WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE OF WEST VIRGINIA SECRETARY OF STATE

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

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

CITE AUTHORITY W. Va. Code §§16-3-1 and 16-1-7

AMENDMENT TO AN EXISTING RULE: YES _____ NO X

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 7

TITLE OF RULE BEING PROPOSED: Reportable Diseases, Events and Conditions

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.

Joan E. Ohl

Joan E. Ohl, Secretary

$13.20

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: July 28, 1998

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Division of Health
Department of Health and Human Resources
State Capitol Complex, Building 3, Room 265, Charleston, WV 25305
Telephone: (304) 558-3223

LEGISLATIVE RULE TITLE: Reportable Diseases, Events and Conditions, 64 CSR 74

1. Authorizing statute(s) citation: WV Code Section 16-3-1 & 16-1-7.

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

July 1, 1998

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

Copies were distributed to all local health departments, the WV Department of Education, WV State Medical Association, WV Society for Osteopathic Medicine, WV Hospital Association, hospital and commercial laboratories and managed care organizations. A notification was printed in the Division of Surveillance and Disease Control's newsletter.

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

July 31, 1998

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

Attached X No comments received _____

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

August 3, 1998

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

Marsha Dadisman, Acting Director

Regulatory Development/Department of Health and Human Resources

Building 3 Room 265, Capitol Complex

Charleston, West Virginia 25305

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

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

Loretta Haddy

Director, Division of Surveillance and Disease Control

1422 Washington Street, East

Charleston, West Virginia 25301

Phone: (304) 558-5358 or 1-800-423-1271

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

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

N/A

b. Date of hearing or comment period:

N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

BRIEF SUMMARY OF THE RULE

This rule addresses WV Code, Chapters 16-3-1, 16-4, and 16-3-5. It is entitled, Legislative Rule, Title 64, Series 7, and establishes procedures governing the reporting of certain diseases and conditions, unusual health events, and clusters or outbreaks of diseases to the division of health. It also establishes the responsibility of various individuals and facilities in controlling communicable diseases.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

This rule has been totally restructured to reflect current format. There are four new sections included relating to confidentiality, administration of immunizations, designation of diseases as sexually transmittable, and responsibilities of managed care organizations. Passage of House Bill 4483 during the 1998 Legislative Session required rules to be filed to designate sexually transmitted diseases. Also, House Bill 4516 was passed on March 3, 1994, requiring, among other things, establishment of a Childhood Immunization Advisory Committee to track immunization compliance.

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Reportable Diseases, Events and Conditions: 64 CSR 7

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

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

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

1. Effect of the Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	$	$	$	$0	$0
Personal Services					
Current Expense					
Repairs & Alterations					
Equipment					
Other					
Revenue				0	0

2. Explanation of above estimates.

There are not costs or revenues associated with this rule.

3. Objectives of this rule:

To establish procedures governing the reporting of certain diseases and conditions, unusual health events, and clusters or outbreaks of diseases to the division of health. It also establishes the responsibility of various individuals and facilities in controlling communicable diseases.

4. **Explanation of Overall Economic Impact of Proposed Rule.**

A. **Economic Impact on State Government.**

None anticipated.

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

None anticipated.

C. **Economic Impact on Citizens/Public at Large.**

None anticipated.

Date: 7/1/98

Signature of Agency Head or Authorized Representative

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

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

SERIES 7
REPORTABLE DISEASES, EVENTS AND CONDITIONS

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

TITLE 64
LEGISLATIVE RULES
DIVISION OF 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 division of health. It also establishes the responsibility of various individuals and facilities in controlling communicable diseases.

1.2. Authority - W. Va. Code §§16-3-1 and 16-1-7; related §§16-3C-1 *et seq.* and 16-4-1 *et seq.*

1.3. Filing Date -

1.4. Effective Date -

1.5. Repeal and Replacement of Former Rule - This rule repeals and replaces West Virginia Division of Health Legislative Rule, Reportable Diseases, 64 CSR 7, effective March 24, 1994.

1.6. Applicability - This rule applies to physicians and other licensed health practitioners; local health officers; other public health providers; private or public laboratories; all health care facilities; managed care organizations; 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, and medical examiners; and any other person investigating or treating disease, health conditions, or cause of death.

1.7. Enforcement - This rule is enforced by the director of the West Virginia division of health or his or her lawful designee.

§64-7-2. Definitions.

2.1. 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.

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

2.3. Director - The director of the division of health[1] of the West Virginia department of health and human resources or his or her designee.

2.4. Division - The division of health of the West Virginia department of health and human resources.

2.5. Epidemiologic Information - Medical data or other information, interviews, investigative reports, other records and notes collected during the course of an epidemiologic investigation of a disease, condition, or outbreak.

2.6. Health care provider - Any physician, dentist, nurse, or other individual who provides medical, dental, nursing, or other health care services of any kind to individuals.

2.7. Health care facility - Any hospital, nursing home, clinic, cancer treatment center, laboratory, or other facility which provides health care or diagnostic services to individuals, whether public or privately owned.

2.8. Hospital - A facility licensed as a hospital under W. Va. Division of Health Legislative Rule, Hospital Licensure, 64 CSR 12.

2.9. Isolation - The separation of infected persons or animals from other persons or animals, under the necessary time frame and conditions to prevent the direct or indirect transmission of the infectious agent from the infected persons or animals to other persons or animals who are susceptible or who may spread the disease to others.

2.10. Laboratory - Any facility or place, however named, for the biologic, microbiologic, serologic, virologic, chemical, hematologic, immuno-hematologic, biophysical, cytologic, pathologic, or other examination of materials for the purpose of providing medical or epidemiologic information for the diagnosis, prevention or treatment of any disease, or the impairment of, or the assessment of the health of human beings. The term "laboratory" includes both public and private laboratories, free-standing laboratories, and hospital laboratories.

2.11. Local Board of Health - A board of health serving one (1) or more counties, one (1) or more municipalities, or a combination thereof.

2.12. Local Health Department - The staff of the local board of health.

2.13. Local Health Officer - The individual who fulfills the duties and responsibilities of the health officer for a county, municipal, or combined board of health, or his or her

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[1]The Department of Health and Human Resources (DHHR) was created by the Legislature's reorganization of the executive branch of State government in 1989, and the Department of Health was renamed the Division of Health and made a part of the DHHR (W. Va. Code §5F-1-1 *et seq.*). Administratively within the DHHR, the Bureau for Public Health through its Commissioner carries out the public health functions of the Division of Health.

designee.

2.14. Managed Care Organization (MCO) - An entity that integrates financing and management with the delivery of health care services to an enrolled population. A MCO provides, offers or arranges for coverage of designated health services needed by members for a fixed, prepaid amount. There are three basic models of MCOs: group or network model, individual practice association, and staff model.

2.15. Medical Information - Data or other information regarding the history, examination, lab findings, diagnosis, treatment, or other clinical care for a person examined or treated for a suspected or actual disease.

2.16. Nursing Home - Any facility licensed as a nursing home under W. Va. Legislative Rule, Nursing Home Licensure, 64 CSR 13, or any extended care facility operated in conjunction with a hospital.

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

2.18. 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 said disease or hazard within or beyond the placarded home, building, or structure.

2.19. 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.

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

2.21. STD - Sexually transmitted disease.

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

3.1. Selection and Categorization of Required Reportable Diseases and Conditions.

3.1.a. The director may, by order filed with the Secretary of State, add or delete a disease or condition in any category. The director 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 (e.g., potential epidemics), the director may require same day reporting for diseases and conditions in any of the categories listed in this rule.

3.2. Reporting of Diseases and Conditions.

3.2.a. The director shall establish specific protocols[2] for reporting diseases and conditions. The protocols shall include any information to be reported beyond that listed in this rule and any additional information necessary regarding reporting or appropriate public health management.

3.2.b. The reports required by this rule may be made electronically in a manner approved by the director or on forms supplied by the director (see footnote 2).

3.3. Category I Reportable Diseases and Conditions.

3.3.a. Cases of Category I diseases or conditions listed in Sections 3.3.b and 3.3.c of this rule shall be reported by telephone to the local health department in the patient's county of residence within twenty-four (24) hours of diagnosis. The reports shall include the patient's name, address, date of birth, sex, and any other information requested by the director relevant to the purposes of this rule.

3.3.b. Category I.A diseases and conditions reportable by health care providers and health care facilities are:

3.3.b.1. Botulism;
3.3.b.2. Cholera;
3.3.b.3. Dengue Fever;
3.3.b.4. Diphtheria;
3.3.b.5. E. Coli O157:H7 Disease;
3.3.b.6. Foodborne Disease;
3.3.b.7. Gonococcal Disease* -- Conjunctivitis in the newborn, Drug-resistant disease, or Pelvic Inflammatory Disease;
3.3.b.8. *Haemophilus influenzae*, Invasive Disease;
3.3.b.9. Hemolytic Uremic Syndrome, postdiarrheal;
3.3.b.10. Hepatitis A, Acute;
3.3.b.11. Hepatitis B, Acute or perinatal;
3.3.b.12. Hepatitis D;
3.3.b.13. Meningococcal Disease, Invasive;
3.3.b.14. Outbreak or cluster of any illness or condition - suspect or

[2]Protocols can be found in the West Virginia Reportable Diseases Protocol Manual. This manual, standard disease report cards, and disease-specific supplemental forms necessary for the division or for the Centers for Disease Control and Prevention (CDC) can be obtained from the West Virginia Bureau for Public Health, Division of Surveillance and Disease Control through the local health department. Protocols and report forms are updated as necessary to accomplish the purposes of this rule.

confirmed;

3.3.b.15. Pertussis (Whooping Cough);
3.3.b.16. Plague;
3.3.b.17. Poliomyelitis;
3.3.b.18. Rabies in Animals or in Man;
3.3.b.19. Rubella (German Measles);
3.3.b.20. Rubeola (Measles);
3.3.b.21. Syphilis* -- Primary, Secondary, Early Latent (less than one (1) year), or Congenital;
3.3.b.22. Typhoid Fever;
3.3.b.23. Waterborne Disease; and
3.3.b.24. Yellow Fever.

3.3.c. Reports of Category I.A diseases and conditions marked with an asterisk (*) shall be made on the sexually transmitted disease report card (VD-91). Others should be submitted on standard reporting cards and supplemental forms. (See Footnote 2.)

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

3.3.d.1. *Bordatella pertussis*, microbiologic evidence;
3.3.d.2. *Clostridium botulinum*, microbiologic or toxicologic evidence;
3.3.d.3. *Corynebacterium diphtheriae,* microbiologic or histopathologic evidence;
3.3.d.4. Dengue Fever, serologic evidence;
3.3.d.5. *E. Coli* O157:H7 from any site;
3.3.d.6. *E. Coli* O157:NM, Shiga-like toxin-producing, from any clinical specimen;
3.3.d.7. *Haemophilus influenzae* from any normally sterile body site;
3.3.d.8. Hepatitis A, positive IgM;
3.3.d.9. Hepatitis B, positive anti-HBc IgM or HBsAg;
3.3.d.10. Hepatitis D, positive serology;
3.3.d.11. *Neisseria gonorrheae* (drug resistant) from any site*;
3.3.d.12. *Neisseria gonorrheae* from female upper genital tract*;
3.3.d.13. *Neisseria gonorrheae* from the eye of a newborn*;
3.3.d.14. *Neisseria meningitidis* from a normally sterile site;
3.3.d.15. Outbreak or cluster of any illness or condition - suspect or confirmed;
3.3.d.16. Poliomyelitis, virologic or serologic evidence;
3.3.d.17. Rabies, animal or human;
3.3.d.18. Rubella, virologic or serologic evidence;
3.3.d.19. Rubeola, virologic or serologic evidence;
3.3.d.20. *Salmonella typhi* from any site;
3.3.d.21. *Treponema pallidum*, positive dark-field examination*;
3.3.d.22. *Vibrio cholerae*, microbiologic or serologic evidence;
3.3.d.23. Yellow Fever, virologic or serologic evidence;

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

3.3.d.25. Other laboratory evidence suggestive of any of the diseases or conditions listed in Category I.A.

3.3.e. Reports of category I.B diseases and conditions marked with an asterisk (*) shall be made on the appropriate sexually transmitted disease report form (VD-91). Others should be submitted on standard reporting cards and supplemental forms. (See Footnote 2.)

3.4. Category II Reportable Diseases and Conditions.

3.4.a. Cases of Category II diseases or conditions shall be reported to the local health department in the patient's county of residence within at most one (1) week of diagnosis. The reports shall include the patient's name, address, date of birth, sex, and any other information requested by the director relevant to the purposes of this rule.

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

3.4.b.1. Amebiasis;
3.4.b.2. Anthrax;
3.4.b.3. Brucellosis;
3.4.b.4. Campylobacteriosis;
3.4.b.5. Chancroid*;
3.4.b.6. Chickenpox (numerical totals only);
3.4.b.7. Chlamydia trachomatis*;
3.4.b.8. Cryptosporidiosis;
3.4.b.9. Cyclospora;
3.4.b.10. Encephalitis, Arboviral;
3.4.b.11. Encephalitis, Other primary and unspecified;
3.4.b.12. Giardiasis;
3.4.b.13. Gonorrhea (except Category I diseases)*;
3.4.b.14. Hantavirus Disease;
3.4.b.15. Hepatitis C / Other non-A or non-B, acute;
3.4.b.16. Herpes, genital*;
3.4.b.17. Influenza-like Illness (numerical totals only);
3.4.b.18. Leptospirosis;
3.4.b.19. Listeria;
3.4.b.20. Lyme Disease;
3.4.b.21. Malaria;
3.4.b.22. Meningitis, Other Bacterial (cases not reported as other specific disease types);
3.4.b.23. Meningitis, Viral or Aseptic;
3.4.b.24. Mumps;
3.4.b.25. Psittacosis;
3.4.b.26. Rheumatic Fever;

3.4.b.27. Rocky Mountain Spotted Fever;
3.4.b.28. Rubella, Congenital Syndrome;
3.4.b.29. Salmonellosis (except Typhoid Fever);
3.4.b.30. Shigellosis;
3.4.b.31. Streptococcal Disease, Invasive Group A, (*Streptococcus pyogenes*);
3.4.b.32. Streptococcal Toxic Shock Syndrome;
3.4.b.33. *Streptococcus pneumoniae,* drug resistant invasive disease, (include antibiotic susceptibility patterns);
3.4.b.34. Syphilis (late latent)*;
3.4.b.35. Tetanus;
3.4.b.36. Trichinosis;
3.4.b.37. Tuberculosis (All Forms, include antibiotic susceptibility patterns)**;
3.4.b.38. Tularemia; and
3.4.b.39. Unexplained or ill-defined illness, condition, or health occurrence of potential public health significance.

3.4.c. Reports of Category II.A diseases and conditions marked with an asterisk (*) shall be made on the sexually transmitted disease report card (VD-91).

3.4.d. Reports of Category II.A diseases and conditions marked with two (2) asterisks (**) shall be made on the tuberculosis report form.

3.4.e. Category II.B conditions reportable by laboratories are:

3.4.e.1. *Bacillus anthracis*;
3.4.e.2. *Borrelia burgdorferi* from culture, or diagnostic levels of IgG or IgM, (preferably followed by a western blot);
3.4.e.3. Brucellosis, microbiologic or serologic evidence;
3.4.e.4. *Campylobacter*;
3.4.e.5. *Chlamydia trachomatis* by culture, antigen, DNA probe methods, or other procedures declared reportable by the director of health*;
3.4.e.6. *Cryptosporidium*;
3.4.e.7. Encephalitis, virologic, serologic, or other evidence of arboviral or other encephalitides;
3.4.e.8. *Entamoeba histolytica*;
3.4.e.9. *Giardia lamblia*, microscopic or immunodiagnostic evidence;
3.4.e.10. Hantavirus infection, serologic, PCR, immunohistochemistry, or other evidence;
3.4.e.11. Hepatitis C, positive HCV antibody confirmed with approved supplemental test (e.g. RIBA);
3.4.e.12. *Herpes simplex virus**, isolation of herpes simplex virus from cervix, urethra or anogenital lesion, or demonstration of virus by antigen detection technique in clinical specimens from cervix, urethra or anogenital lesion, or demonstration of multinucleated giant cells on a Tzanck smear of scrapings from an

anogenital lesion;

3.4.e.13. Leptospirosis, virologic or serologic evidence;

3.4.e.14. Malaria organisms on smear of blood;

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

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

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

3.4.e.18. *Mycobacterium tuberculosis* from any site (include drug susceptibility patterns)**

3.4.e.19. *Neisseria gonorrheae**, culture or other positive laboratory evidence, (from sites not mentioned under Category I);

3.4.e.20. Psittacosis, microbiologic or serologic evidence;

3.4.e.21. Rocky Mountain Spotted Fever, serologic evidence;

3.4.e.22. *Salmonella* (any species, excluding *Salmonella typhi*);

3.4.e.23. *Shigella* (any species);

3.4.e.24. *Streptococcus pyogenes* (Group A Streptococcus) from a normally sterile site;

3.4.e.25. *Streptococcus pneumoniae*, from a normally sterile site (include antibiotic susceptibility patterns on all isolates);

3.4.e.26. Syphilis*, serologic evidence;

3.4.e.27. Trichinosis, demonstration of cysts or serologic evidence;

3.4.e.28. Tularemia, culture, antigen or serologic evidence;

3.4.e.29. Unexplained or ill-defined illness, condition, or health occurrence of potential public health significance; and

3.4.e.30. Other laboratory evidence suggestive of any of the diseases or conditions listed in Category II.A.

3.4.f. Reports of Category II.B diseases and conditions marked with an asterisk (*) shall be made on the sexually transmitted disease report card (VD-91).

3.4.g. Reports of Category II.B diseases and conditions marked with two (2) asterisks (**) shall be made on the tuberculosis report form.

3.5. Category III Diseases and Conditions.

3.5.a. Category III diseases and conditions shall be reported to the division within at most one (1) week of diagnosis unless otherwise indicated in a disease specific legislation (e.g., cancer). Reports shall include the patient's name, address, date of birth, sex, and any other information requested by the director relevant to the purposes of this rule.

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

3.5.b.1. AIDS diagnosed from the presence of AIDS defining diseases or conditions (including previously reported HIV positive individuals);

3.5.b.2. Birth Defects, including Down's Syndrome;

3.5.b.3. Cancer[3];
3.5.b.4. Hemophilia;
3.5.b.5. HIV (Human Immunodeficiency Virus)[4];
3.5.b.6. Lead Poisoning (blood lead concentration equal to or greater than 10 micrograms per deciliter);
3.5.b.7. Occupational Illnesses; and
3.5.b.8. Traumatic Brain Injury.

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

3.5.c.1. Lead poisoning (blood concentration greater than or equal to 10 micrograms per deciliter);
3.5.c.2. CD4+ T-lymphocyte counts of two hundred or less per cubic millimeter (200/mm^3) or a percentage less than fourteen (14) percent;
3.5.c.3. Down's Syndrome chromosomal anomaly; and
3.5.c.4. HIV (Human Immunodeficiency Virus) Type 1 or 2, confirmed antibody or virus detection test (serology, culture, antigen, PCR, DNA, RNA probe, etc.).

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

4.1. The director shall arrange for the timely reporting of birth defects identified from birth certificates, health care facility medical records, pediatric health care providers or human genetic services providers. After case review, evaluation and referrals, reports will be consolidated in the Maternal and Child Health database. Appropriate report forms are provided for this reporting by the division.

§64-7-5. Other Reportable Events: Potentially Rabid Animal Bites, Rabid Animals.

5.1. If a person is bitten, scratched, or otherwise exposed (gets saliva, neural tissue, or other potentially infectious fluid into an open cut, wound, or mucous membrane) to an animal which has or is suspected of having rabies, then the incident, including the person's full name, date of birth, and address, shall be reported to the local health officer by the following individual:

5.1.a. The physician or other health care provider caring for or observing the person;

5.1.b. 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

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[3]Reporting of cancer is further delineated in West Virginia Division of Health Legislative Rules, Title 64, Series 68, Cancer Registry.

[4]Reporting of HIV infection is further delineated in West Virginia Division of Health Legislative Rules Title 64, Series 64, AIDS Related Medical Testing and Confidentiality.

exposed is an adult;

5.1.c. Whoever is caring for the person, if no physician or other health care provider is in attendance and the person bitten, scratched, or otherwise exposed is incapacitated; or

5.1.d. 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 to the director the name, date of birth, address, circumstances of the exposure, and action taken for every person bitten, scratched, or otherwise exposed to an animal which has or is suspected of having rabies.

5.3. If the animal is a domestic dog or cat, 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 (10) days. The owner of the dog or cat, 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.

5.4. If the local health officer cannot determine the owner of the domestic dog or cat, he or she shall direct the county humane officer, dog warden or sheriff to pick up the suspect dog or cat that has bitten a person and confine it in isolation for a period of ten (10) days. If the animal shows symptoms compatible with rabies or dies, 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.

5.5. If a person is reported bitten by any animal having or suspected of having rabies other than a domestic dog or cat, the local health officer, if necessary, shall 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.

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.

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

6.1. The director shall establish and maintain a centralized registry for tracking compliance with nationally recommended immunization schedules and for monitoring vaccine use.

6.2. Administration of each immunization against the following diseases shall be reported: diphtheria, whooping cough, tetanus, polio, measles, mumps, rubella, hepatitis-B, *Haemophilus influenzae* type b disease, chicken pox, and any additional immunizations required by the director for public health purposes as published by order filed with the secretary of state.

6.3. Physicians and other health care providers, hospitals and other health care facilities, local health officers, and any other provider or facility administering immunizations shall report immunizations administered to the centralized immunization registry as required by this rule.

6.4. All immunizations administered to children of ages six (6) and under shall be reported to the immunization registry within one (1) week of the administration of the immunization.

6.5. Immunization reports shall contain the name of the child 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 director for development, maintenance, and use of the immunization registry and vaccine tracking system.

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

7.1. 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 the local health officer for the county in which the death occurred and to the county in which the decedent resided, with the exception of Category III diseases and conditions. These are reported directly to the division.

7.2. If a pathologist, coroner, medical examiner, physician, other health care provider, or other individual investigating the cause of death determines from the examination of a corpse or from a history of the events leading to death, that at the time of death, the decedent had a disease or condition required to be reported by this rule, he or she shall report the case promptly as required by this rule as if the diagnosis had been established prior to death.

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

8.1. Physicians and Other Health Care Providers; Hospitals and Other Health Care Facilities.

Any physician, other health care provider, hospital, or health care facility who suspects, diagnoses, or cares for a patient with a disease or condition listed in Categories I.A, II.A, III.A or elsewhere in this rule shall:

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

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

8.1.c. Make every effort to submit the specimens identified in protocols specified by the director (see footnote 2) to establish an accurate diagnosis of the disease or condition to a laboratory approved by the director;

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

8.1.e. Follow a method of control specified by the director in established protocols (see footnote 2) or by methods developed in consultation with the director; and

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

8.2. Laboratories.

8.2.a. All laboratories, whether public, private or hospital-based, are responsible for reporting the diseases or conditions listed in Categories I.B, II.B, III.B and shall otherwise comply with the requirements of this rule.

8.2.b. The laboratory which receives a specimen yielding *Mycobacterium tuberculosis* is responsible for the submission of the first isolate to the Office of Laboratory Services (OLS), Division of Health. Additionally, any isolate of *M. tuberculosis* from a patient collected ninety (90) days after the initial specimen must also be forwarded to OLS.

8.2.c. The laboratory must 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/agency who submitted the specimen is notified.

8.2.d. 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 must be submitted to the OLS.

8.2.e. Clinical laboratories that identify acid fast bacillus (AFB) on a smear from a patient must culture and identify the AFB, or refer to another laboratory for those purposes.

8.2.f. Clinical laboratories that isolate Salmonella, Shigella, or suspect or confirmed E. coli 0157:H7 from any patient specimen or *Neisseria meningitidis* or *Haemophilus influenzae* from a sterile site should submit the first isolate or a subculture of that isolate to the OLS.

8.2.g. Information that must be included in any of the specimens listed includes:

8.2.g.1. The name, address, and date of birth of the patient;
8.2.g.2. The specimen accession number or other unique identifier;
8.2.g.3. The date the specimen was obtained from the patient;
8.2.g.4. The source of the specimen;
8.2.g.5. The type of test performed;
8.2.g.6. The name, address, and telephone number of the submitting laboratory; and
8.2.g.7. The name, address, and telephone number of the physician or health care provider for whom the examination or test was performed.

8.3. Administrators of Schools, Camps, Vessels, and Department-Operated Health Care Facilities.

When no physician or other responsible health care provider is in attendance, the administrator of any school, camp, vessel or department-operated health care facility shall:

8.3.a. Report any reportable disease or condition occurring in the school, camp, vessel or department-operated health care facility as required by this rule;

8.3.b. Assist public health officials in appropriate case and outbreak investigation or management and in any necessary contact investigation and management;

8.3.c. Follow a method of control specified by the director in established protocols (see footnote 2) or by recommendations developed in consultation with the director;

8.3.d. If the disease or condition is communicable, advise, in consultation with State and local public health officials, the patient, and as necessary, members of the patient's household and other patient contacts regarding the precautions to be taken to

prevent further spread of the disease. In cases of sexually transmitted diseases, HIV, and tuberculosis the division recommends that health care providers and health care facilities refer contact notification activities to the division for STD and HIV and local health departments for tuberculosis rather than attempt to accomplish the notification themselves; and

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

§64-7-9. Responsibilities of Managed Care Organizations.

9.1. Managed Care Organizations.

9.1.a. Managed Care Organizations shall notify any contracted providers, facilities, or laboratories serving residents of West Virginia of their legal responsibilities delineated in this rule.

9.1.b. Managed Care Organizations shall annually provide contracted healthcare providers, facilities, and laboratories serving residents of West Virginia with a list of currently reportable diseases and conditions[5].

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

10.1. Local health officers shall comply with the requirements of this rule.

10.2. Local health officers shall maintain a record of the information they collect and the reports they make pursuant to this rule according to the record retention schedule for the local health department. They shall give the information and reports to their successor.

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

10.3.a. As circumstances require, investigate the source of the disease or condition, identify contacts, and look for undetected and unreported cases. Implement the prevention and control methods specified by the protocols (see footnote 2) or developed in consultation with the director;

10.3.b. Act in accordance with the protocols established by the director (see footnote 2) or recommendations developed in consultation with the director.

10.3.c. Determine if required specimens have been collected and submitted;

[5]Obtainable through the Division of Health.

and if not, arrange for collection and submission of necessary specimens to investigate the case, determine the source of the infection, and identify infection of contacts, as necessary. Specimens shall be submitted to the division laboratory or other laboratory approved by the director;

10.3.d. Give the patient, those caring for the patient, household members, and other contacts instructions and advice necessary to prevent the spread of the disease or condition; and

10.3.e. Report any disease or condition listed in Category I, II, III, or elsewhere in this rule to the division within the time frame specified in each category.

10.4. If the report received is a death certificate listing a reportable disease or condition, the local health officer shall ascertain whether the disease or condition was reported according to the requirements of this rule prior to the individual's death. As with any other report, the local health officer shall investigate the source of the disease or condition, identify contacts, and look for undetected and unreported cases and implement prevention and control measures as circumstances require.

10.5. Whenever a local health officer knows of or suspects the existence of any reportable disease or condition, and either no licensed physician or other health care provider is in attendance, or the physician or other health care provider has failed or refused to comply with this rule, the local health officer shall investigate the alleged reportable disease or condition. If the investigation establishes the existence of a reportable disease or condition, the local health officer shall further investigate, manage, and report the disease or condition as required by this rule.

10.6. If the local health officer determines that a health care provider, health care facility, laboratory, or other individual named in this rule as responsible for reporting failed to report a reportable disease or condition, the local health officer shall notify the responsible individual or facility and shall request an explanation for the failure to report the disease as required by this rule.

10.7. The local health officer shall report to the director the name and address of the health care provider, health care facility, laboratory, or other responsible individual named in this rule and his or her reason for failure to comply with the requirements of this rule.

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

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

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

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

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

13.1. 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 shall be 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 director deems sexually transmittable, by order filed with the Secretary of State. The director may, by order filed with the Secretary of Sate, also remove the designation of diseases he or she has, by order, previously designated.

§64-7-14. Confidentiality.

14.1. Any epidemiologic information collected and maintained pursuant to this rule by local health officers or the director which identifies an individual or facility as having or suspect for 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.

14.2. In the case of an individual, the director or a local health officer may release confidential information identified in §14.1. of this rule to the following:

14.2.a. The patient;

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

14.2.c. Individuals who maintain and operate the data and medical record systems used for the purposes of this rule, if the systems are protected from access by persons not otherwise authorized to receive the information;

14.2.d. 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 director or the local health officer, to be used solely for the purpose of medical evaluation or treatment of the patient;

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

14.2.f. Staff of a federal, State, or local health department or other local agency with the responsibility for the control and treatment of disease, to the extent necessary for the agency to enforce specific relevant provisions of federal, State and local law, rules and regulations concerning the control and treatment of disease;

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

14.2.h. The manager of a facility employing the case or suspect case if deemed absolutely necessary by the director for protection of the public's health under the following provisions:

14.2.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 shall take to assure protection of the health of the public; and

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

14.2.i. For purposes of reports required under W. Va. Code § 49-6A-1 et seq., reports of children suspected to be abused or neglected. However, all records protected by W. Va. Code, §§16-4-10, 16-29-1, 16-3C-3, or any other applicable code section shall be kept confidential in accordance with those sections.

14.3. In the case of a facility, the director 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 deemed necessary by the director.

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

15.1. 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 director. This authority extends to local health officers when following protocols established by the director for management of reportable diseases and conditions, or established following consultation with the director for these or other health risks.

15.2. When an individual or a group of individuals is suffering from a communicable disease in which isolation is required for the control of the disease, the local health officer has the authority to initiate and to terminate the necessary isolation, unless the case 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 when it should be terminated.

15.3. 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 other health hazard. In addition, no person shall conceal, mutilate or remove any such placard, except by permission of the local health officer.

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

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

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

16.2. 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 from a physician, local health officer or his authorized representative stating that such individual is no longer liable to transmit the disease to others. The return is subject to compliance with jointly developed Department and Department of Education rules and policies governing such cases.

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

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

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

17.3. 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 such exam is undertaken and the individual no longer presents a threat to public health.

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

§64-7-18. Penalties.

18.1. Any physician or other licensed health practitioner; local health officer; other public health provider; private, public, or hospital laboratory; hospital or health care

facility; managed care organization; individual administering immunizations; administrator of school, camp, or vessel; administrator of a health care facility operated by the department; the State registrar of vital statistics; county humane officer, dog warden, sheriff, pathologist, coroner, or medical examiner; and any other person investigating or treating disease, health conditions, or cause of death 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 two hundred dollars ($200) or be imprisoned for not more than thirty (30) days or both. Violations of each provision are considered a separate offense.

18.2. Any local health officer who fails or neglects to appropriately investigate cases or suspect cases of reportable diseases or other public health threats reported to him by any physician 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 Director, be removed from office in accordance with W. Va. Code §16-2A-8.

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

§64-7-19. 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 division of health procedural rule, Rules of Procedure for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

§64-7-20. Severability.

The provisions of this rule are severable. If any provisions of this rule are held invalid, the remaining provisions remain in effect.

64 CSR 7

Reportable Diseases, Events and Conditions

Commenters

T. Randolph Cox, State Retained Counsel on behalf of Health Insurance Association of America

John M. Collins, Chairman, West Virginia HMO Organization

J. Fred Earley, II, Vice President, External Operations and General Counsel, Mountain State BlueCross BlueShield, Parkersburg, WV

Earl D. Allara, MD, Health Officer, Jefferson County Health Department, Kearneysville, WV

Omayma Touma, MD, Cabell Huntington Health Department, Huntington, WV

Nawal Lutfiyya, WVDHHR/BPH/OMCH, Charleston, WV

Discussion of Public Comments Received
Concerning the Proposed Rule
Reportable Diseases, Events and Conditions, 64 CSR 7

A public comment period on the proposed rule, **Reportable Diseases, Events and Conditions, 64 CSR 7**, was held beginning July 1, 1998 and ending July 31, 1998. There were six (6) commenters. Comments are summarized below, and the Department's responses and changes to the rule are detailed.

§64-7-1 **Comment:** Questioning the authority of the West Virginia division of health to promulgate regulations regarding managed care organizations and comments regarding the rule imposing additional tasks on MCOs which will, in turn, increase the cost of health insurance coverage for enrollees.

Response: The authority for promulgating these regulations, Chapter 16-3-1 of the West Virginia Code, allows the State Board of Health the authority to issue regulations to control infectious or contagious diseases. West Virginia Code does not limit applicability of these rules to health care providers or organizations directly delivering services. The intent for including managed care organizations (MCOs) in Legislative Rule 64 CSR 7 is to enlist them as a partner in the statewide effort to conduct communicable disease surveillance and control activities. Nothing undertaken by MCOs under the proposed rules would replace public health activities. Rather, the Bureau for Public Health has learned throughout the years that surveillance and disease control systems work better if multiple sources work to remind providers and facilities of their responsibilities under these rules.

The Bureau for Public Health is not attempting to place significant "burdens" on MCOs, nor is it the intent to "increase the cost of health coverage for the enrollees of managed care organization plans".

Recognizing the potential complexity of MCOs holding contracted providers "accountable for compliance with these responsibilities", we will remove this language as well as the language related to policies and procedures developed by managed care organizations.

§64-7-1, 1.2 **Comments:** Change to add 16-4, and 16-3-5 to "Authority".

Response: Recommend insertion in this section to read as follows: Authority - W.Va. Code 16-3-1, **16-4, and 16-3-5.**

Comments: Questions regarding the definition of managed care organization.

Response: No change in definition is recommended.

§64-7-4, 4.1 **Comments:** Suggestion to insert the following into second line: ...from birth certificates, health care facility medical records, **pediatricians during well-child examinations,** or human....

Response: Rather than identifying pediatricians as the only physicians examining children, we have decided to use the term health care provider to include the full spectrum of those providing well-child care, e.g., family practitioners, general practitioners, physician assistants, etc.

The new language will read as follows: ...from birth certificates, health care facility medical records, **pediatric health care providers,** or human...

§ 64-7-5, 5.2 **Comments:** Not clear as to what defines "Suspected of having rabies". More detail needed concerning report procedure...will a specific form be provided and what is the frequency of the reports to be submitted (i.e., within 24 hours of receipt, weekly, quarterly, etc.)

Response: No change is required in proposed rule. "Suspected of having rabies" relates to whether or not the species of animal undertaking the bite is likely to carry rabies, the circumstances surrounding the behavior of the biting animal and the vaccination status of the biting animal. Examples of the type of information needed to assess whether or not an animal is "suspect" may include the species of animal, the geographic distribution of rabies in the species, the behavior history of the animal, the nature of the bite situation, the vaccination status of the offending animal (if domestic), a history consistent with potential contact with a wild/rabid animal, etc. The Office of Environmental Health currently has an animal encounter form for use by local health departments.

§ 64-7-6, 6.1 **Comments:** More information is needed detailing specifics for establishing a central registry.

Response: No change is required in proposed rule. This section was included to implement the intent of Chapter 16-3-5 which grants the Childhood Immunization Advisory Committee the responsibility of tracking the immunization compliance in accordance with federal and state laws. The approach being taken in WV and all states is to establish an automated software system to house statewide childhood immunization records. The funding comes from the National Immunization Program as a part of the President's Childhood Immunization Initiative.

§ 64-7-6, 6.5 **Comments:** Why is mother's maiden name included on report and not the parent's names? The immunization card (orange card, mch 1117-A) currently used does not have a space for mother's maiden name - will cards be updated to include this information?

Response: No change is required in proposed rule. This section lists, as

examples, only a few of several fields of data to be gathered. The rest are covered by "and any other information required by the director." The statement is correct, the parent's name is one of the fields and can be inserted in this section. This information will be entered by local health departments into computer software developed by Scott Stevenson, Health Stat 2000, and uploaded into the central data repository. Whether or not the "orange card" will be needed in the future is currently unclear. There are no plans to alter or expand the information collected on this card.

§ 64-7-10, 10.2 **Comments:** Is three years an adequate time to keep records?

Response: Three (3) years is probably not long enough. A change will be made to the legislative rules referring local health departments to the Records Retention Schedule for Local Health Departments. This document, developed by the Bureau for Public Health, gives detailed recommendations for the retention and disposal of records.

§ 64-7-13 **Comments:** The "h" has been inadvertently omitted from the word on page 16, 64-7-13, 13.1, fourth line, fifth word causing the word to be misspelled.

Response: A correction will be made to spell the word as follows: lymphogranuloma.

§ 64-7-16, 16.1 **Comments:** Licensed daycare centers should be included in this section.

Response: Day care centers can be included in this section. A little researching of day care laws and policies for control of communicable diseases will be required first. Time has not permitted this effort to be completed to enable the drafting of new language. As soon as this effort is completed, the information can be provided to the Legislative Rule Making Committee to be considered as an amendment. Appropriate language can be drafted at that time.

§ 64-7-17 **Comments:** Recommendation that food service workers training be mandatory.

Response: The Bureau for Public Health does not oppose required food service worker training. However, before such a change would be considered, all local health departments would need to be surveyed to acquire endorsement/consensus of such a requirement. The current language is a change made several years age at the request of local health officers.

§ 64-7-18, 18.1 **Comments:** Questioning whether the Bureau for Public Health has the authority to impose penalties on managed care organizations as set forth in this rule.

Response: Response to first comment in this document removes this section from applicability to MCOs. *"Recognizing the potential complexity of MCOs holding contracted providers "accountable for compliance with these responsibilities", we will remove this language as well as the language related to policies and procedures developed by managed care organizations."*

§ 64-9-1.a **Comments:** All managed care organizations do not necessarily contract with all providers. It is not an MCO's responsibility to alert providers of their statutory requirements, past or future. Regulations as proposed would misplace the accountability for compliance of the same on health insurers who have no such authority over the operations of various health care providers.

Response: MCOs have contracts with various organizations providing care to WV residents. These include in and out of state health care providers, laboratories, hospitals, etc. Each is a valuable source of information for accomplishing disease control functions. In the case of out of state laboratories, providers or facilities, the department would have no knowledge that such entities serve West Virginia residents. Only the MCO is aware of this fact. Thus, it is critical that MCOs contracting with these entities notify them of the these responsibilities. In the case of in state providers and facilities, the MCO becomes a partner, supportively reminding them of mandated responsibilities. Hearing this message multiple times from multiple sources results in more effective surveillance and more efficient disease control activities. This ultimately results in reduced spread of disease, healthier communities, and lower health care costs. The fulfillment of section 9.1.a. could be accomplished by something as simple as the MCO including a copy of this rule with other information initially provided to each newly contracted provider, facility, or organization.

§ 64-9-1.b. **Comments:** Concern that this section requires MCOs to duplicate services already provided by the Bureau for Public Health and questions how physicians, hospitals and laboratories who do not contract with health maintenance organizations will be informed.

Response: No change recommended to proposed rule. While the rule does not significantly change regularly, the list of reportable diseases does change from time to time. Inclusion of this list in one mailing a year to the providers, labs, and facilities with whom MCOs contract helps to assure an updated list is accessible and serves to remind them of these responsibilities. Such mailings will be in addition to, not in lieu of public health dissemination efforts. A copy of the current list is obtainable from the Bureau for Public Health. Inclusion of this list in an annual mailing should be an overly burdensome request of MCOs, yet it has the potential to significantly enhance disease control efforts.

§ 64-9-1.c. **Comments:** Unclear what a managed care organization is required to do under this section.

Response: Section 9.1.c. will be removed from the proposed rules unless specific situations deem it necessary in the future. It is extremely important that policies or procedures developed by MCOs not hinder diagnosis of reportable diseases or hinder reporting or public health follow-up. For example, a protocol for managing acute diarrhea that did not support submission of a stool culture on the first visit, especially in the setting of bloody diarrhea or fever, would hinder rapid diagnosis of such infections as *E. coli* O157:H7, *Salmonella*, or *Shigella*. Without cultures, the disease would not be specifically diagnosed or reported to public health, could not be followed up on by public health, and could thus present a higher risk for continued spread. Similarly, it could delay identification of a larger outbreak. Managed care organizations cannot be expected to always see the potential public health implications of their decisions. It is critical that we work together to assure rapid diagnosis, reporting, and follow up of reportable diseases among both enrollees and other community members.

64CSR7

RULE TO BE REPLACED

The rule proposed to be replaced is "Reportable Diseases," 64CSR7, that was effective on March 24, 1994, and that established the procedures governing reportable diseases required to be reported to the West Virginia Division of Health.

TITLE 64

WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

REPORTABLE DISEASES

SERIES 7

1994

WEST VIRGINIA LEGISLATIVE RULES
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
REPORTABLE DISEASES
64 CSR 7

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TITLE 64
WEST VIRGINIA LEGISLATIVE RULES
DIVISION OF HEALTH

SERIES 7
REPORTABLE DISEASES

§64-7-1. General.

1.1. **Scope** - These legislative rules establish procedures governing reportable diseases required to be reported to the West Virginia department of health.

1.2. **Authority** - W. Va. Code §16-1-7; and §16-3-1

1.3. **Filing Date** - March 24, 1994.

1.4. **Effective Date** - March 24, 1994.

§64-7-2. Supersession and Repeal of Former Regulations

These legislative rules amend and reenact Reportable Diseases, 64 CSR 7, 1992.

§64-7-3. Application and Enforcement.

3.1. **Application** - These legislative rules apply to physicians, county health officers, primary care or public health providers, private or public laboratories, hospitals, nursing homes, administrators of sanitariums, schools, camps, vessels, state institutions, other licensed health practitioners, persons or facilities specifically mentioned within these regulations.

3.2. **Enforcement** - The enforcement of these legislative rules is vested with the director of the West Virginia department of health or his lawful designee.

§64-7-4. Definitions.

4.1. **Communicable Disease** - An illness due to an infectious agent or its toxic products which is transmitted, directly or indirectly, to a susceptible host from an infected person, animal, or arthropod, or through the agency of an intermediate host or a vector or through the inanimate environment.

4.2. **Department** - The West Virginia department of health.

4.3. **Isolation** - The separation for the period of communicability of infected persons or animals from other persons or animals, in places and under conditions that shall prevent the direct or indirect transmission of the infectious agent from infected persons or animals to other persons or animals who are susceptible or who may spread the disease to others.

4.4. **Quarantine** - The limitation of freedom of movement of persons or animals who have been exposed to a communicable dis-

ease, for a period of time equal to the longest usual incubation period of the disease, in such manner as to prevent effective contact with those not exposed.

4.5. **Placarding** - The posting on any home or other building of a sign or notice warning of the presence of communicable disease within and the danger of infection therefrom.

4.6. **Reportable Disease** - Any communicable disease declared reportable by regulations; any unusual prevalence or clusters of illness which, in the opinion of the state board of health, may be a public health emergency; noncommunicable diseases and conditions for which the state health director may authorize reporting to provide data and information which are needed to effectively carry out those programs of the department designed to protect and promote the health of the people of West Virginia, or in order to determine the need for the establishment of such programs.

4.7. **Surveillance** - The close supervision of persons and animals exposed to a communicable disease without restriction of movement.

§64-7-5. Diseases or Conditions Declared to be Reportable and Required to be Reported to the State Department of Health.

When used in the public health law and in the regulation of the state board of health, the term reportable disease shall be held to include the following diseases or conditions plus any other diseases or conditions requested by the director of health. A report is required by the state board of health and in the manner specified by the state health director to be made to the county health department for Categories I, II and III, and to the state department of health for Category IV.

Reportable Diseases in West Virginia

5.1. **Category I** - Diseases or conditions to be reported immediately by telephone to the county health department, including case name, address, age and sex. Call within 24 hours to report:* (See Table 64-7A found at the end of this regulation.)

* Note: In some situations, such as potential epidemics, same day reporting may be appropriately requested by county health officers for categories II and III.

5.2. **Category II** - Diseases or conditions reported weekly by name, address, age, and sex to the county health department. (See Table 64-7B found at the end of this regulation.)

5.3. **Category III** - Diseases to be reported weekly by numerical totals to the county health department.

Chickenpox
Influenza-like illness

5.4. **Category IV** - Illnesses of unusual prevalence or clusters of unexplained health occurrences to be reported by name, age, sex, and specific disease information to the state health department according to protocols specified by the director of the department. (See Table 64-7C found at the end of this regulation.)

5.5. The state director of health may by order add or delete a condition or disease to any Category as deemed necessary.

§64-7-6. Laboratories, Hospitals, Nursing Homes, and Other Institutions Who Diagnose or Treat Patients with Reportable Diseases or Conditions.

It shall be the duty of every public and private laboratory, hospital, and administrator of nursing homes or other institutions to report immediately to the county health department, the reportable diseases as listed in Section 5, Categories I, II and III, and Category IV to the department.

§64-7-7. Physicians Who Treat Patients with Reportable Diseases or Conditions.

It shall be the duty of every practicing physician or other person engaged in the treatment of the sick to follow a protocol as specified by the state health director for reporting to the county health department within whose jurisdiction they practice as designated in Section 5, Categories I, II and III, and Category IV to the department, unless the case is admitted to a hospital or nursing home at which time the regulation in Section 6 shall be followed.

§64-7-8. Physicians to Assist in Control of Suspected Reportable Diseases.

It shall be the duty of the attending physician, upon suspecting a case of a reportable disease to follow a method of control as specified by the state health director. If the reported case should be communicable, such physician shall also advise other members of the household regarding the precautions to be taken to prevent further spread of the disease, (using caution where venereal disease is involved) and shall cooperate with the county health officer in seeing that the methods of the state director of health concerning the control of such reportable diseases are carried out by the patient and other members of the household.

§64-7-9. Physicians to Submit Specimens for Laboratory Examination in Suspected Reportable Diseases.

It shall be the duty of each and every physician who shall be in attendance on any person suspected of suffering from any of the diseases or conditions specified in this regulation to make every reasonable effort to submit to an approved laboratory for examination suitable specimens as delineated in the protocol specified by the state health director to accurately establish

the diagnosis of such reportable disease.

§64-7-10. Duties of Physicians and Others in Reference to the Prevention of Acute Infectious Conjunctivitis (Ophthalmia Neonatorum).

(See Chapter 16, Article 3, Sections 7, 8, 9, 10, 11, 12, of the West Virginia Code.)

§64-7-11. Others Who Treat or Come in Contact with Persons with Reportable or Suspected Reportable Diseases or Conditions.

When no physician is in attendance, it shall be the duty of any primary care or public health provider or administrator of any sanitarium, school, camp, vessel or state institution to follow a protocol as specified by the state health director and report immediately the reportable diseases as listed in Section 5, Categories I, II and III, to the county health department and Section 5, Category IV to the department.

§64-7-12. Reporting of Rabid Animals and of Persons Bitten by Such Animal.

12.1. For the purposes of this section the term bitten shall also include direct contact with an animal which causes a breaking of the skin on the person by the animal, such as a scratching or clawing.

12.2. It shall be the duty of every physician or other attending licensed health practitioner to report immediately to the county health officer the full name, age, and address of any person under his care or observation who has been bitten by an animal having or suspected of having rabies. If no physician is in attendance and the person is a child, it shall be the duty of the parent or guardian to make such report immediately. If the person bitten is an adult, such person shall make the report, or if incapacitated, it shall be made by whomever is caring for the person bitten. It shall be the duty of every person having knowledge of the existence of an animal apparently afflicted with rabies to report immediately to the county health officer the existence of such animal, the place where seen, the owner's name if known, and the symptoms suggesting rabies. The county health officer shall forthwith report to the department the name, age, and address of every person bitten by an animal having or suspected of having rabies, together with the action taken in each individual case.

A reasonable attempt shall be made by the county health officer to determine the owner of a dog or cat if the animal is domestic, and shall direct the owner to confine the animal for a period of fourteen (14) days. If ownership cannot be determined, the county health officer shall direct the county humane officer, dog warden or sheriff to pick up the suspected dog or cat that has bitten a person and confine it in isolation for a period of fourteen (14) days. The county humane officer, dog warden or sheriff shall notify the county health officer immediately should

the animal show symptoms of illness or die and the county health officer, county humane officer, dog warden or sheriff shall arrange for appropriate examination of the brain. Provided, however, that when a person is reported bitten by any wild animal, other than a dog or cat having or suspected of having rabies, the county health officer shall direct the county humane officer, dog warden or sheriff to have it immediately destroyed. The county health officer shall arrange for appropriate examination of the brain.

§64-7-13. Registrar of Vital Statistics to Notify County Health Officers When Birth Defects and Deaths From Reportable Diseases Are Reported.

13.1. It shall be the duty of the state registrar of vital statistics whenever a certificate of birth has been received, to send a copy of birth certificates which indicate a birth defect to Maternal and Child Health's Birth Registrar, who immediately will send a copy of such birth certificate to the county health officer having jurisdiction in the county of residence of the mother.

13.2. It shall be the duty of the state registrar of vital statistics whenever a certificate of death from a reportable disease has been received to send a copy of the death certificate immediately to the county health officer having jurisdiction in the county in which the death occurred and the county of residence of the decedent.

13.3. It shall be the duty of every county health officer, upon receiving such death certificate to immediately ascertain whether such person has been reported during life as suffering with a reportable disease, as identified in Section 5 except those in Category III and IV. If the health officer shall ascertain that a physician has failed to report the case of reportable disease for which the death certificate has been issued, he shall notify the physician signing the death certificate of his failure to conform with the state law and require a satisfactory reason for such failure. The health officer shall report the name and address of the physician who failed to so report, together with his reason for failure to comply with the state requirements in such case to the state director of health.

§64-7-14. Reporting Cases of Communicable Diseases Diagnosed After Death.

If a pathologist, coroner, medical examiner, physician or other person determines from examination of a corpse or from history of the events leading to death, that at the time of death this individual apparently was affected with a communicable disease, he shall report the case promptly to the proper health authority according to the manner indicated in Sections 6 and 7 of these regulations as if the diagnosis had been established prior to death.

§64-7-15. Reporting by County Health Officers to the Department.

All cases of reportable diseases reported to or discovered by the county health officer shall be made a matter of record for a period of three years and he shall make a report in accordance with Section 5, Categories I, II and III all such reportable diseases to the department on forms supplied for that purpose. The record of reportable diseases is required to be kept by county health officers at the county health department, and shall be turned over by every health officer to their successor when such health officer's official duties are terminated.

§64-7-16. Duties of County Health Officers in Connection with Prevention and Control of Communicable Diseases.

It shall be the duty of the county health officer, either personally or through a qualified representative, within a reasonable period of time after receipt of report of a case of a communicable disease:

16.1. To make such an investigation as the circumstances may require for the purpose of ascertaining the source of the infection and discovering contacts and unreported cases.

16.2. To determine if required specimens have been collected and submitted, or cause to be collected and submitted, to the State Hygienic Laboratory or other approved laboratory such specimens as may be required to supply necessary or desirable information in determining the source of the infection and the possible infection of contacts.

16.3. To give to the patient, his attendants, members of the household and contacts with the infected person such instructions and advice as may be necessary to prevent the spread of the disease.

16.4. Make the appropriate report in accordance with Section 5, Categories I, II and III.

§64-7-17. County Health Officer to Act in Cases of Suspected Reportable Diseases.

Whenever a county health officer shall know, suspect, or be informed of the existence of any reportable disease listed in Section 5 of these regulations and no licensed physician is in attendance; or, should the attending physician fail or refuse to report such case to the county health department, it shall be the duty of the county health officer or his designee to investigate such case or cases of alleged reportable diseases and to act in accordance with the protocols established by the state health director governing cases of reportable diseases if his investigation establishes the existence of such reportable disease.

§64-7-18. Case of Doubt or Disputed Diagnosis.

Where doubt exists as to the diagnosis of a suspected case of a reportable disease, the county health officer shall enforce the methods of control and protocol for reporting provided for

the suspected reportable disease and shall refer the matter to the state director of health, or his authorized representative, who if he deems necessary, will have an investigation made for final decision. Whenever a case of undetermined illness shall be reported to the health officer, which upon investigation, presents symptoms of communicable disease but in which, in the judgment of the county health officer, sufficient time has not elapsed to render a positive diagnosis possible, the county health officer shall enforce control methods applicable in actual cases of communicable diseases until such time as a positive diagnosis can be established; and if the disease proved not to be communicable, the temporary methods of control shall be terminated at once.

§64-7-19. Failure of County Health Officer to Investigate Case of Reportable Diseases Reported to Him Constitutes Neglect of Duty.

Any county health officer who fails or neglects to investigate appropriate cases of reportable diseases reported to him by any physician or other person within a reasonable period of time after the receipt of the report, shall be deemed guilty of neglect of duty and may, at the discretion of the state health director, be removed from office.

§64-7-20. Failure of County Health Officer to make Weekly Reports to the Department Constitutes Neglect of Duty.

The failure on the part of any county health officer to make to the department the weekly report in the manner specified by the director of health of reportable diseases occurring within his jurisdiction, as required by law, shall be deemed guilty of neglect of duty and may, at the discretion of the state health director, be removed from office.

§64-7-21. Exclusion from School Due to a Communicable Disease; Readmission.

When a pupil or school personnel in any school has suffered from a communicable disease and on account of such disease has been excluded from school, such pupil or school personnel shall be permitted to return to school subject to complying with all the requirements of the rules governing such cases, or has presented a certificate of health from a physician, county health officer, or his authorized representative stating that such pupil, or school personnel has entirely recovered from the disease and is no longer liable to communicate the disease to others.

§64-7-22. Isolation, Quarantine and Placarding.

When any person or persons are suffering from a communicable disease in which isolation or quarantine should be required for the control of such disease, such isolation or quarantine shall be terminated only at the discretion of the county health officer, or his authorized representative, unless the case is in a hospital, nursing home, or other institution, in which case the

attending physician or other appropriate official within the institution shall assume responsibility for isolation and when it should be terminated. No person shall interfere with or obstruct any health officer, or his authorized representative, in the posting of any placard stating the existence of a case of communicable disease in or on any place or premises; nor shall any person conceal, mutilate or remove any such placard except by permission of the county health officer. In the event any such placard is concealed, mutilated or torn down it shall be the duty of the occupant of the premises whereon such placard was posted to notify the county health officer of such fact immediately.

§64-7-23. Reports of Reportable Diseases to be Made on Forms Supplied by Department of Health.

The reports required to be made by physicians, hospitals, primary care or public health providers, public or private laboratories, administrators, of a nursing home, state or other institution, a sanitarium, school, camp or vessel, to county health officers of reportable diseases coming under their observation shall be made upon forms supplied for that purpose through the county health officer by the department and such reports shall contain such information as may be required by the department.

§64-7-24. Failure to Report a Case of Reportable Disease as Required by the State Board of Health.

Any physician, hospital, primary care or public health provider; private or public laboratory, administrator of a nursing home, state institution or other institution, or a sanitarium, school, camp, or vessel who fails to report a reportable disease according to Section 5, Categories I, II, III, and IV, shall be guilty of a misdemeanor, and, upon conviction thereof, shall be fined not more than two hundred dollars or by imprisonment for not more than thirty days or both. Violations of each such provision shall be considered a separate offense.

§64-7-25. Examination and Training of Food Service Workers.

25.1. Food service management training or food service workers' training may be provided by the county health departments at the discretion of the county health officer.

Food service management training courses, when conducted, must be approved by the state director of health. Such training by the county health departments in lieu of food service workers' training, must satisfy the county health officer that such training of management personnel will result in suitable training for the other food service workers within that particular food service establishment.

25.2. If at any time, for the protection of the public, the county health officer considers an examination advisable, the food service worker must be examined by a physician approved by the county health officer. The county health officer may require such laboratory examinations as are necessary to detect any con-

ditions in the food service worker which might constitute a hazard to the public's health.

§64-7-26. Administrative Due Process.

Those persons adversely affected desiring a contested case hearing shall do so in a manner prescribed in and by **Rules of Procedure for Contested Case Hearings and Declaratory Rulings**, West Virginia Department of Health Procedural Rules, Series 1, 1983. The aforementioned rules of procedure are incorporated by reference.

§64-7-27. Severability.

If any provisions of these regulations or the application thereof to any person or circumstance shall be held invalid, such invalidity thereof shall not affect the provisions or application of these regulations which can be given effect without the invalid provisions or application, and to this end the provisions of these regulations are declared to be severable.

TABLE 64-7A. Category I - Diseases or conditions to be reported immediately by telephone to the county health department, including case name, address, age and sex. Call within 24 hours to report[1]:

Diseases (reportable by physicians and hospitals)

Botulism
Cholera
Diphtheria
Foodborne Diseases
Gonococcal Disease -- Pelvic Inflammatory Disease
-- Drug-resistant
-- Conjunctivitis in the newborn

Meningitis, septicemia or other invasive disease due to Neisseria meningitidis or Hemophilus influenzae
Plague
Poliomyelitis
Syphilis -- primary, secondary, early latent (less than one year) and congenital
Waterborne Disease
Yellow Fever

Conditions (reportable by public and private laboratories, and by hospital laboratories)

Isolation of drug-resistant Neisseria gonorrheae from any site
Isolation of Neisseria gonorrheae from female upper genital tract
Isolation of Neisseria gonorrheae from the eye of a newborn
Isolation of Neisseria meningitidis from spinal fluid or blood
Isolation of Hemophilus influenzae from spinal fluid, blood, or any other normally sterile body site
Isolation of Corynebacterium diphtheriae from throat
Isolation of Vibrio cholerae from stool
Isolation of Yersinia pestis from any site
Positive dark-field examination for Treponema pallidum

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[1]In some situations, such as potential epidemics, same day reporting may be appropriately requested by county health officers for categories II and III.

TABLE 64-7B. Category II - Diseases or conditions reported weekly by name, address, age and sex to the county health department.

Diseases (reportable by physicians and hospitals)

- Amebiasis
- Anthrax
- Brucellosis
- Campylobacteriosis
- Chancroid**
- Chlamydia trachomatis
- Conjunctivitis in the newborn, other than gonococcal
- Encephalitis
  - -- Post-infectious
  - -- Primary and unspecified
- Giardiasis
- Gonorrhea (except those forms in category I)**
- Hepatitis
  - -- Type A
  - -- Type B
  - -- Non-A, non-B
    - -- Type C (non-A, non-B)
  - -- Type D
- Herpes Simplex Virus, Type 2
- Leptospirosis
- Lyme Disease
- Malaria
- Meningitis, Other Bacterial
- Meningitis, Viral or Aseptic
- Mumps
- Pertussis
- Psittacosis
- Rabies in Animals and in Man
- Rheumatic Fever
- Rickettsial Diseases
  - Typhus Group:
    - Epidemic Typhus (louse borne)
    - Murine Typhus (endemic - flea borne)
  - Spotted Fever Group:
    - Rocky Mountain Spotted Fever (RMSF) (tick borne)
- Rubella
- Rubella, Congenital Syndrome
- Rubeola
- Salmonellosis (except Typhoid Fever)
- Shigellosis
- Syphilis (late latent)**
- Tetanus
- Trichinosis
- Tuberculosis (All Forms)***
- Tularemia
- Typhoid Fever

(TABLE 64-7B CONTINUED)

Conditions (reportable by public and private laboratories, and by hospital laboratories):

Identification of **Entameba histolytica** from stool or tissue
Isolation of **Bacillus anthracis** from any site
Isolation of any bacterium (e.g., **Streptococcus pneumoniae**) from spinal fluid
Isolation of **Campylobacter jejuni** from stool
Isolation of **Chlamydia trachomatis** by culture, or demonstration of **Chlamydia trachomatis** in a clinical specimen by antigen or DNA probe methods or procedures deemed reportable by the director of health
Identification of **Giardia lamblia** in stool or intestinal contents or by biopsy
Positive IgM serologic test for hepatitis A
Positive anti-HBc IgM test (indicating recent hepatitis B infection)
Isolation of **Herpes simplex virus, type 2** from oral, cervical, urethral, or anogenital lesions, or demonstration of virus by antigen detection or DNA probe technique in clinical specimens from oral, cervical, urethral, or anogenital lesions or demonstration of cellular changes associated with herpes simplex virus or scrapings from an oral or anogenital lesion or other procedures deemed reportable by the director of health
Isolation of **Borrelia burgdorferi** from any site and/or positive serology on well characterized late Lyme Disease case
Identification of malaria organisms on smear of blood
Isolation of **Bordetella pertussis** from sputum or nasopharynx
Isolation of **Salmonella** (any species, including **S. typhi**) from stool, blood, or any other normally sterile body site
Isolation of **Shigella** (any species) from stool
Isolation of **Mycobacterium tuberculosis** from any site
Virological or serological diagnosis of infection with arboviruses, brucellosis, leptospirosis, mumps, psittacosis, rubella, rubeola, toxoplasmosis, or tick-borne or flea-borne typhus (Rocky Mountain Spotted Fever or Murine Typhus)
Isolation of **Neisseria gonorrheae** from sites not mentioned under Category I, and other positive laboratory tests for gonorrhea infection**
Positive serologic tests for syphilis**

**Use Venereal Disease Report Form
***Use Tuberculosis Report Form

TABLE 64-7C. Category IV - Illnesses of unusual prevalence or clusters of unexplained health occurrences to be reported by name, age, sex, and specific disease information to the State health department according to protocols specified by the director of the department.

Human Immunodeficiency Virus (HIV) infection, including persons with AIDS and with other illnesses falling in Clinical Categories A, B and C of the CDC HIV infection classification
Birth Defects
Cancer
Dengue
Hemophilia
Lead Poisoning
Occupational-related Illnesses
Unusual or Ill-Defined Conditions

Conditions (reportable by public and private laboratories, and by hospital laboratories):

Positive serologic test for Human Immunodeficiency Virus
CD4+ cell counts of two hundred per cubic millimeter ($200/mm^3$) or less
Chromosomal anomaly defining Down's syndrome
Blood lead greater than 25 micrograms per deciliter (dl)
Serologic tests diagnostic of dengue fever

Jefferson County Health Department

EARL D. ALLARA, M.D.
HEALTH OFFICER

44-1 WILTSHIRE ROAD
KEARNEYSVILLE, W. VA.
25430
ENVIRONMENTAL: 728-8415
MEDICAL: 728-8416

To: Marsha Dadisman, Acting Director

From: Jefferson County Health Department

Re: Comments after review of the proposed legislature rule concerning Reportable Diseases, Events and Conditions.

64-7-5
-(5.2) Not clear as to what defines "Suspected of having rabies". More detail needed concerning report procedure... will a specific form be provided and what is the frequency of the reports to be submitted (ie, within 24 hours of receipt, weekly, quarterly, etc.)

64-7-6
-(6.1) More information is needed detailing specifics for establishing a central registry.

-(6.5) Why is mothers maiden name included on report and not the parent's names? The immunization card (orangecard mch1117-A) currently used does not have a space for mothers maiden name - will cards be updated to include this information?

64-7-10
-(10.2) Is three years an adequate time to keep records?

64-7-16
-(16.1) Licensed daycare centers should be included in this section.

64-(7-17) Is food service workers training required? (It should be mandatory) (17.1) says "may provide at the discretion of the Local Health Officer.) And (17.2) says "Food service management personnel will result in suitable training for the other food service workers within that particular food service establishment.

facsimile
TRANSMITTAL

To: Marsha Dadisman

Fax: 558-1130

Pages: One, including this cover sheet.

Date: July 30, 1998

Comments on proposed legislative rule: Reportable Diseases, Events and Conditions, 64 CSR 74

On page 7, §64-7-4, 4.1, second line, I suggest the insertion of the following bold and underlined text:

....from birth certificates, health care facility medical records, **pediatricians during well-child examinations**, or human .....

On page 16, §64-7-13, 13.1, fourth line, fifth word is misspelled; should be corrected as follows:

lymphogranuloma (the "h" is currently omitted)

Thank you for the opportunity to comment on the legislative rule.

This comment was from
Nawal Lutfiyya
WVDHHR/BPH/OMCH
1411 Va St E
Charleston

From the desk of...

Omayma Touma, MD
Cabell-Huntington Health Department
1336 Hal Greer Boulevard
Huntington, WV 25701

July 31, 1998

VIA HAND DELIVERY
Regulatory Development
Department of Health and
Human Resources
Capitol Complex – Building 3, Room 265
Charleston, West Virginia 25305
ATTENTION: Marsha Dadisman, Acting Director

Re: Proposed Rule - 64 CSR 7
Reportable Diseases, Events and Conditions

Dear Ms. Dadisman:

On behalf of the West Virginia Health Maintenance Organization Association ("HMO Association"), I would like to provide these comments on the above-referenced proposed rule. The HMO Association consists of five of seven health maintenance organizations currently licensed to do business in West Virginia.

The proposed regulations, among other things, require Managed Care Organizations ("MCO"), as defined in Section 2.14 in the proposed regulations, to undertake certain responsibilities with respect to their contracted providers. Our primary concern with these regulations is that the Department of Health appears to have exceeded its authority by imposing these requirements on managed care organizations. In particular, managed care organizations in West Virginia are primarily health maintenance organizations regulated exclusively by the Insurance Commissioner under Chapter 33, Article 25A of the West Virginia Code. To the extent that a managed care organization is not registered as a health maintenance organization, but still meets the definition of managed care organization under the proposed regulations, it would be an insurance company, and also regulated exclusively by the Insurance Commissioner pursuant to Chapter 33 of the West Virginia Code. The Department of Health cites as its authority to promulgate these regulations West Virginia Code §§ 16-3-1 et seq. and also 16-4-1 et seq. These provisions do not in any way refer to managed care organizations or in any way authorize the Department of Health to regulate

managed care organizations; nor am I aware of any other authority which would allow the Department of Health to regulate MCOs. Accordingly, the Department of Health has exceeded its authority by proposing rules which would regulate managed care organizations.

Even assuming that the Department of Health does have the authority to regulate managed care organizations, the regulations are bad public policy insofar as they would apply to MCOs. The proposed rules will not only increase the cost of health coverage for the enrollees of managed care organization plans, but also will unnecessarily and improperly transfer the responsibilities of the Department of Health to the MCOs, with little to no added benefit. In particular, requiring a managed care organization to hold a provider accountable for compliance with the regulations will require a managed care organization to undertake certain tasks, which tasks are not presently undertaken by an MCO and which tasks will require additional, unnecessary expenditures and costs by the managed care organizations. These additional costs will unnecessarily be borne by the enrollees through increased costs for health care services. Under the law providers are responsible for reporting certain diseases and events and the Department of Health is responsible for enforcing this obligation. The imposition of this enforcement requirement on MCOs merely increases the MCOs' costs without any resultant benefit to the public.

The duties imposed by the regulations are precisely those which are the primary responsibility of the Department of Health. A managed care organization only has a contractual obligation with its providers. Failure of a provider to comply with its contractual obligation will only result in a breach of contract, the only remedy for which will be the termination of the contractual relationship. Other than the remedy for breach of contract, the managed care organization has no other remedy against a provider who fails to comply with the requirements of these regulations. The appropriate place for ensuring compliance with these regulations is with the Department of Health, which has many remedies against a non-complying provider, including criminal sanctions, rather than with the managed care organizations.

The obligation of a provider to comply with these regulations exists notwithstanding the attempts by the Department of Health to place another layer of oversight by managed care organizations. Physicians, hospitals, laboratories, and other providers have a legal obligation to comply with these regulations. They are deemed, by law, to know their requirements and to comply with these requirements. To place an additional burden on managed care organizations when the obligation already exists for health care providers merely places these managed care organizations in an untenable position which we believe is improper, but also one which creates unnecessary costs on the price of health care coverage.

In addition to the general comments, we have more specific comments regarding certain sections.

> **Section 9.1.a. - Managed Care Organization shall notify any contracted providers, facilities or laboratories serving residents of West Virginia of their legal responsibilities delineated in this rule and shall hold them accountable for compliance with these responsibilities.**

All managed care organizations do not necessarily contract with all providers. It is not an MCO's responsibility to alert providers of their statutory requirements, past or future.

It is unclear what a managed care organization is required to do when it is required to hold its providers "accountable for compliance with these responsibilities." As indicated earlier, other than contractually requiring its providers to comply with all laws, which is already contained in a provider contract, what else may a managed care organization do to require compliance. Clearly, the entity with actual power to hold providers, et al. accountable is the Department of Health.

> **Section 9.1.b. - Managed care organization shall annually provide contracted health care providers, facilities and laboratories serving residents of West Virginia with a list of currently reportable diseases and conditions.**

This requirement appears to be redundant to what the Department of Health is required to do. I assume that the Department of Health and the public health officials provide physicians, hospitals and laboratories with this information. To require a managed care organization to duplicate services that are already provided seems foolish and creates unnecessary costs for managed care organizations. In particular, a vast number of providers in West Virginia do not have contracts with health maintenance organizations. How do these entities presently receive this information if not by the Department of Health or by local public health organizations? It appears the Department of Health is attempting to shift its responsibilities to the MCOs.

> **Section 9.1.c. - Managed care organization shall work with public health officials to assure that policies or procedures developed by the managed care organizations support the capacity of enrolled providers, facilities or laboratories to diagnose reportable diseases, undertake the responsibilities**

delineated in this rule, and assist in public health investigation/follow-up of reportable diseases or conditions.

It is unclear what a managed care organization is required to do under this section. To the extent the Department of Health is requiring a managed care organization to expand its benefits, then this clearly is outside the scope of authority of the Department of Health. The Insurance Commissioner regulates managed care organizations and regulates those benefits which a managed care organization is required to provide. The benefits that are provided by an MCO are dictated by statute. The Department of Health does not have the authority to obligate an MCO to provide this benefit.

Section 64-7-18 – Penalties.

Section 18.1 – Section 18.1 makes it a misdemeanor for a managed care organization to fail to comply with these requirements. Neither West Virginia Code §§ 16-3-1, 16-3-5 or 16-4-1, et seq., expressly indicate that the Department of Health has the authority to impose the penalties set forth in this rule.

For the foregoing reasons, we recommend that any reference to Managed Care Organizations be deleted from the proposed regulations.

Respectfully submitted by:

John M. Collins by TRC

John M. Collins
Chairman
West Virginia HMO Association

July 31, 1998

VIA HAND DELIVERY
Regulatory Development
Department of Health and
Human Resources
Regulatory Development
Capitol Complex – Building 3, Room 265
Charleston, West Virginia 25305
ATTENTION: Marsha Dadisman, Acting Director

Re: Proposed Rule - 64 CSR 7
Reportable Diseases, Events and Conditions

Dear Ms. Dadisman:

I am providing these comments on behalf of the Health Insurance Association of America, a national trade association representing health insurers.

The proposed regulations, among other things, require managed care organizations (MCOs), as defined in Section 2.14 in the proposed regulations, to undertake certain responsibilities with respect to their contracted providers, facilities or laboratories. Managed care organizations (MCO) in West Virginia are regulated exclusively by the West Virginia Insurance Commissioner under Chapter 33 of the West Virginia Code. In particular, health maintenance organizations are regulated pursuant to Article 25 and insurance companies are regulated by a number of articles in Chapter 33. The Department of Health cites as its authority to promulgate these regulations West Virginia Code §§ 16-3-1 et seq. and also 16-4-1 et seq. Articles 3 and 4 of Chapter 16 do not in any way refer to managed care organizations, appear in any way to authorize the Department of Health to regulate managed care organizations or appear in any way to allow the Department of Health to impose these responsibilities on MCOs. This attempt by the Department of Health to regulate managed care organizations in these proposed regulations appears to be outside the scope of the Department of Health's authority and, therefore, improper.

Even assuming that the Department of Health does have the authority to regulate managed care organizations, the imposition of these requirements on managed care organizations is not only misplaced, but will impose additional tasks on the MCOs which will in turn unnecessarily increase the cost of health insurance coverage for the enrollees of managed care organizations, thus increasing the cost of health care coverage in West Virginia.

The duties that these regulations impose on managed care organizations are exactly those which are the primary responsibility of the Department of Health. The Department of Health is in a better position to enforce these requirements than a managed care organization, whose only remedy if a provider does not comply with these requirements is to terminate its relationship with the provider and any so attempts may result in separate litigation.

Providers are already required to comply with these regulations and failure to do so subjects them to criminal penalties. A health insurer or managed care organization does not directly provide these services. It is the provider that has the primary responsibility for undertaking this obligation.

The definition of managed care organizations is very broad, and arguably could be interpreted to include not only HMOs, but also insurers licensed in West Virginia, who may provide a managed care product, such as a preferred provider organization, an exclusive provider organization, or other managed care arrangements. However, by including the three models in the definition, it arguably only applies to health maintenance organizations. This definition should be clarified.

If the definition is to apply to any type of managed care organization, the requirements of this rule could not be enforced because the only arrangement in certain circumstances existing between a provider and a plan is the payment of fees. Further, a managed care organization attempting to comply with this requirement may violate patient confidentiality laws.

In addition, we offer the following comments:

Section 9.1.a. – Managed Care Organization shall notify any contracted providers, facilities or laboratories serving residents of West Virginia of their legal responsibilities delineated in this rule and shall hold them accountable for compliance with these responsibilities.

All managed care organizations do not necessarily contract with all providers. It is not an MCO's responsibility to alert providers of their statutory requirements, past or future.

It is unclear what a managed care organization is required to do when it is required to hold its providers "accountable for compliance with these responsibilities." Under

many circumstances, a plan is not accountable for its providers. Even HMOs who may have a contractual relationship with their providers have no contractual relationship with providers who are out of network. Clearly, the entity with actual power to hold providers, et al. accountable is the Department of Health.

> **Section 9.1.b. – Managed care organization shall annually provide contracted health care providers, facilities and laboratories serving residents of West Virginia with a list of currently reportable diseases and conditions.**

This requirement appears to be redundant to what the Department of Health is required to do. The list of currently reportable diseases and conditions is currently being provided to providers, presumably by the Department of Health. To require a MCO to also provide this information merely duplicates services and creates unnecessary costs for managed care organizations.

> **Section 9.1.c. – Managed care organization shall work with public health officials to assure that policies or procedures developed by the managed care organizations support the capacity of enrolled providers, facilities or laboratories to diagnose reportable diseases, undertake the responsibilities delineated in this rule, and assist in public health investigation/follow-up of reportable diseases or conditions.**

It is unclear what a managed care organization is required to do under this section. To the extent the Department of Health is requiring a managed care organization to expand its benefits, then this clearly is outside the scope of authority of the Department of Health. The Insurance Commissioner regulates managed care organizations and regulates those benefits which a managed care organization is required to provide. The benefits that are provided by an MCO are dictated by statute. The Department of Health does not have the authority to obligate an MCO to provide this benefit.

Respectfully submitted by:

T. Randolph Cox
State Retained Counsel on behalf of
Health Insurance Association of America

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July 28, 1998

Marsha Dadisman, Acting Director
Department of Health & Human Resources
Regulatory Development
Capitol Complex-Building 3, Room 265
Charleston, WV 25305

RE: Proposed Rulemaking: Title 64, Series 7.

Dear Ms. Dadisman:

This is in response to the above referenced proposed rulemaking filed earlier this month regarding the reporting of certain diseases and conditions and the responsibilities of various entities with such. The proposed rules, unlike the current series they propose to replace, include responsibilities for Managed Care Organizations.

The term "Managed Care Organization" appears to be defined over broadly and could be interpreted to include numerous persons or entities, from the actual providers of health service to the insurance companies offering health benefits. Mountain State Blue Cross Blue Shield would fit within the latter category as it offers various pre-paid health benefits programs through contracted networks of providers. These providers are independent entities whose relationships to Mountain State are governed solely by the terms and scope of their contracts. These contracts do not contain provisions to enforce the provisions of the proposed rules.

Notwithstanding the above, the proposed regulations would require, among other things, that Managed Care Organizations notify any contracted providers of the rules and hold them accountable for compliance within the numerous responsibilities set forth in the regulations. Accordingly, these regulations as proposed would misplace the accountability for compliance of the same on health insurers like Mountain State who have no such authority over the operations of the various health care providers.

In addition, it appears that these regulations exceed the authority of the underlying state law, WV Code Section 16-3-1 et al. in that Mountain State is governed by WV Code Section 33-24-1 et. seq., and Section 16-3-1 has no authority over its operations.

In light of the above, we respectfully request the Department to reconsider the definition which would require providers to comply with these proposed regulations of managed care organizations in enforcing compliance with these rules.

Sincerely,

J. Fred Earley II
Vice President, External Operations and General Counsel

cc: Joan E. Ohl, Secretary