENTS AND CONDITIONS

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ___

TITLE 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.

Authorized Signature

FISCAL NOTE FOR PROPOSED RULES

Rule Title: **64CSR7 Reportable Diseases, Events and Conditions**

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

Agency: **Health and Human Resources**

Address: **One Davis Square**
Suite 100 East
Charleston, WV 25301

Phone Number: **(304) 356-4090** Email: **becky.a.surface@wv.gov**

Fiscal Note Summary

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

This legislative rule establishes procedures governing the reporting of certain diseases and conditions, unusual health events, and clusters or outbreaks of diseases to the Bureau for public health. The Bureau for Public Health receives reports from physicians, local health departments, other health care providers and facilities, public and private laboratories and many others on a wide array of diseases, events and conditions. The landscape of disease reporting has changed since the last amendment of this rule with the addition of new sections on Hospital Associated Infections (HAI), Electronic laboratory reporting and surveillance as well as reporting requirements for reporting and notification of disease clusters in communities. It is anticipated that the Department will incur costs of $137,300 as a result of this rule amendment.

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.

Effect of Proposal	Fiscal Year		
	2012 Increase/Decrease (use"-")	2013 Increase/Decrease (use"-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	137,300
Personal Services	0	0	122,000
Current Expenses	0	0	15,300
Repairs and Alterations	0	0	0
Buildings	0	0	0
Equipment	0	0	0
Land	0	0	0
Other Assets	0	0	0
2. Estimated Total Revenues	0	0	0

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

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

Personnel: Includes 100% of personnel time for 2 employees, 2 FTE's at $90,000 and associated fringe at approximately $32,000 = $122,000. One employee, an epidemiologist I, will support outbreak and complex case investigations full-time. A second employee, a Nurse 3, will support local health departments to work with healthcare facilities to prevent and investigate outbreaks and help local health departments educate healthcare facilities to prevent outbreaks and cases of healthcare associated infections. Reports of healthcare associated outbreakshave more than doubled over the past 3 years. One hundred healthcare associated outbreaks were reported in 2011.

Current expenses include $12,000 for in-state travel to support outbreak and complex case investigations; office supplies of $500; monthly conference calls at $300 per call x 6 calls = $1,800; printing $1,000, which includes 5,000 copies of the revised reportable disease rule and 5,000 copies of the two-sided color wall chart of diseases and reported conditions.

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.

This rule informs the mandated reporters about what must be reported and when. As new diseases and events or conditions occur, this rule needs to be revised from time to time. The last rule revision was in 2006. This filing is an update to bring this rule up to the current standard of scientific knowledge. The rule also acknowledges the advancements in electronic disease reporting including syndromic surveillance and development of databases or registries.

Date 8/30/12

Agency

Department of Health and Human Resources

Authorized Representative

Rocco S. Fucillo
Cabinet Secretary

Legislative Rule, 64CSR7
Department of Health and Human Resources
Bureau for Public Health
Reportable Diseases, Events and Conditions

BRIEF SUMMARY

The Bureau for Public Health receives reports from physicians, local health departments, other health care providers and facilities, public and private laboratories and many others on a wide array of diseases, events and conditions. The landscape of disease reporting has changed since the last amendment of this rule with the addition of new sections on Hospital Associated Infections (HAI), Electronic laboratory reporting and syndromic surveillance as well as reporting requirements for reporting and notification of disease clusters in communities.

STATEMENT OF CIRCUMSTANCES

This rule informs the mandated reporters about what must be reported and when. As new diseases and events or conditions occur, this rule needs to be revised from time to time. The last rule revision was in 2006. This filing is an update to bring this rule up to the current standard of scientific knowledge. The rule also acknowledges the advancements in electronic disease reporting and development of databases or registries. The rule brings us forward into the present day so that the State Bureau for Public Health can be responsive to public health needs and to protect the public in a timely manner.

QUESTIONNAIRE

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

DATE: August , 2012

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) Bureau for Public Health
350 Capitol Street, Room 702
Charleston, WV 25301
(304) 558-2971

LEGISLATIVE RULE TITLE: 64CSR7 Reportable Diseases, Events and Conditions

1. Authorizing statute(s) citation W. Va. Code §§16-3-1, 16-1-4, 16-3C-1, et seq., 16-4-1, et seq., 16-35-4 and 16-40-7.

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

July 30, 2012

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

N/A

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

August 29, 2012

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

Attached X No comments received _____

3 commenters

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

N/A

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

Ann Goldberg, Director
Public Health Regulations
Bureau for Public Health
350 Capitol Street, Room 702
Charleston, WV 25301
ann.a.goldberg@wv.gov
(304) 558-2971 Phone
(304) 558-1035 Fax

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

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

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

N/A

b. Date of hearing or comment period:

July 30, 2012 to August 29, 2012

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

64CSR7 Comment #1

Goldberg, Ann A

2nd Agency response

From: Goldberg, Ann A
Sent: Wednesday, August 22, 2012 4:02 PM
To: Thomas, Carrie A
Cc: Haddy, Loretta E; Bixler, Dee
Subject: RE: Reportable Disease Rule Comment

Thanks very much, Carrie for catching that other reference to Rubella in the lab section.

From: Thomas, Carrie A
Sent: Wednesday, August 22, 2012 3:54 PM
To: Goldberg, Ann A
Cc: Haddy, Loretta E; Bixler, Dee
Subject: RE: Reportable Disease Rule Comment

2nd comment from Carrie Thomas

Thank you Ann. I didn't realize you'd be revising as comments came in or I would have outlined the exact changes for you. Your changes regarding rubella look good, but we also need to change the lab guidance. "3.4.d.15 Rubella, virologic or serologic evidence;" needs to be removed from page 12, and added on page 9. I have highlighted the wording that needs to be removed from page 12 and indicated where to add the wording on page 9 with a comment.

Thanks again,
Carrie

From: Goldberg, Ann A
Sent: Wednesday, August 22, 2012 2:19 PM
To: Thomas, Carrie A
Cc: Haddy, Loretta E; Bixler, Dee
Subject: RE: Reportable Disease Rule Comment

Agency response #1

I am attaching the REVISED rule, 64CSR7, for your review. I made the changes you suggested by adding the word "immediately" to §3.3.b. on page 7; and inserting Rubella in §3.3.b.10 and Rubella, Congenital Syndrome in §3.3.b.11 on page 8 as Category IA diseases, reportable immediately. Those two §§ have then been deleted from the Category II diseases in §§ 3.4.b.16. and3.4.b.17., requiring reporting within 24 hours.

Thank you for your comment.

Ann
Ann A. Goldberg
350 Capitol Street, Room 702
Charleston, WV 25301
304-356-4122
Ann.A.Goldberg@wv.gov

From: Thomas, Carrie A
Sent: Tuesday, August 21, 2012 2:13 PM
To: Goldberg, Ann A
Cc: Haddy, Loretta E; Bixler, Dee
Subject: Reportable Disease Rule Comment

Original Comment from Carrie Thomas

The Council for State and Territorial Epidemiologists (CSTE) considers rubella to be an immediately notifiable condition (http://www.cste.org/ps2012/12-ID-09FINAL.pdf), because

- The condition has been declared eliminated (absence of endemic disease transmission) in the United States.
- A majority of state and territorial jurisdictions—or jurisdictions comprising a majority of the US population—have laws or regulations requiring **immediate** reporting of rubella to public health authorities;
- The Centers for Disease Control and Prevention (CDC) requests **immediate** notification of rubella; and the CDC has condition-specific policies and practices concerning its response to, and use of, notifications (http://www.cdc.gov/osels/ph_surveillance/nndss/phs/files/NNC_2011_Notification_Requirements_Alphabetical_By_Condition.pdf).

In order to be consistent with national standards, West Virginia should move Rubella (3.4.b.17) and Rubella, Congenital Syndrome (3.4.b.18) from Category II conditions, requiring report within 24 hours, to Category I conditions, requiring immediate report to the local health department.

Carrie A. Thomas, PhD
Epidemiologist (VPD/IBD)
Division of Infectious Disease Epidemiology
Office of Epidemiology & Prevention Services
Bureau for Public Health
West Virginia Department of Health & Human Resources
350 Capitol St. Rm. 125
Charleston, WV 25301
Phone: 304-356-4037(direct), 304-558-5358(Main)
Fax: 304-558-8736
Email: Carrie.A.Thomas@wv.gov
Website: www.dide.wv.gov

Goldberg, Ann A

To: Goldberg, Ann A
Subject: RE: Reportable Diseases rule revisions.

From: Goldberg, Ann A
Sent: Wednesday, August 29, 2012 3:39 PM
To: Pitrolo, James L
Cc: Wenmoth, Amy
Subject: RE: Reportable Diseases rule revisions.

Agency Response to James Pitrolo

Jim,

It was an oversight. It was not put back in, it just wasn't taken out in time when the rule had to be filed for Public Comment. The Agency Approved rule will reflect the revised content of subsection 8.1. as follows:

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~~ surveillance evaluation, the Commissioner may request any of the following information from providers, facilities, laboratories, or other individuals named in this rule:"

I hope this version is what Amy and others at the HCA agree to and expected to see in this subsection.

Thank you for your Comment.

Ann
Ann A. Goldberg
350 Capitol Street, Room 702
Charleston, WV 25301
304-356-4122
Ann.A.Goldberg@wv.gov

From: Pitrolo, L. James [mailto:JPitrolo@hcawv.org]
Sent: Tuesday, August 28, 2012 10:43 AM
To: Goldberg, Ann A
Cc: Wenmoth, Amy
Subject: FW: Reportable Diseases rule revisions.

Comment # 2 from James Pitrolo

Ann,

Is this an oversight or was it put back in for a reason?

Jim Pitrolo

From: Wenmoth, Amy
Sent: Wednesday, August 22, 2012 4:30 PM
To: Pitrolo, L. James
Subject: RE: Reportable Diseases rule revisions.

Jim,

Please find attached the BPH reportable disease rule that has been posted for public comment through August 29, 2012. Previously, Dee Bixler agreed to remove the reference to §16-5B-17 in section 8.1 of this rule based on a conversation

we had on July 3, 2012 (the language we agreed to is in the attached email). This reference is not included in the version released to the advisory group on July 24, 2012. However, the rule released for public comment does include the reference to §16-5B-17 in section 8.1 (see attached rule, page 24).

Thank you,
Amy

Amy B. Wenmoth
Epidemiologist/Director of Clinical Analysis
West Virginia Health Care Authority
100 Dee Drive
Charleston, WV 25311
Ph: 304-558-7000
Fax: 304-558-7001
awenmoth@hcawv.org

West Virginia
HEALTH CARE Association

August 27, 2012

Ann Goldberg, Director
Public Health Regulations
350 Capitol Street, Rm 702
Charleston, WV 25301

Loretta Haddy, PhD
State Epidemiologist
350 Capitol Street, Rm 125
Charleston, WV 25301

Dear Ms. Goldberg and Dr. Haddy,

On behalf of the members of the West Virginia Health Care Association, I wish to express our opposition to the proposed amendment to Rule 64-7 regarding Reportable Diseases, Events and Conditions.

The rule places a substantial, unfunded mandate on long term care providers. Currently, nurses spend a significant amount of their time performing "paperwork" functions rather than caring for residents. This rule will further remove nurses from providing valuable, direct resident care.

The data gathering and reporting requirements on long term care facilities seems to grow daily. For example, the West Virginia Legislature recently required nursing homes to report all patients with dementia to the West Virginia Alzheimer's Disease Registry. Some facilities report that each resident's information took in excess of 20 minutes to complete. Because a large percentage of nursing home residents have a diagnosis of dementia, this task took considerable time to complete at each facility. No funding was provided to complete this task, and of course, the requirement is ongoing.

We do not believe that long term care facilities are the appropriate reporters. Many of the residents arrive at the facility with the reportable diseases. In many

110 Association Drive • Charleston, WV 25311 • Phone: (304) 346-4575 • Fax: (304) 342-0519 • www.wvhca.org

cases, it will be impractical for the facilities to investigate the sources. Some residents come from home with the disease, others from the hospital. If a patient was self-cathetering at home prior to admission, how would the facility know the source of the infection? Similarly, if a patient is transferred from a hospital, how will the facility know the source of the infection? The time required investigating and reporting is substantial and for smaller facilities, it would be an undue burden.

In addition to reporting and investigating the diseases, long term care facilities must meet all of the specifications, time lines and training requirements of the National Healthcare Safety Network (NHSN). Attached are four pages from the NHSN website which generally outline the requirements of participation and link readers to more details. The training requirements alone are extensive. A sixty bed facility does not have a full-time records custodian to learn the system and perform the reporting. Existing nursing staff will be required to stay abreast of NHSN requirements and if any personnel turnover occurs, new staff will have to be trained. Continuity of reporting could become a problem and result in facilities receiving survey deficiencies.

Additional questions and concerns:

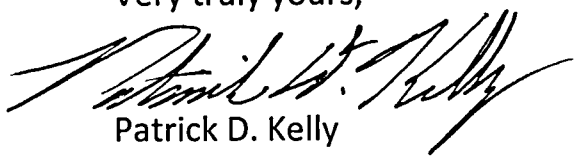
1. Presently, long term care facilities have to report much of this information to local health departments. Why can't the Bureau study the information that is currently reported? Will facilities be required to report information to both the local health departments and NHSN?
2. All of the information requested is available from laboratories. Why doesn't the Bureau require labs to report the information? The labs easily could develop the requisite expertise in reporting.
3. Will the Bureau provide the initial and long term training necessary for facility staff to be able to comply with state and NHSN requirements? Other providers report that many problems occurred when they began reporting to the NHSN.
4. Will the prevention collaborative be statewide or regional?
5. Will the data be used to educate and strengthen our prevention and disease management or will it be used for punitive purposes?
6. Will facilities be required to report to the NHSN in perpetuity even if the Bureau's funding for this project ebds?

7. If the reported data indicates that no problem exists with a particular disease, will the reporting requirement be terminated?

Instead of placing additional reporting burdens on long term care facilities, why doesn't the Bureau move directly to implementing programs to combat the diseases? Let's spend our scarce resources on improving health care rather than continually studying it. We are concerned that all of this data will be collected and placed on a shelf and never implemented because of grant or funding cuts.

We cannot stress enough that our nursing staff needs to be providing direct care to our residents. The amount of nursing time currently spent on record keeping and reporting is disheartening. Please do not add to the burden. We encourage you to find another way to collect the information that you want.

Very truly yours,



Patrick D. Kelly
Chief Executive Officer
West Virginia Health Care Association

Centers for Disease Control and Prevention
CDC 24/7: Saving Lives. Protecting People.™

Voluntary or State Mandated Enrollment

Eligibility Criteria

Facilities participating in NHSN must meet the following criteria:

- Be a bona fide healthcare facility in the United States, e.g., be listed in or associated with a facility that is listed in one of the following national databases: American Hospital Association (AHA); Centers for Medicare and Medicaid Services (CMS); or Veteran's Affairs (VA).
- Have email addresses for NHSN users and high-speed Internet connections on the computers they will use to access NHSN.
- Comply with secure access control requirements of the system.
- Be willing to follow the selected NHSN component protocols exactly and report complete and accurate data in a timely manner during months when reporting data for use by CDC.
- Be willing to share such data with CDC for the purposes stated above.
- Be able to provide written consent for participation in NHSN by a member of the facility's chief executive leadership (e.g., Chief Executive Officer).

Data Collection and Reporting Requirements for Participation

Once enrolled in the NHSN, each facility must:

- Use the NHSN Internet-based data entry interface and/or data import tools for reporting data to CDC.
- Successfully complete an annual survey for each component selected.
- Successfully complete one or more modules of the component selected. Successful completion requires the following:
    - For the selected component, submit a reporting plan each month to inform CDC which, if any, of the modules will be used for that month. Data for at least one module must be submitted for a minimum of six months of the calendar year to maintain active status.
    - Adhere to the selected module's protocol(s) exactly as described in the NHSN Manual during the months when one or more NHSN modules are used. This includes using surveillance methodology appropriate for the module and as described in the protocol.
    - Report adverse events/exposures and appropriate summary or denominator data as required for the module(s) indicated on the reporting plan to CDC within 30 days of the end of the month.
    - For those months when the Healthcare Worker Exposure module is followed and no exposures are reported, confirm that none occurred.
    - Pass quality control acceptance checks that assess the data for completeness and accuracy.
- NHSN facilities must agree to report to state health authorities those adverse event outbreaks that are identified in their facility by the surveillance system and about which they are contacted by CDC.
- Failure to comply with these requirements will result in withdrawal from NHSN.

Such facilities will be offered the opportunity to download their data before being withdrawn. Six months after withdrawal, a facility may apply for re-enrollment into NHSN.

Required Training

Before enrolling in or using the system NHSN requires that each of its users, including the facility administrator, is thoroughly trained. The training requirements differ depending on the role of the NHSN user.

See the following roles to review the training requirements:

Facility Administrator

- Read the NHSN Facility Administrator Enrollment Guide [PDF - 496 KB] October 2011.
- View the NHSN Enrollment & Facility Start-up training.
- View all training sessions and read slidesets & manuals relating to the NHSN methodology of data collection and data entry for the type of facility enrolling and/or enrolled component:

Trainings:

- Patient Safety Component
- Healthcare Personnel Safety Component
- Biovigilance Component

Documents:

- NHSN Facility Administrator Enrollment Guide [PDF - 496 KB] October 2011.
- NHSN Manual: Patient Safety Component Protocols
- NHSN Manual: Healthcare Personnel Safety Component [PDF - 356KB]
- NHSN Manual: Biovigilance Component Protocol Hemovigilance Module [PDF - 785 KB]
  Guidelines and procedures for monitoring hemovigilance.
  June 2011.

NOTE: The person designated as the **NHSN Facility Administrator** is the only person who can enroll a facility in NHSN or reassign the role of Facility Administrator. This person will also have the ability to confer rights to groups, that is, entities with which your hospital wants to share some/all of its data (e.g., state or county health department, corporate headquarters). Therefore, this role should be given to an individual who has the authority to perform these functions within your hospital's organizational structure. In many hospitals participating only in the NHSN Patient Safety Component, this will likely be the lead Infection Preventionist (IP). In that case, the NHSN Facility Administrator may also be designated as the NHSN Patient Safety Primary Contact Person. For facilities participating only in the NHSN Healthcare Personnel Safety Component, the person responsible for the occupational health functions is a good candidate for both NHSN Facility Administrator and NHSN Healthcare Personnel Safety Primary Contact Person. For facilities participating only in the NHSN Biovigilance Component, the transfusion medicine specialist or laboratorian collecting and entering data would be a good candidate for both NHSN Facility Administrator and Biovigilance Primary Contact

Person. For facilities participating in more than one NHSN Component, the NHSN Facility Administrator should be a person with authority across the involved departments.

User (other than Facility or Group Administrator)

User Start-up Guide [PDF - 433 KB] October 2011
A step-by-step start-up guide for NHSN Users who are not Facility Administrators or Group Administrators.

- Read the User Start-up Guide.
- View training sessions and read slidesets and manuals, applicable to their task.

Trainings:

- Patient Safety Component
- Healthcare Personnel Safety Component
- Biovigilance Component

Documents:

- NHSN Facility Administrator Enrollment Guide [PDF - 496 KB] October 2011.
- NHSN Manual: Patient Safety Component Protocols Guidelines and procedures monitored in the Patient Safety Component includes instructions for completing data collection forms.
- NHSN Manual: Biovigilance Component Protocol Hemovigilance Module [PDF - 785 KB]
  Guidelines and procedures for monitoring hemovigilance.
  June 2011.

Group Administrator

- Read the NHSN Group Administrator Guide [PDF - 1.32MB]
  A step-by-step start-up guide for forming a group in NHSN.
  June 2009.
- View all training sessions and read slidesets and manuals relating to the NHSN methodology of data collection for the type of group nominated

Trainings:

- Patient Safety Component
- Healthcare Personnel Safety Component
- Biovigilance Component

Documents:

- NHSN Facility Administrator Enrollment Guide [PDF - 496 KB] October 2011.
- NHSN Manual: Patient Safety Component Protocols Guidelines and procedures monitored in the Patient Safety Component includes instructions for completing data collection forms.
- NHSN Manual: Healthcare Personnel Safety Component [PDF - 356KB]

- NHSN Manual: Biovigilance Component Protocol Hemovigilance Module [PDF - 785 KB]
  Guidelines and procedures for monitoring hemovigilance.
  June 2011.

System Requirements

The following recommended system requirements were developed to ensure the best use of the key features of the NHSN which demand high processor performance, such as Java graphical interface, Internet audio / video streaming, professional 3D graphics, multimedia, data analysis, graphical data visualization.

It is the responsibility of the healthcare facility to choose the specific microcomputer brand and model to purchase.

Minimum System Requirements

- 1 GHz equivalent or greater Intel Pentium III processor
- 512MB of RAM
- Windows XP
- Email account
- High-speed internet access (greater than 200Kbs)
- 500 MB available disk space
- Microsoft Internet Explorer 6 or higher
  NOTE: The only internet browser that can be used with NHSN is Microsoft Internet Explorer. Do not use another browser when accessing NHSN

Additional System Recommendations

- **Computer**
  2 GHz processor - Intel Pentium IV, or AMD
  K6/Athlon/Duron family, or compatible processor recommended
  512MB of RAM
  Sound card
  Speakers or headphones (optional)
  CD-ROM or DVD drive (optional)
  Hard disk 40 GB
- **Monitor**
  17" Super VGA (800 X 600) or higher resolution video adapter and monitor
- **Operating System (OS)**
  Windows XP/ Windows 2000 / Windows Vista / Windows 7
- **Printer**
  Laser Printer

Page last reviewed: November 02, 2011
Page last updated: November 02, 2011
Content source: Centers for Disease Control and Prevention
National Center for Emerging and Zoonotic Infectious Diseases (NCEZID)
Division of Healthcare Quality Promotion (DHQP)

Centers for Disease Control and Prevention 1600 Clifton Rd. Atlanta, GA 30333, USA
800-CDC-INFO (800-232-4636) TTY: (888) 232-6348 - cdcinfo@cdc.gov

Response to Comment letter Regarding 64CSR7 from West Virginia Health Care Association, received 8/28/2012

Thank you for your comments.

Subsections 9.2. and 9.6. have been removed.

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

SERIES 7
REPORTABLE DISEASES, EVENTS AND CONDITIONS

§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 Bureau for public health. It also establishes the responsibility of various individuals and facilities in controlling communicable diseases. The W. Va. Code is available in public libraries and on the Legislature's web page, http:/ /www.legis.state.wv.us/.

1.2. Authority - W. Va. Code §§16-3-1, 16-1-4; related 16-3C-1 et seq., 16-4-1 et seq., 16-22-3, 16-35-4 and 16-40-7.

1.3. Filing Date - ~~May 8, 2006~~.

1.4. Effective Date - ~~May 8, 2006. (Revised January 16, 2007; June 8, 2009; December 16, 2010)~~

1.5. Applicability - This rule applies to physicians and other licensed health practitioners; local health officers; other public health providers; private or public laboratories; administrators of the West Virginia Health Information Network (WVHIN) 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 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 using HL7 messaging such that data is automatically transferred from a laboratory database to the West Virginia Health Information Network (WVHIN) or the West Virginia Electronic Disease Surveillance System (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.

2.6. 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~~ www.dide.wv.gov)

2.8. Center for Medicare and Medicaid Services (CMS) – The Federal agency responsible for providing health coverage for Medicare and Medicaid beneficiaries and promoting quality of care for these beneficiaries.

~~2.8.~~ 2.9. 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.

~~2.9.~~ 2.10 Commissioner - The Commissioner of the Bureau for public health of the West Virginia department of health and human resources or his or her designee.

~~2.10.~~ 2.11. 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.

~~2.11.~~ 2.12. Department - The West Virginia department of health and human resources.

2.13. Electronic laboratory reporting – Reporting of laboratory data to the West Virginia Health Information Network (WVHIN) or the West Virginia Electronic Disease Surveillance System (WVEDSS) by use of HL7 messaging standards.

2.14. Extensible Markup Language (XML) - A markup language that defines a set of rules for encoding documents in a format that is both human-readable and machine-readable.

~~2.12.~~ 2.15. 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.

~~2.13.~~ 2.16. Epidemiologic Information - Medical and risk factor 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.~~ 2.17. 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.~~ 2.18. 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.

~~2.16.~~ 2.19. 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.

~~2.17.~~ 2.20. 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.

2.21. Health level 7 (HL7) messaging – Consensus standards for sharing electronic clinical and administrative data between health information systems. HL7 standards are found at: http://hl7.org.

2.22. Health or Safety Emergency – As defined under the Family Educational Rights and Privacy Act's (FERPA) health or safety emergency provision. "Health or Safety Emergency Situation" may include an outbreak of infectious disease occurring in a school or a case of reportable disease in a school that may be transmitted by casual contact in a school or community setting.

2.23. Healthcare Associated Infection (HAI) – Infections caused by a wide variety of common and unusual bacteria, fungi and viruses during the course of receiving medical care.

~~2.18.~~ 2.24. Hospital - A facility licensed as a hospital under WV Division of Health Legislative Rule, Hospital Licensure, 64 CSR 12.

~~2.19.~~ 2.25. 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.~~ 2.26. 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.

2.27. International Society for Disease Surveillance (ISDS) – A 501(c)(3) nonprofit organization founded in 2005 and dedicated to the improvement of population health by advancing the science and practice of disease surveillance. Information is available at: http://www.syndromic.org/.

2.28. Isolate – A pure culture of a bacteria, usually identified by a clinical laboratory from culture of a specimen from a patient. Isolates are usually stored on an agar plate or slant or in nutrient broth.

~~2.21.~~ 2.29. 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.

~~2.22.~~ 2.30. 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 assessment of the health of human beings. The term "laboratory" includes both public and private laboratories, free-standing laboratories, and hospital laboratories.

~~2.23.~~ 2.31. Law Enforcement Personnel - Any person who is employed by a local, county, state or federal agency with law enforcement responsibilities.

~~2.24.~~ 2.32. Local Board of Health - A board of health serving one or more counties, one or more municipalities, or a combination thereof.

~~2.25.~~ 2.33. Local Health Department - The staff of the local board of health.

~~2.26.~~ 2.34. 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.

~~2.27.~~ 2.35. Medical Information - Data or other information regarding the history, examination, radiological or laboratory findings, diagnosis, treatment, or other clinical care for a person examined or treated for a suspected or actual disease.

2.36. National Healthcare Surveillance Network (NHSN) – A secure, internet-based surveillance system for patient and healthcare personnel safety systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC. Enrollment is open to all types of healthcare facilities in the United States, including acute care hospitals, long term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, outpatient dialysis centers, ambulatory surgery centers and long term care facilities. NHSN can accept retrospective reports beginning with January of the year that the facility first enrolled in NHSN.

~~2.28.~~ 2.37. 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.~~ 2.38. 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.~~ 2.39. OLS - The office of laboratory services in the Bureau.

~~2.31.~~ 2.40. Physician - An individual licensed to practice medicine by either the board of medicine or the board of osteopathy.

~~2.32.~~ 2.41. 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.

2.42. Prevention collaborative – A group of health care facilities that are engaged in an effort to reduce HAIs. Members of the collaborative use a common, though not necessarily identical, approach. The members discuss progress regularly and share lessons learned in real time so that others in the group can benefit from the experience of each facility.

~~2.33.~~ 2.43. 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.

2.44. Real time electronic feed – Automated electronic reporting, usually of laboratory results, such that electronic laboratory reports are routinely delivered to the Bureau within no more than 24 hours after results are available.

~~2.34.~~ 2.45. Reportable Disease or Condition - Any disease or condition required to be reported by this rule.

~~2.35.~~ 2.46. STD - Sexually transmitted disease.

~~2.36.~~ 2.47. 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.

2.48. Surveillance Region – a grouping of counties for the purposes of aggregating surveillance data and providing coverage by a regional epidemiologist. Surveillance regions are usually self-selected by the counties and are listed at: www.dide.wv.gov.

2.49. Syndromic surveillance – Systematic collection of data from the point of care, usually based on chief complaint data, often without a definitive diagnosis for the purpose of supplementing other sources of surveillance data.

2.50. Validated Submitter – A laboratory whose transmission of electronic laboratory data to WVHIN or WVEDSS by HL7 messaging has been validated by the Commissioner. Validation involves submission of paper and electronic copies of laboratory data until it is established that electronic reporting is at least as accurate and complete as paper-based reporting.

~~2.37.~~ 2.51. Veterinarian - A doctor of veterinary medicine.

~~2.38.~~ 2.52. 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.~~ 2.53. 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~~ reported from local health departments and laboratories to the department and to the Centers for Disease Control and Prevention (CDC). WVEDSS is part of the national electronic disease surveillance system (NEDSS). WVEDSS may use either HL7 or XML data formats.

2.54.WVHIN – West Virginia Health Information Network – An electronic system for data exchange operated by the West Virginia Healthcare Authority for the purpose of exchanging information between laboratories, health providers and health facilities. WVHIN is capable of receiving HL7 messaging through a real time data feed.

2.55. WVSIIS – West Virginia Statewide Immunization Information System – An electronic registry of immunization information for children and adults for the purpose of having an integrated immunization record for all people in the state. WVSIIS data may be made available to immunization providers, healthcare providers, public health investigators and school personnel to search immunization records for school entry requirements, with appropriate limits on access. Adult immunization should also be reported to WVSIIS.

2.56. Zoonotic disease – a disease that is potentially transmitted to humans by direct or indirect contact with animals or animal products or by exposure to animals or animal products.

§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, mass exposures, or mass casualty events, the Commissioner may require same day reporting for selected diseases conditions or injuries by rapid written notification of :

3.1.b.1. local health departments;

3.1.b.2. health care facilities and health providers;

3.1.b.3. animal health providers, if the disease is Zoonotic;

3.1.b.4. laboratories;

3.1.b.5. schools, camps or vessels;

3.1.b.6. emergency shelters;

3.1.b.7. "911" operators and disaster response workers;

3.1.b.8. funeral directors; and

3.1.b.9. Medical examiners or coroners.

3.1.c. Written notification shall list required diseases, injuries or conditions to be reported; case definitions to be used; the required time frame for reporting; information to be reported for each case or suspected case; and information on how reports should be made to local health departments or the Bureau. The Commissioner shall establish a time for the required reporting not to exceed the duration of the emergency. Disease and conditions under surveillance may include:

3.1.c.1 fatalities, including cause of death;

3.1.c.2. injuries;

3.1.c.3. exposures to chemicals, toxins or radiation; and

3.1.c.4. other diseases or conditions established by the order of the Commissioner.

~~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 may be found in the West Virginia Reportable Diseases Protocol Manual (available online at ~~http://www.wvdhhr.org/idep~~ www.dide.wv.gov). 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 shall be reported electronically to WVEDSS in a manner approved by the Commissioner or on forms supplied by the commissioner.~~ Facilities and providers shall report diseases and conditions to the local health department in the county of residence of the patient on forms provided in the West Virginia Reportable Disease Protocol Manual (available online at: www.dide.wv.gov).

3.2.c. Laboratories shall send a paper copy of the laboratory report to the local health department in the county where the patient resides. When electronic reporting to WVHIN or WVEDSS is validated by the department, the laboratory shall report laboratory data in real time by HL7 messaging. When reporting directly to WVEDSS it is permissible to use XML.

3.2.d. Local health departments shall report diseases and conditions to WVEDSS in a manner approved by the Commissioner.

3.3. Category I Reportable Diseases and Conditions.

3.3.a. Health care providers~~,~~ and health care facilities ~~and laboratories~~ shall report cases of Category I diseases or conditions listed in this section by telephone to the local health department serving the patient's county of residence 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~~ file a written report as required in the Reportable Disease Protocol Manual (available at: www.dide.wv.gov). Reports from health care providers and health care facilities shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity 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.

3.3.a.1. Laboratories shall report cases of Category I diseases or conditions listed in this section by telephone to the local health department serving the patient's county of residence immediately and follow up with a copy of the written laboratory report. When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time electronic laboratory reporting using HL7 messaging may substitute for the required paper-based reporting. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity; 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. All local health departments shall report the case to the Bureau immediately upon receipt of the report by calling toll free 1 (800) 423-1271 and by filing an electronic report in WVEDSS or as required by the Commissioner.

3.3.b. Category I.A diseases and conditions reportable immediately 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.3. Botulism;

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

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

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

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

3.3.b.8. Novel influenza infection, suspect or confirmed, animal or human;

3.3.b.9. Plague;

3.3.b.10. Rubella;

3.3.b.11. Rubella, Congenital Syndrome;

~~3.3.b.10.~~ 3.3.b.12. Rubeola (Measles);

~~3.3.b.11.~~ 3.3.b.13. SARS coronavirus infection, suspect or confirmed;

~~3.3.b.12.~~ 3.3.b.14. Smallpox;

~~3.3.b.13.~~ 3.3.b.15. Tularemia;

~~3.3.b.14.~~ 3.3.b.16. Viral hemorrhagic fevers, including filoviruses such as ebola and Marburg and arenaviruses such as lassa fever; and

~~3.3.b.15.~~ 3.3.b.17. Waterborne outbreak, suspect or confirmed.

3.3.c. ~~Reports~~ After reporting by phone, reports of Category I.A diseases and conditions ~~should~~ shall 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~~ www.dide.wv.gov).

3.3.d. Category I.B diseases and conditions reportable by laboratories are:

3.3.d.1. *Bacillus anthracis*;

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

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

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

3.3.d.5. *Francisella tularensis*;

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

3.3.d.7 Novel influenza infection, suspect or confirmed, animal or human;

3.3.d.8. Orthopox infection, virologic, electron microscopic or molecular evidence;

3.3.d.9. Outbreak or cluster of any illness or condition - suspect or confirmed;

3.3.d.10. Rubella, virologic or serologic evidence;

~~3.3.d.10.~~ 3.3.d.11. Rubeola (measles), virologic or serologic evidence;

~~3.3.d.11.~~ 3.3.d.12. SARS coronavirus infection, serologic evidence or PCR;

~~3.3.d.12.~~ 3.3.d.13. Smallpox, virologic or serologic evidence;

~~3.3.d.13.~~ 3.3.d.14. Viral hemorrhagic fever;

~~3.3.d.14.~~ 3.3.d.15. Waterborne outbreak, suspect or confirmed;

~~3.3.d.15.~~ 3.3.d.16. *Yersinia pestis*, microbiologic or serologic evidence; and

~~3.3.d.16.~~ 3.3.d.17. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category I.A.

3.3.e. After reporting by phone, laboratory reports of Category I.B. diseases and conditions shall be submitted to the local health department in accordance with the West Virginia Reportable Disease Protocol Manual (online at: www.dide.wv.gov). When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time electronic laboratory reporting using HL7 messaging may substitute for the required paper-based reporting.

3.4. Category II Reportable Diseases and Conditions.

3.4.a. Health care providers~~,~~ and health care facilities ~~and laboratories~~ shall report cases of Category II diseases or conditions listed in this section by telephone to the local health department serving the patient's county of residence within ~~twenty-four~~ 24 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.~~ and follow up with a written report on standard reporting forms in accordance with the Reportable Disease Protocol Manual (available at: www.dide.wv.gov). Reports from providers shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity 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.

3.4.a.1. Laboratories shall report cases of Category II diseases or conditions listed in this section by telephone to the local health department serving the patient's county of residence within 24 hours of diagnosis, and follow up with a written copy of the laboratory report. When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time

electronic laboratory reporting using HL7 messaging may substitute for the required paper-based reporting Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity; 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. All local health departments shall report the case to the Bureau within 24 hours of receipt of the report by filing an electronic report in WVEDSS or as required by the Commissioner.

3.4.b. Category II.A diseases and conditions reportable by health care providers and health care facilities are:

3.4.b.1. Animal bites;

3.4.b.2. Brucellosis;

3.4.b.3. Cholera;

3.4.b.4. Dengue Fever;

3.4.b.5. Diphtheria;

3.4.b.6. *Haemophilus influenzae*, invasive disease;

3.4.b.7. Hemolytic Uremic Syndrome, postdiarrheal;

3.4.b.8. Hepatitis A, acute, including results of hepatitis serologies, transaminase levels and bilirubin;

3.4.b.9. Hepatitis B, acute, chronic or perinatal, including results of hepatitis A and B serologies, transaminase levels and bilirubin;

3.4.b.10. Hepatitis D including results of hepatitis A and B serologies, transaminase levels and bilirubin;

3.4.b.11. Meningococcal Disease, invasive;

3.4.b.12. Mumps, acute infection;

~~3.4.b.12.~~ 3.4.b.13. Pertussis (whooping cough);

~~3.4.b.13.~~ 3.4.b.14. Poliomyelitis;

~~3.4.b.14.~~ 3.4.b.15. Q-fever (*Coxiella burnetii*);

~~3.4.b.15.~~ 3.4.b.16. Rabies; human or animal;

~~3.4.b.16. Rubella;~~

~~3.4.b.17. Rubella, Congenital Syndrome;~~

~~3.4.b.18.~~ 3.4.b.17. Shiga toxin-producing *Escherichia coli* (STEC) including but not limited to *E. Coli 0157:H7;*

~~3.4.b.19.~~ 3.4.b.18. *Staphylococcus aureus* with glycopeptide-intermediate (GISA/VISA) or glycopeptide-resistant (GRSA/VRSA) susceptibilities, including results of susceptibility testing;

~~3.4.b.20.~~ 3.4.b.19. Tuberculosis all forms, including antibiotic susceptibility patterns;

~~3.4.b.21.~~ 3.4.b.20. Typhoid fever (*Salmonella typhi*);

~~3.4.b.22.~~ 3.4.b.21. Yellow fever; and

~~3.4.b.23.~~ 3.4.b.22. Any other unusual condition or emerging infectious disease of potential public health importance;

3.4.c. Reports of Category II.A diseases and conditions 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~~ www.dide.wv.gov) ~~or preferably by filing an electronic report with WVEDSS~~.

3.4.d. Category II.B diseases and conditions reportable by laboratories are:

3.4.d.1. *Bordatella pertussis*, microbiologic or molecular evidence;

3.4.d.2. ~~Brucellosis~~ *Brucella*, microbiologic or serologic evidence;

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.6. *Haemophilus influenzae* from any normally sterile body site, including results of susceptibility testing;

3.4.d.7. Hepatitis A, positive IgM, including transaminase and bilirubin levels;

3.4.d.8. Hepatitis B, positive anti-HBc IgM or HBsAg, including hepatitis A serologies and transaminase and bilirubin levels;

3.4.d.9. Hepatitis D, positive serology, including hepatitis A and B serologies and transaminase and bilirubin levels;

3.4.d.10. Mumps, evidence of acute infection from any site;

~~3.4.d.10.~~ 3.4.d.11. *Mycobacterium tuberculosis* from any site (include drug susceptibility patterns);

~~3.4.d.11.~~ 3.4.d.12. *Neisseria meningitidis* from a normally sterile site;

~~3.4.d.12.~~ 3.4.d.13. Poliomyelitis, virologic or serologic evidence;

~~3.4.d.13.~~ 3.4.d.14. Rabies, animal or human;

~~3.4.d.14. Rubella, virologic or serologic evidence;~~

3.4.d.15. *Salmonella typhi* from any site;

3.4.d.16. Shiga toxin-producing *Escherichia coli* (STEC) including but not limited to *E. Coli 0157:H7;*

3.4.d.17. *Staphylococcus aureus* with glycopeptide-intermediate (GISA/VISA) or glycopeptide-resistant (GRSA/VRSA) susceptibilities, including the results of susceptibility testing;

3.4.d.18. *Vibrio cholerae*, microbiologic or serologic evidence;

3.4.d.19. Yellow Fever, virologic or serologic evidence;

3.4.d.20. Any other unusual condition or emerging infectious disease of public health importance; and

3.4.d.21. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category IIA.

3.4.e. After reporting by phone, laboratory reports of Category II.B diseases and conditions shall be reported to the local health department in accordance with the Reportable Disease Protocol Manual (available at: www.dide.wv.gov). When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time electronic laboratory reporting by HL7 messaging may substitute for the required paper-based reporting.

3.5. Category III Reportable Diseases and Conditions.

3.5.a. Health care providers~~,~~ and health care facilities ~~and laboratories~~ shall report cases of Category III diseases and conditions to the local health department serving the patient's county of residence within seventy-two hours of diagnosis, ~~preferably by~~ on reporting forms as listed in the Reportable Disease Protocol Manual (available at: www.dide.wv.gov). ~~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 conditions daily.~~ Reports from health care providers and health care facilities shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity 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.

3.5.a.1. Laboratories shall report cases to the local health department serving the patient's county of residence by submitting a copy of the laboratory report. When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time electronic laboratory reporting by HL7 messaging may substitute for the required paper-based reporting. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity;

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. The local health department shall report the case to the Bureau within 72 hours of receiving the report by filing an electronic report with WVEDSS in accordance with guidance in the Reportable Disease Protocol Manual.

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

~~3.5.b.1. Amebiasis;~~

~~3.5.b.2.~~ 3.5.b.1. Campylobacteriosis;

~~3.5.b.3.~~ 3.5.b.2. Cryptosporidiosis;

~~3.5.b.4.~~ 3.5.b.3. Cyclospora;

~~3.5.b.5.~~ 3.5.b.4. Giardiasis;

~~3.5.b.6.~~ 3.5.b.5. Listeria;

~~3.5.b.7.~~ 3.5.b.6. Salmonellosis (except Typhoid Fever), including results of susceptibility testing;

~~3.5.b.8.~~ 3.5.b.7. Shigellosis, including the results of susceptibility testing;

~~3.5.b.9.~~ 3.5.b.8. Trichinosis; and

~~3.5.b.10.~~ 3.5.b.9. ~~Yersiniosis~~ Vibriosis.

3.5.c. Reports of Category III.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~~ www.dide.wv.gov). ~~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. *Campylobacter* species;

3.5.d.2. *Cryptosporidium;*

3.5.d.3. *Cyclospora;*

~~3.5.d.4. *Entamoeba histolytica;*~~

~~3.5.d.5.~~ 3.5.d.4. *Giardia lamblia,* microscopic or immunodiagnostic evidence;

~~3.5.d.6.~~ 3.5.d.5. *Listeria monocytogenes;*

~~3.5.d.7.~~ 3.5.d.6. *Salmonella* (any species, excluding Salmonella typhi), including the results of susceptibility testing;

~~3.5.d.8.~~ 3.5.d.7. *Shigella* (any species), including the results of susceptibility testing;

~~3.5.d.9.~~ 3.5.d.8. ~~Trichinosis~~ *Trichinella*, demonstration of cysts or serologic evidence;

~~3.5.d.10.~~ 3.5.d.9. ~~*Yersinia enterocolitica,* microbiologic evidence~~ Non-cholera *Vibrio* species; and

~~3.5.d.11.~~ 3.5.d.10. Any other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category III.A.

3.5.e. Laboratory reports of Category III.B. diseases and conditions shall be submitted to the local health department in accordance with the West Virginia Reportable Diseases Protocol Manual (available online at www.dide.wv.gov). When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time electronic laboratory reporting by HL7 messaging may substitute for the required paper-based reporting.

3.6. Category IV Reportable Diseases and Conditions.

3.6.a. Health care providers~~,~~ and 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~~ by filing a written report with the local health department in the county of residence of the patient. Reports from health care providers and health care facilities shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity, 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.

3.6.a.1. Laboratories shall report to the local health department in the patient's county of residence through a written copy of the laboratory report. When the laboratory is designated by the Commissioner to be a validated submitter to the WVHIN or WVEDSS, real time electronic laboratory reporting by HL7 messaging may substitute for the required paper-based reporting. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity; 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.~~ The local health department shall file an electronic report with WVEDSS within one week of receiving the report from the provider, facility or laboratory.

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

3.6.b.1. Anaplasmosis;

3.6.b.2. Arboviral infection;

3.6.b.3. Babesiosis;

~~3.6.b.2.~~ 3.6.b.4. Chickenpox (numerical totals only);

~~3.6.b.3. Community-acquired methicillin-resistant *Staphylococcus aureus*, invasive, include susceptibility patterns;~~

~~3.6.b.4. Death from Chickenpox;~~

3.6.b.5. Erlichiosis;

3.6.b.6. Hantavirus Pulmonary Syndrome;

3.6.b.7. Influenza-like illness (numerical totals only);

3.6.b.8. Influenza-related death in an individual less than 18 years of age;

3.6.b.9. Legionellosis;

3.6.b.10. Leptospirosis;

3.6.b.11. Lyme Disease;

3.6.b.12. Malaria;

~~3.6.b.13. Mumps;~~

~~3.6.b.14.~~ 3.6.b.13. Psittacosis;

~~3.6.b.15.~~ 3.6.b.14. Rocky Mountain Spotted Fever;

~~3.6.b.16. Streptococcal Disease, invasive Group A, (*Streptococcus pyogenes*), including results of susceptibility testing;~~

~~3.6.b.17.~~ 3.6.b.15. Streptococcal Disease, invasive Group B;

~~3.6.b.18.~~ 3.6.b.16. Streptococcal Toxic Shock Syndrome;

~~3.6.b.19.~~ 3.6.b.17. *Streptococcus pneumoniae*, invasive disease, (include antibiotic susceptibility patterns);

~~3.6.b.20.~~ 3.6.b.18. Tetanus;

~~3.6.b.21.~~ 3.6.b.19. Toxic Shock Syndrome; and

~~3.6.b.22.~~ 3.6.b.20. 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~~ www.dide.wv.gov). ~~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. *Anaplasmosis phagocytophilum*, laboratory evidence;

3.6.d.2. Arboviral infection, virologic, serologic, or other evidence;

3.6.d.3. *Babesia* species, laboratory evidence;

~~3.6.d.2.~~ 3.6.d.4. Borrelia burgdorferi from culture, or diagnostic levels of IgG or IgM, (with Western blot confirmation);

3.6.d.5.Carbapenem-resistant *Enterobacteriacueae* (carbapenem-resistant *Escherichia coli and Klebsiella pneumonia*);

~~3.6.d.3.~~ 3.6.d.6. ~~Ehrlichiosis~~ *Ehrlichia* species, serologic, ~~microbiologic~~ or other laboratory evidence;

~~3.6.d.4.~~ 3.6.d.7. Hantavirus infection, serologic, PCR, immunohistochemistry, or other evidence;

~~3.6.d.5.~~ 3.6.d.8. Legionella, bacteriologic or serologic evidence;

~~3.6.d.6.~~ 3.6.d.9. Leptospirosis, ~~virologic or serologic~~ laboratory evidence;

~~3.6.d.7.~~ 3.6.d.10. Malaria organisms on smear of blood;

~~3.6.d.8. Mumps, virologic or serologic evidence;~~

~~3.6.d.9.~~ 3.6.d.11. Psittacosis, microbiologic or serologic evidence;

~~3.6.d.10.~~ 3.6.d.12. Rocky Mountain Spotted Fever, serologic evidence;

~~3.6.d.11. *Streptococcus pyogenes* (Group A Streptococcus) from a normally sterile site;~~

~~3.6.d.12.~~ 3.6.d.13. *Streptococcus*, Group B, from a normally sterile site;

~~3.6.d.13.~~ 3.6.d.14. *Streptococcus pneumoniae*, from a normally sterile site (include antibiotic susceptibility patterns on all isolates); and

~~3.6.d.14.~~ 3.6.d.15. 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, and health care facilities ~~and laboratories~~ shall report Category V diseases and conditions~~, preferably by WVEDSS to~~ by filing a written report with the Bureau within one week of diagnosis unless otherwise indicated. Reports shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity, 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.a.1. Laboratories shall report Category V conditions through a written copy of the laboratory report. When the laboratory is designated by the Commissioner to be a validated submitter to WVHIN or WVEDSS, real time electronic laboratory reporting using HL7 standards may substitute for the required paper-based reporting. Reports from laboratories shall include the patient's name, address, telephone number, date of birth, sex, race, ethnicity; 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. The Commissioner may request that local health departments complete an investigation of the disease or condition using WVEDSS.

3.7.b. Category V.A diseases and conditions reportable by health care providers and health care facilities are:

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 **.

3.7.b.2. Autism Spectrum Disorder; reportable to researchers at Marshall University Autism Training Center at (800)-344-5115 or (304) 696-2332 or http://www.marshall.edu/wvasdr/

3.7.b.3. Birth Defects, including Down's Syndrome;

3.7.b.4. Cancer, including non-malignant intracranial 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. Gonococcal Disease** -- conjunctivitis in the newborn or drug-resistant disease (within 24 hours);

3.7.b.8. Gonorrhea (all other sites);**

3.7.b.9. Hemophilia;

3.7.b.10. Hepatitis C, acute, including results of hepatitis A and B serologies and transaminase and bilirubin levels;

3.7.b.11. HIV (Human Immunodeficiency Virus) according to the time frame in the Bureau rule, "AIDS Related Medical Testing and Confidentiality", 64CSR64;**

3.7.b.12. Lead, all blood lead test results;

3.7.b.13. Pelvic inflammatory disease;**

3.7.b.14. Syphilis (late latent, late symptomatic, or neurosyphilis);** and

3.7.b.15. Syphilis** -- primary, secondary, early latent (less than one (1) year), or congenital (all within 24 hours); and.

~~3.7.b.16. 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~~ www.dide.wv.gov).

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. Enterovirus (non-polio), culture confirmed, (numerical totals only, by serotype as available, and including echovirus, coxsackievirus, and parechovirus);

3.7.d.5. *Haemophilus ducreyi*;**

3.7.d.6. 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.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 rule, "AIDS Related Medical Testing and Confidentiality", 64CSR64;**

3.7.d.8. Influenza, confirmed by culture, PCR or immunofluorescence, (numerical totals only, by type of test performed, and by influenza type and subtype);

3.7.d.9. Lead, all blood lead test results;

3.7.d.10. *Mycobacterium tuberculosis* from any site** (include drug susceptibility patterns) (within 24 hours);

3.7.d.11. *Neisseria gonorrheae* (drug resistant) from any site** (within 24 hours);

3.7.d.12. *Neisseria gonorrheae* from female upper genital tract** (within 24 hours);

3.7.d.13. *Neisseria gonorrheae* from the eye of a newborn** (within 24 hours);

3.7.d.14. *Neisseria gonorrheae***, culture or other positive laboratory evidence, (all other);

3.7.d.15. Syphilis**, serologic evidence;

3.7.d.16. *Treponema pallidum*, positive dark-field examination** (within 24 hours); and

3.7.d.17. 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.

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 and Family Health database. The 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,~~ a terrestrial mammal or bat, 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~~ 24 hours, by phone, or ~~preferably by WVEDSS~~ other rapid means of communication, 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.c. The humane or animal control officer;

~~5.1.c.~~ 5.1.d. 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.d.~~ 5.1.e. 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.e.~~ 5.1.f. 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 within ~~twenty-four~~ 24 hours or one working day 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, 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, 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. If the bite is to the head, face or neck or is unusually severe or results in hospitalization or death or if the animal is unlikely to have an owner at the end of the 10 day observation period, the local health officer may request that the animal be humanely destroyed and arrange for appropriate examination of the animal's brain at the OLS.

5.4. After a reasonable attempt to identify the owner of the animal, if ~~If~~ the local health officer cannot determine the owner of the domestic dog cat or ferret, he or she shall direct the county humane officer, dog warden or sheriff to pick up the suspect dog 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. If the bite is to the head, face or neck or is unusually severe or results in hospitalization or death or if the animal is unlikely to have an owner at the end of the 10 day observation period, the local health officer may request that the animal be humanely destroyed and arrange for appropriate examination of the animal's brain at the OLS.

5.5. If a person is reported bitten by any ~~animal having or suspected of having rabies~~ mammal other than a domestic dog, cat or ferret, especially a ~~wild mammal~~ terrestrial mammalian carnivore, such as a raccoon, fox, skunk, coyote, bobcat or other similar species or hybrid, the local health officer 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~~ OLS.

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~~ the local health department. The local health officer shall report animal bites and rabies post-exposure prophylaxis in WVEDSS.

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

6.1. The Commissioner shall establish and maintain a centralized registry – West Virginia Statewide Immunization Information System – WVSIIS - for tracking compliance with nationally recommended immunization schedules, school entry requirements and for monitoring vaccine use.

6.2. ~~Health care providers, health care facilities, local health officers, and any other provider or facility administering immunizations~~ WVSIIS is an electronic reporting system. The following persons shall report immunizations administered to ~~the centralized immunization registry~~ WVSIIS, as required by this rule;

6.2.a. Health care providers;

6.2.b. Health care facilities;

6.2.c. Local Health Officers;

6.2.d. Pharmacists;

6.2.e. Any other providers or facilities administering immunizations; and

6.2.f. School officials shall report immunizations of enrolled students to WVSIIS if newly enrolled students have vaccinations recorded for school entry as required by W. Va. Code §16-3-4 and 64CSR95 and those immunizations are not already recorded in WVSIIS.

6.3. Administration of immunizations against the following diseases are reportable: diphtheria, whooping cough, tetanus, polio, measles, mumps, rubella, hepatitis-B, hepatitis A Haemophilus influenzae type b disease, chickenpox, peumococcal diseases, meningococcal diseases, rotavirus, influenza, human papilloma virus (HPV) 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.~~ 6.4. All immunizations administered to persons eighteen years of age and under shall be reported to the immunization registry within two weeks of the administration of the immunization. The entities listed in subsection 6.2. of this section are strongly encouraged to report all immunizations across the lifespan ~~Immunizations of adults may also be reported~~ to maintain an accurate and useful database of all immunization information.

~~6.4.~~ 6.5. ~~Immunization reports shall contain the name of the person 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~~ The Commissioner shall publish detailed instructions for WVSIIS for entities required to report as set forth in subsection 6.2. of this section. The instructions will be available on immunization.wv.gov. The instruction shall contain information on:

6.5.a. A full description of required data elements;

6.5.b. Electronic transmission standards.

~~6.5.~~ 6.6. 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.~~ 6.7. 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~~ 24 hours.

~~6.7.~~ 6.8. In the event of an influenza or other pandemic or a bioterrorist 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.

6.9. All of the data in WVSIIS is confidential and exempt from disclosure. In certain circumstances WVSIIS may release immunization information to the following:

6.9.a. A licensed physician, a licensed facility or other licensed healthcare professional in the state of West Virginia for the purpose of delivering medical or immunization services or for the purpose of identifying under-vaccinated persons;

6.9.b. A local health department for the purposes of delivering medical or immunization services or investigating or managing an outbreak or other reportable disease;

6.9.c. A school official for the purpose of determining if enrolled children have all of the immunizations required by W. Va. Code §§16-3-4 and the Bureau's rule, Immunization Requirements and Recommendations for New School Enterers, 64CSR95, or for the prevention or control of vaccine-preventable disease within the school.

6.9.d. To other appropriate persons for public health purposes and to prevent or control the spread of communicable disease.

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

7.1. When a health care facility, health care provider, ~~or~~ laboratory, school, daycare, camp, vessel, correctional facility or other facility becomes aware of ~~a community~~ an outbreak or cluster in a community, school, camp, daycare, healthcare facility, correctional facility or other facility or related to a restaurant or food establishment, 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 by calling toll-free (800) 423-1271.

7.3. As appropriate, the local health officer shall collaborate in investigation of the outbreak or cluster 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. Case-finding, to include:

7.4.d.1. Notification of laboratories and providers in the jurisdiction to identify and report additional cases; or

7.4.d.2. Notification of the school, camp, daycare, healthcare facility or food establishment or other facility or location to identify and report additional cases; or

7.4.d.3. Public notification to identify and report additional cases, only if other means of case-finding are not feasible;

7.4.e. Systematic collection of demographic, clinical, laboratory 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; and

7.4.i. Ongoing surveillance to establish that the outbreak is over.

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, W. Va. 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 including persons suspected of being exposed to or carrying an infectious agent. Laboratory results obtained on ill and well persons are confidential and not discoverable under the state freedom of information act, W. Va. 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.

7.7. The identity of the community, school, camp, daycare, healthcare facility, restaurant or food establishment or other setting may not be released by the Commissioner or the local health officer unless that release is necessary to inform the public to take preventive action to stop the spread of disease or to notify the public or providers or laboratories to identify additional cases of disease. Data on community outbreaks and clusters may be released by the Commissioner in aggregate on a regular basis, identifying the county of occurrence of the outbreak or cluster. Data on healthcare-associated outbreaks and clusters may be released by the Commissioner in aggregate on a regular basis, identifying the surveillance region of occurrence of the outbreak or cluster.

7.8. If the Commissioner becomes aware of an ongoing risk to public health through investigation of outbreaks in healthcare facilities and the healthcare facility fails to take appropriate corrective action

within a reasonable period of time after notification by the Commissioner, the Commissioner shall file a complaint with the Office of Health Facilities Licensure and Certification. If the Commissioner becomes aware that a licensed practitioner is practicing in such a way as to place the health of the public at risk and the licensed practitioner fails to take appropriate corrective action within a reasonable period of time after notification by the Commissioner, the Commissioner shall file a complaint with the licensing board for the practitioner.

7.9. During the course of an outbreak or exposure investigation, if the Commissioner learns of patient(s) who may have been exposed to a serious infectious condition, such as, but not limited to, hepatitis B or C or human immunodeficiency virus (HIV), and the health of the patient(s) or their family members or close contacts may be at risk, the Commissioner shall notify the patient(s) of the nature of the exposure or possible exposure and action that may be taken by the patient(s) to prevent further risk to their health or the health of their family members or close contacts. In the course of notification of the patient(s), the Commissioner may identify a healthcare provider or facility to the extent necessary to inform the patient(s) of the nature of the exposure or possible exposure.

§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~~ surveillance 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, case-control 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, W. Va. 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: Healthcare Associated Infections (HAIs) Surveillance.

9.1. The WV Health Care Authority (WV HCA) shall allow access to all healthcare associated infection data reported to and collected by WV HCA to the appropriate persons at the Bureau for Public Health in the Office of Epidemiology and Prevention Services. The purpose of the reporting includes monitoring and reporting the prevalence of antimicrobial resistance in association with specific HAIs, and investigation of outbreaks and clusters in healthcare settings and other public health surveillance and

investigation activities consistent with the mission of the Bureau. The responsibility for communication with hospitals regarding data collection, data quality and completeness rests with the WV Health Care Authority.

9.2. If not already reportable to the Bureau under subsection 9.1. of this section, all healthcare associated infections designated as reportable to Center for Medicare and Medicaid Services (CMS) to the National Healthcare Safety Network (NHSN) shall also be reported to the Bureau. The reporting shall be accomplished by the healthcare facility by giving the Bureau access to the data reported to NHSN. The purpose of the reporting includes monitoring and reporting the prevalence of antimicrobial resistance in association with specific HAIs, and investigation of outbreaks and clusters in healthcare settings and other public health surveillance and investigation activities.

9.3. For HAIs not reportable to the Bureau under subsection 9.1. of this section, the Commissioner shall publish detailed reporting requirements for data reported under this section, including specific case definitions; required timeframe for reporting; and specific data elements required to be reported. Reporting requirements shall conform to published NHSN methods at www.cdc.gov/nhsn so that rates of infection can be calculated and reported consistent with NHSN methods.

9.4. Data reported to the Bureau under this section are confidential and not subject to disclosure under the state freedom of information act, W. Va. Code 29B-1-1, et seq. Information may be released in aggregate for the purpose of informing the public about the health issue under surveillance.

~~§64-7-9.~~ §64-7-10. Other Reportable Events: Bioterrorism response.

~~9.1.~~ 10.1. 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.~~ 10.2. Suspect disease due to bioterrorism agents may be identified by the following epidemiological findings:

~~9.2.a.~~ 10.2.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.~~ 10.2.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.~~ 10.2.c. A large number of cases of acute flaccid paralysis with prominent bulbar palsies, suggestive of a release of botulinum toxin;

~~9.2.d.~~ 10.2.d. A laboratory finding characteristic of one of the known bioterrorism agents;

~~9.2.e.~~ 10.2.e. An unusually high number of laboratory samples, particularly from the same biologic medium, such as blood or stool cultures;

~~9.2.f.~~ 10.2.f. Unusual requests for testing or culturing; or

~~9.2.g.~~ 10.2.g. Any other unusual medical, laboratory or epidemiological findings not consistent with known patterns of transmission of naturally-occurring infectious agents.

~~9.3.~~ 10.3. Bioterrorism agents may include, but are not limited to:

~~9.3.a.~~ 10.3.a. Anthrax (*Bacillis anthracis*);

~~9.3.b.~~ 10.3.b. Botulism (*Clostridium botulinum* toxin);

~~9.3.c.~~ 10.3.c. Brucellosis (*Brucella* species);

~~9.3.d.~~ 10.3.d. Epsilon toxin of *Clostridium perfringens;*

~~9.3.e.~~ 10.3.e. Food safety threats (e.g., *Salmonella* species, *Escherichia coli* O157:H7, *Shigella*);

~~9.3.f.~~ 10.3.f. Glanders (*Burkholderia mallei*);

~~9.3.g.~~ 10.3.g. Melioidosis (*Burkholderia pseudomallei*);

~~9.3.h.~~ 10.3.h. Plague (*Yersinia pestis*);

~~9.3.i.~~ 10.3.i. Psittacosis (*Chlamydia psittaci*);

~~9.3.j.~~ 10.3.j. Q fever (*Coxiella burnetii*);

~~9.3.k.~~ 10.3.k. Ricin toxin from *Riccinus communis* (castor beans);

~~9.3.l.~~ 10.3.l. Smallpox (variola major);

~~9.3.m.~~ 10.3.m. Staphylococcal enterotoxin B;

~~9.3.n.~~ 10.3.n. Tularemia (*Francisella tularensis*);

~~9.3.o.~~ 10.3.o. Typhus fever (*Rickettsia prowazekii*);

~~9.3.p.~~ 10.3.p. Viral encephalitis (alphaviruses [e.g., Venezuelan equine encephalitis, eastern equine encephalitis, western equine encephalitis]);

~~9.3.q.~~ 10.3.q. Viral hemorhagic fevers (filoviruses [e.g., Ebola, Marburg] and arenaviruses [e.g., Lassa, Machupo]);and

~~9.3.r.~~ 10.3.r. Water safety threats, such as *Vibrio cholerae, Cryptosporidium parvum.*

~~9.4.~~ 10.4. 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.~~ 10.5. 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~~ The local health officer shall also report cases by using WVEDSS.

~~9.6.~~ 10.6. As appropriate, the local health officer shall collaborate in an investigation of the bioterrorist event with:

~~9.6.a.~~ 10.6.a. Other local health officers if cases from other local health jurisdictions are identified;

~~9.6.b.~~ 10.6.b. Public health officials from other states if cases from those states are identified;

~~9.6.c.~~ 10.6.c. The department;

~~9.6.d.~~ 10.6.d. Federal public health officials; and

~~9.6.e.~~ 10.6.e. Law enforcement personnel.

~~9.7.~~ 10.7. 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.~~ 10.8. 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.~~ 10.8.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.~~ 10.8.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~~ §64-7-11. ~~Syndromic surveillance and electronic~~ 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).Once established, the commissioner may request health care facilities 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.~~

~~10.2. Clinical syndromes reportable may 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.~~ 11.1. Laboratories participating in WVHIN shall report laboratory data to WVHIN by HL-7 messaging. Until the laboratory is designated by the department as a validated submitter, the laboratory shall submit laboratory reports to the Bureau by paper in the time frame required. When the laboratory is designated as a validated submitter by the Commissioner, the laboratory may substitute electronic reporting to WVHIN or WVEDSS through HL-7 in real time for the required paper reporting. When ~~electronic laboratory reporting is certified as operational by the commissioner, laboratories with automatic reporting capability~~ the laboratory is designated a validated submitter they shall report the conditions listed in this subsection ~~on a daily basis~~ through a real time electronic feed. 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 and ethnicity; the name of the person or agency submitting the specimen for testing; the specimen source and date of specimen collection; the date of result, name of the test, test result, normal value or range; and the name, address, phone and fax number of the laboratory. Conditions to be reported include:

~~10.3.a.~~ 11.1.a. Adenovirus, ~~by culture, antigen or PCR~~ laboratory evidence of acute infection;

~~10.3.b.~~ 11.1.b. Enterovirus (non-polio), ~~by culture or PCR; by serotype~~ laboratory evidence of acute infection;

11.1.c. Human metapneumovirus, laboratory evidence of acute infection;

~~10.3.c.~~ 11.1.d. Influenza, ~~by culture, antigen or PCR~~ laboratory evidence of acute infection, including type and subtype, as available;

~~10.3.d.~~ 11.1.e. Parainfluenza virus, ~~by antigen detection or culture~~ laboratory evidence of acute infection;

~~10.3.e.~~ 11.1.f. Respiratory syncitial virus, ~~by antigen detection or viral isolation~~ laboratory evidence of acute infection; and

~~10.3.f.~~ 11.1.g. Rotavirus, ~~by antigen detection or electron microscopy~~ laboratory evidence of

acute infection.

§64-7-12. Syndromic Surveillance.

12.1. The Commissioner shall develop a syndromic surveillance system consistent with International Society for Disease Surveillance (ISDS) guidelines. The purpose of the surveillance system is to detect changes in the occurrence of disease in the population, especially as a result of a disease outbreak or other public health emergency, disaster or special event. When the surveillance system is implemented, emergency rooms and urgent care facilities shall transmit data electronically on a schedule determined by the Commissioner, taking into consideration the capacity of the facility to electronically report the data elements, the funding available for implementation, and other relevant factors, including improved efficiencies and resulting benefits to the reporting facility.

12.2. When the syndromic surveillance system is determined to be functional by the Commissioner, emergency rooms and urgent care facilities in the state shall report daily all data elements for each registered patient visit as required by the Commissioner.

12.3. The Commissioner shall publish detailed instructions for emergency departments and urgent cares on the required reporting as part of the Reportable Disease Protocol Manual, available online at: www.dide.wv.gov. The instructions shall contain information on:

12.3.a. A full description of required data elements;

12.3.b. Electronic transmission standards;

12.3.c. The transmission schedule; and

12.3.d. The surveillance objectives and other information related to the purpose of the surveillance system and the intended uses of the data.

12.4. None of the following data for patients or their relatives, employers or household members shall be collected by the syndromic surveillance system: names; postal or street address information, other than town or city, county, state, and the first five digits of the zip code; geocode infomation; telephone number; account numbers; certificate or license numbers; vehicle identifiers, and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; and full face photographic images and any comparable images.

12.5. The Commissioner shall maintain the confidentiality of syndromic surveillance data in accordance with section 20 of this rule. The Commissioner may share the data with local health departments and the Centers for Disease Control and Prevention for public health purposes.

~~§64-7-11~~ §64-7-13. **Deaths from Reportable Diseases and Conditions; Reportable Diseases and Conditions Diagnosed After Death.**

~~11.1.~~ 13.1. Upon receipt of any death certificate showing a reportable disease or condition, the State registrar of vital statistics shall send a copy of the death certificate to WVEDSS. The State registrar shall report all deaths due to diseases listed in this rule to the Bureau.

~~11.2.~~ 13.3 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.

~~§64-7-12~~ §64-7-14. Persons, Facilities, and Laboratories Required to Report; Other Related Responsibilities.

~~12.1.~~ 14.1. Health Care Providers and health care facilities.

~~12.1.a.~~ 14.1.a. Any health care provider who or health care facility which suspects, diagnoses, or cares for a patient with a disease or condition listed in this rule shall:

~~12.1.a.1.~~ 14.1.a.1. Report the disease or condition as required by this rule;

~~12.1.a.2.~~ 14.1.a.2. Assist public health officials in appropriate case and outbreak investigation and management and in any necessary contact investigation and management;

~~12.1.a.3.~~ 14.1.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;

~~12.1.a.4.~~ 14.1.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 Bureau recommends that health care providers and health care facilities refer contact notification activities to the STD/HIV/TB program and local health departments for tuberculosis rather than attempt to accomplish the notification themselves;

~~12.1.a.5.~~ 14.1.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~~ www.dide.wv.gov), or by methods developed in consultation with the Commissioner;

~~12.1.a.6.~~ 14.1.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.~~ 14.1.a.7. Assist the Commissioner or local health officer in ruling out previously reported cases of infectious disease by submitting copies of negative laboratory tests of medical evaluations.

~~12.2.~~ 14.2. Laboratories.

~~12.2.a.~~ 14.2.a. All laboratories, whether public, private or hospital-based, shall report evidence of current infection with the diseases or conditions listed in this rule and shall otherwise comply with the requirements of this rule.

~~12.2.b.~~ 14.2.b. A laboratory which receives a specimen yielding *Mycobacterium tuberculosis*

shall submit the first isolate to the ~~office of laboratory services~~ OLS~~, 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~~ OLS. 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~~ OLS. 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.

~~12.2.b.1.~~ 14.2.b.1. Clinical laboratories that isolate *Bacillis anthracis, Clostridium botulinum, Corynebacterium diphtheriae, Tularemia, Salmonella, Shigella, ~~Campylobacter,~~ Listeria monocytogenes*, or suspect or confirmed shigatoxin-producing *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~~ OLS. Laboratories that confirm *Campylobacter* by non-culture methods shall submit the specimen to office of laboratory services by culture and identification. 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~~ www.dide.wv.gov) and by written notification of laboratories of the specific requirement. During outbreak or other special investigations, the Commissioner may request submission of clinical specimens or isolates from persons with disease during a timeframe specified by the Commissioner.

~~12.2.b.2.~~ 14.2.b.2. Information that shall be included in any of the specimens listed in this section includes:

~~12.2.b.2.A.~~ 14.2.b.2.A. The name, address, and date of birth of the patient;

~~12.2.b.2.B.~~ 14.2.b.2.B. The specimen accession number or other unique identifier;

~~12.2.b.2.C.~~ 14.2.b.2.C. The date the specimen was obtained from the patient;

~~12.2.b.2.D.~~ 14.2.b.2.D. The source of the specimen;

~~12.2.b.2.E.~~ 14.2.b.2.E. The type of test performed;

~~12.2.b.2.F.~~ 14.2.b.2.F. The name, address, telephone and fax number of the submitting laboratory; and

~~12.2.b.2.G.~~ 14.2.b.2.G. The name, office address, office telephone and fax number of the physician or health care provider for whom the examination or test was performed.

~~12.2.b.3.~~ 14.2.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~~ www.dide.wv.gov) and by written notification of laboratory directors. During an outbreak or other special investigations, the Commissioner may request submission of clinical specimens or isolates from persons with disease during a timeframe specified by the Commissioner.

~~12.2.b.4.~~ 14.2.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.

~~12.3.~~ 14.3. Administrators of schools, camps, vessels, correctional facilities, daycares and department-operated health care facilities.

~~12.3.a.~~ 14.3.a. ~~When no physician or other responsible health care provider is in attendance, the~~ The administrator or any responsible healthcare provider of any school, camp, vessel, correctional facility, daycare or department-operated health care facility shall:

~~12.3.a.1.~~ 14.3.a.1. Report any reportable disease, outbreak or condition occurring in the school, camp, vessel, correctional facility, daycare or department-operated health care facility as required by this rule;

~~12.3.a.2.~~ 14.3.a.2. Assist public health officials in appropriate case-finding for additional cases, including sharing information such as name and contact information for persons who have signs and symptoms of illness;

14.3.a.3. Assist public health officials with appropriate case and outbreak investigation or management and in any necessary contact investigation and management, including sharing name and contact information for persons who may have been exposed to an infectious disease;

~~12.3.a.3.~~ 14.3.a.4. 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~~ www.dide.wv.gov) or by recommendations developed in consultation with the Commissioner;

~~12.3.a.4.~~ 14.3.a.5. 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, including daycare staff and attendees, school staff and students and correctional staff and inmates regarding the precautions to be taken to prevent further spread of the disease. In cases of sexually transmitted diseases, HIV, and tuberculosis the Bureau recommends that ~~health care providers and health care facilities~~ the school, camp, vessel, correctional facility, daycare or department-operated healthcare facility refer contact notification activities to the STD/HIV/AIDS program and local health departments for tuberculosis rather than attempt to accomplish the notification themselves; and

~~12.3.a.5.~~ 14.3.a.6. 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.

14.3.b. For schools, disclosure of personally identifiable information from student's education records to the Commissioner for investigation of a case or outbreak of communicable disease is classified as a Health and Safety Emergency under FERPA allowing for the release of information needed for

protection of public health.

~~§64-7-13~~ §64-7-15. Distribution of Rule.

The 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.

~~§64-7-14~~ §64-7-16. Responsibilities of Local Health Officers.

~~14.1.~~ 16.1. Local health officers shall comply with the requirements of this rule.

16.2. Local health officers shall notify providers, facilities and laboratories in their jurisdiction of the reporting requirements in this rule annually. Local health officers shall notify veterinarians, animal control officers, humane shelters and others of their responsibility for reporting animal bites and related potential rabies exposures under this rule annually.

~~14.2.~~ 16.3. 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.

~~14.3.~~ 16.4. Upon receipt of a reportable disease or condition report, a local health officer shall:

~~14.3.a.~~ 16.4.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~~ www.dide.wv.gov), or developed in consultation with the Commissioner;

~~14.3.b.~~ 16.4.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~~ www.dide.wv.gov), or recommendations developed in consultation with the Commissioner;

~~14.3.c.~~ 16.4.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;

~~14.3.d.~~ 16.4.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

~~14.3.e.~~ 16.4.e. Report any disease or condition listed in this rule to the Bureau within the time frame specified in each category.

~~14.4.~~ 16.5. 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.

~~14.5.~~ 16.6. Whenever a local health officer knows of or suspects the existence of any reportable disease, outbreak 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, outbreak or condition. If the investigation establishes the existence of a reportable disease, outbreak or condition, the local health officer shall further investigate, manage, and report the disease or condition as required by this rule.

~~14.6.~~ 16.7. 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, outbreak 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.

~~14.7.~~ 16.8. 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.

~~§64-7-15~~ §64-7-17. Management of Undiagnosed Diseases or Conditions Suggesting a Reportable Disease or Condition.

When presenting symptoms of an undiagnosed disease or condition suggest a reportable disease, outbreak 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 immediately.

~~§64-7-16~~ §64-7-18. Disputed Diagnoses of Reportable Diseases or Conditions.

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, outbreak 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.

~~§64-7-17~~ §64-7-19. Designation of Diseases as Sexually Transmittable.

As allowed under W. Va. Code §16-4-1 and for the purposes of treatment under W. Va. Code §16-4-10, the following diseases are designated as potentially sexually transmittable: chlamydia trachomatis, gonorrhea, 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.

~~§64-7-18~~ §64-7-20. Confidentiality.

~~18.1.~~ 20.1. 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 W. Va. Code §29B-1-1, et seq., the freedom of

information act. The same information is also confidential and exempt from disclosure pursuant to a subpoena, unless accompanied by a Court Order signed by a Judge.

~~18.2.~~ 20.2. In the case of an individual, the Commissioner or a local health officer may release confidential information identified in subsection ~~18.1.~~ 20.1. of this ~~rule~~ section to the following:

~~18.2.a.~~ 20.2.a. The patient;

~~18.2.b.~~ 20.2.b. The patient's legal representative whose authority encompasses the authority to access the patient's confidential information;

~~18.2.c.~~ 20.2.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;

~~18.2.d.~~ 20.2.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;

~~18.2.e.~~ 20.2.e. Any individual with the written consent of the patient and of all other individuals identified, if applicable, in the information requested;

~~18.2.f.~~ 20.2.f. Staff of a federal, State, or local health department or other 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;

~~18.2.g.~~ 20.2.g. Medical personnel caring for a potentially exposed individual to the extent necessary to protect the health or life of the exposed individual;

~~18.2.h.~~ 20.2.h. The manager or director of a licensed facility, restaurant, school or daycare ~~employing~~ where the case or suspected case resides, or is employed or in attendance, if determined absolutely necessary by the Commissioner for protection of the public's health under the following provisions:

~~18.2.h.1.~~ 20.2.h.1. 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 or director shall take to assure protection of the health of the public; and

~~18.2.h.2.~~ 20.2.h.2. The personal identity of the employee shall be kept confidential by the manager ~~of the licensed facility~~ or director to whom a disclosure was made; and

~~18.2.i.~~ 20.2.i. The persons to whom reports are required to be filed under W. Va. Code §49-6A-1, et seq., regarding children suspected to be abused or neglected are subject to the confidentiality protections of W. Va. Code §§16-4-10, 16-29-1 and 16-3C-3, or any other applicable confidentiality code section.

~~18.3.~~ 20.3. 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.

~~§64-7-19~~ §64-7-21. Isolation, Quarantine and Placarding.

~~19.1.~~ 21.1. 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.

~~19.2.~~ 21.2 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.

~~19.3.~~ 21.3. 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.

~~19.4.~~ 21.4. 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.

~~§64-7-20~~ §64-7-22. Exclusion from School Due to a Communicable Disease; Readmission.

~~20.1.~~ 22.1. 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 the Department of Education rule, "Communicable Disease Control Policy", 126CSR51.

~~20.2.~~ 22.2. 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 the Department of Education rule, "Communicable Disease Control Policy", 126CSR51.

~~§64-7-21~~ §64-7-23. Examination and Training of Food Service Workers.

~~21.1.~~ 23.1. Food service management training or workers' training may be provided by the local health departments at the discretion of the local health officer.

~~21.2.~~ 23.2. 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.

~~21.3.~~23.3. 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.

~~21.4.~~ 23.4. 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.

~~§64-7-22~~ §64-7-24. Penalties.

~~22.1.~~ 24.1. Any person 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 W. Va. Code §16-1-18. Each violation is considered a separate offense.

~~22.2.~~ 24.2. 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 W. Va. Code §§16-2-4 or 16-2A-8.

~~22.3.~~ 24.3. 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 §16-2-12.

~~§64-7-23~~ §64-7-25. 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 procedural rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64CSR1.