WEST VIRGINIA
SECRETARY OF STATE
JOE MANCHIN, III
ADMINISTRATIVE LAW DIVISION

Form #3

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2001 JUL 27 P 2:27

OFFICE WEST VIRGINIA SECRETARY OF STATE

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

AGENCY: DHHR - Bureau for Public Health TITLE NUMBER: 64

CITE AUTHORITY: W. Va. Code §§ 16-3-1 and 16-1-4

AMENDMENT TO AN EXISTING RULE: YES X NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 7

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

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

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

Paul L. Nusbaum

Authorized Signature

$8.20

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED RULE

The proposed rule, Reportable Diseases, Events, and Conditions, is being offered for legislative approval in accordance with West Virginia Code § 16-3-1, which requires the secretary of the department of health and humans resources to develop rules setting procedures governing the reporting of certain diseases and conditions, unusual health events, and administration of immunizations.

BRIEF SUMMARY OF THE RULE

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.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Reportable Diseases, Events and Conditions, 64CRS7

Type of Rule: X Legislative ____ Interpretive ____ Procedural

Agency: West Virginia Department of Health and Human Resources

Bureau for Public Health

Address: 350 Capitol Street

Charleston, WV 25301-3712

1. Effect of Proposed rule:

	ANNUAL		FISCAL YEAR		
	INCREASE	DECREASE	CURRENT	NEXT	THEREAFTER
ESTIMATED TOTAL COST			$16,000	$ 0	$ 0
PERSONAL SERVICES			$ 0	$ 0	$ 0
CURRENT EXPENSE			$16,000	$ 0	$ 0
REPAIRS & ALTERATIONS					
EQUIPMENT					
OTHER					

2. Explanation of Above Estimates:

The above estimates reflect the funding through General Revenue to the West Virginia Department of Health and Human Resources needed for printing new reporting form, list of disease wall charts, and the associated costs of these documents to persons and facilities required to submit disease reports.

3. Objectives of These Rules:

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

Rule Title: Reportable Diseases, Events and Conditions 64CRS7

4. Explanation of Overall Economic Impact of Proposed Rule:

A. Economic Impact on State Government:

See attached estimated expenses.

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

Reporting sources may incure minimal expenses for complying with required reporting.

C. Economic Impact on Citizens/Public at Large.

None

Date: June 08, 2001

Signature of Agency Head or Authorized Representative:

Paul L. Nusbaum, Secretary
Department of Health and Human Resources

Rule Title: Reportable Diseases, Events and Conditions, 64CRS7

Breakdown of Estimated Total Cost of Amended Rule

CURRENT EXPENSES

Printing:		
	Wall Charts	$ 7,000
	Report Cards	6,000
Postage		3,000
		$16,000

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 27, 2001

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: (Agency name, Address & Phone No.) Bureau for Public Health - DHHR

State Capitol Complex, Building 3, Room 201, Charleston, WV 25305

Telephone: (304) 558-5598

LEGISLATIVE RULE TITLE: Reportable Diseases, Events and Conditions

1. Authorizing statute(s) citation: WV Code §§16-3-1 and 16-1-4

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

June 21, 2001

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

Notice of the proposed rule was sent to the local health departments, the WV Department of Education, the WV State Medical Association, hospitals, commercial laboratories, and health care organizations.

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

July 23, 2001

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):

July 27, 2001

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

Martha Barnitt

Office of Regulatory Support - DHHR

Building 3, Room 201, State Capitol Complex

Charleston, West Virginia 25305 Tel: 558-5598

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

350 Capitol Street, Room 125

Charleston, West Virginia 25301-3715 Tel: 558-8910

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

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

N/A

b. Date of hearing or comment period:

N/A

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

N/A

d. Attach findings and determinations and reasons:

Attached N/A

TITLE 64
LEGISLATIVE RULE
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~~16-1-4; related 16-3C-1 et seq. and 16-4-1 et seq.

1.3. Filing Date. -- ~~April 29, 1999~~.

1.4. Effective Date. -- ~~July 1, 1999~~.

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; the division; health care professional licensing boards and agencies; any individual administering immunizations; administrators of schools, camps, and vessels; administrators of health care facilities operated by the department; the State registrar of vital statistics; county humane officers, dog wardens, sheriffs, pathologists, coroners, 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,

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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.

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 designee.

2.14. 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.

2.15. 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.

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

2.17. 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.

2.18. Quarantine - The limitation of freedom of movement of persons or animals in a time frame and manner to prevent contacts that could lead to spread of disease.

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

2.20. 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 subdivisions 3.3.b and 3.3.c of this section are 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.

[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 developed/updated as necessary to accomplish 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. Anthrax;

3.3.b.2. Botulism;

3.3.b.3. Brucellosis;

3.3.b.4. Cholera;

3.3.b.5. Dengue Fever;

3.3.b.6. Diphtheria;

3.3.b.7. ~~E. Coli O157:H7 Disease~~ Enterohemorrhagic Escherichia coli (EHEC) including but not limited to E. coli O157:H7;

3.3.b.8. Foodborne Disease;

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

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

3.3.b.11. Hepatitis A, Acute;

3.3.b.12. Hepatitis B, Acute or perinatal;

3.3.b.13. Hepatitis D;

3.3.b.14. Meningococcal Disease, Invasive;

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

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

3.3.b.17. Plague;

3.3.b.18. Poliomyelitis;

3.3.b.19. Rabies in Animals or in

Humans:

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

3.3.b.21. Rubeola (Measles):

3.3.b.22. Smallpox

3.3.b.23. Staphylococcus aureus with Glycopeptide-Intermediate (GISA/VISA) or Glycopeptide-Resistant susceptibilities (GRSA/VRSA);

3.3.b.~~22~~24. Tuberculosis (All Forms, include antibiotic susceptibility patterns)*:

3.3.b.~~23~~25. Tularemia:

3.3.b.~~24~~26. Typhoid Fever;

3.3.b.~~25~~27. Waterborne Disease; and

3.3.b.~~26~~28. Yellow Fever.

3.3.c. Reports of Category I.A diseases and conditions marked with one (1) asterisk (*) shall be made on the tuberculosis report form. Others should be submitted on standard reporting cards and supplemental forms. (See Footnote 2.)

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

3.3.d.1. Bacillus anthracis:

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

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

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

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

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

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

~~3.3.d.8 E. Coli O157:NM, Shiga-like toxin-producing, from any clinical specimen~~;

3.3.d.~~9~~8. Haemophilus influenzae from any normally sterile body site;

3.3.d.~~10~~9. Hepatitis A, positive IgM;

3.3.d.~~11~~10. Hepatitis B, positive anti-HBc IgM or ~~HbsAg~~ HBsAg;

3.3.d.~~12~~11. Hepatitis D, positive serology;

3.3.d.~~13~~12. Neisseria meningitidis from a normally sterile site;

3.3.d.~~14~~13. Outbreak or cluster of any illness or condition - suspect or confirmed;

3.3.d.~~15~~14. Poliomyelitis, virologic or serologic evidence;

3.3.d.~~16~~15. Rabies, animal or human;

3.3.d.~~17~~16. Rubella, virologic or serologic evidence;

3.3.d.~~18~~17. Rubeola, virologic or serologic evidence;

3.3.d.~~19~~18. Salmonella typhi from any site;

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

3.3.d.20. Staphylococcus aureus with Glycopeptide-Intermediate (GISA/VISA) or Glycopeptide-Resistant (GRSA/VRSA) susceptibilities;

3.3.d.~~20~~21. Tularemia, culture, antigen or serologic evidence;

3.3.d.~~21~~22. Vibrio cholerae, microbiologic or serologic evidence;

3.3.d.~~22~~23. Yellow Fever, virologic or serologic evidence;

3.3.d.~~23~~24. Yersinia pestis, microbiologic or serologic evidence; and

3.3.d.~~24~~25. Other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category I.A.

3.4. Category II Reportable Diseases and Conditions.

3.4.a. Cases of Category II diseases or conditions are reported to the local health department in the patient's county of residence within 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. Campylobacteriosis;

3.4.b.3. Chickenpox (numerical totals only);

3.4.b.4. Cryptosporidiosis;

3.4.b.5. Cyclospora;

3.4.b.6. Ehrlichiosis;

3.4.b.~~6~~7. Encephalitis, Arboviral;

3.4.b.~~7~~8. Encephalitis, Other primary and unspecified;

3.4.b.~~8~~9. Giardiasis;

3.4.b.~~9~~10. Hantavirus Disease;

~~3.4.b.10. Hepatitis C/Other non-A or non-B, acute;~~

3.4.b.11. Influenza-like Illness (numerical totals only);

3.4.b.12. Legionellosis;

3.4.b.~~12~~13. Leptospirosis;

3.4.b.~~13~~14. Listeria;

3.4.b.~~14~~15. Lyme Disease;

3.4.b.~~15~~16. Malaria;

3.4.b.~~16~~17. Meningitis, Other Bacterial (cases not reported as other specific disease types);

3.4.b.~~17~~18. Meningitis, Viral or Aseptic;

3.4.b.~~18~~19. Mumps;

3.4.b.~~19~~20. Psittacosis;

3.4.b.~~20~~21. Rheumatic Fever;

3.4.b.~~21~~22. Rocky Mountain Spotted Fever;

3.4.b.~~22~~23. Rubella, Congenital Syndrome;

3.4.b.~~23~~24. Salmonellosis (except Typhoid Fever);

3.4.b.~~24~~25. Shigellosis;

3.4.b.~~25~~26. Streptococcal Disease, Invasive Group A, (Streptococcus pyogenes);

3.4.b.27. Streptococcal Disease, Invasive Group B;

3.4.b.~~26~~28. Streptococcal Toxic Shock Syndrome:

3.4.b.~~27~~29. Streptococcus pneumoniae, ~~drug resistant~~ invasive disease, (include antibiotic susceptibility patterns):

3.4.b.~~28~~30. Tetanus:

3.4.b.31. Toxic Shock Syndrome

3.4.b.~~29~~32. Trichinosis:

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

3.4.b.~~30~~34. 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 are reported on standard reporting cards and supplemental forms (See Footnote 2).

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

3.4.d.1. Borrelia burgdorferi from culture, or diagnostic levels of IgG or IgM, (preferably followed by a western blot):

3.4.d.2. Campylobacter;

3.4.d.3. Cryptosporidium;

3.4.d.4. Cyclospora;

3.4.d.5. Ehrlichiosis, serologic, microbiologic or other evidence;

3.4.d.~~5~~6. Encephalitis, virologic, serologic, or other evidence of arboviral or other encephalitides:

3.4.d.67. Entamoeba histolytica;

3.4.d.~~7~~8. Giardia lamblia, microscopic or immunodiagnostic evidence:

3.4.d.~~8~~9. Hantavirus infection, serologic, PCR, immunohistochemistry, or other evidence;

~~3.4.d.9. Hepatitis C, positive HCV antibody confirmed with approved supplemental test (e.g. RIBA).~~

3.4.d.10. Influenza, culture confirmed, (numerical totals only, by type and subtype as available);

3.4.d.11. Legionnella, bacteriologic or serologic evidence;

3.4.d.~~10~~12. Leptospirosis, virologic or serologic evidence:

3.4.d.~~11~~13. Listeria monocytogenes;

3.4.d.~~12~~14. Malaria organisms on smear of blood:

3.4.d.~~13~~15. Meningitis, as indicated by bacterium in spinal fluid:

3.4.d.~~14~~16. Meningitis, Viral, virologic or serologic evidence:

3.4.d.~~15~~17. Mumps, virologic or serologic evidence;

3.4.d.~~16~~18. Psittacosis, microbiologic or serologic evidence;

3.4.d.~~17~~19. Rocky Mountain Spotted Fever, serologic evidence;

3.4.d.~~18~~20. Salmonella (any species, excluding Salmonella typhi);

3.4.d.~~19~~21. Shigella (any species);

3.4.d.~~20~~22. Streptococcus pyogenes (Group A Streptococcus) from a normally sterile site;

3.4.d.23. Streptococcus, Group B,

from a normally sterile site:

3.4.d.~~21~~24. Streptococcus pneumoniae, from a normally sterile site (include antibiotic susceptibility patterns on all isolates);

3.4.d.~~22~~25. Trichinosis, demonstration of cysts or serologic evidence;

~~3.4.d.23. Tularemia, culture, antigen or serologic evidence;~~

3.4.d.~~24~~26. Unexplained or ill-defined illness, condition, or health occurrence of potential public health significance; and

3.4.d.~~25~~27. Other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category II.A.

3.5. Category III Diseases and Conditions.

3.5.a. Category III diseases and conditions are reported to the division within one (1) week of diagnosis unless otherwise indicated. 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) (in time frame noted in HIV legislative rules)[3]:

3.5.b.2. Autism Spectrum Disorder;[4]

3.5.b.~~2~~3. Birth Defects, including Down's Syndrome;

3.5.b.~~3~~4. Cancer (in time frame noted in cancer legislative rules)[5];

3.5.b.~~4~~5. Chancroid**;

3.5.b.~~5~~6. Chlamydia trachomatis**;

3.5.b.~~6~~7. Gonococcal Disease** -- Conjunctivitis in the newborn, Drug-resistant disease, or Pelvic Inflammatory Disease (within 24 hours);

3.5.b.~~7~~8. Gonorrhea (all other)**;

3.5.b.~~8~~9. Hemophilia;

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

3.5.b.~~9~~11. Herpes, genital**;

3.5.b.~~10~~12. HIV (Human Immunodeficiency Virus) (in time frame noted in HIV legislative rules)[3];

3.5.b.~~11~~13. ~~Lead Poisoning (blood lead concentration equal to or greater than 10 micrograms per deciliter)~~ Lead, all blood lead test results;

3.5.b.~~12~~14. Occupational Illnesses;

3.5.b.~~13~~15. Syphilis (late latent, late symptomatic, or neurosyphilis)**;

3.5.b.~~14~~16. Syphilis** -- Primary, Secondary, Early Latent (less than one (1) year), or Congenital (all within 24 hours); and

3.5.b.~~15~~17. Traumatic Brain Injury.[4]

3.5.c. Reports of Category III.A diseases

[3]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.

[4]Not reported to the division, see protocol.

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

and conditions marked with two asterisks (**) are made on the sexually transmitted disease report card (VD-91).

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

3.5.d.1. ~~0CD4~~ CD4+ T-lymphocyte counts of two hundred or less per cubic millimeter ($200/mm^3$) or a percentage less than fourteen (14) percent (in time frame noted in HIV legislative rules)[3];

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

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

3.5.d.4. Haemophilus ducreyi**;

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

3.5.d.~~5~~6. Herpes simplex virus**, isolation of herpes simplex virus from cervix, urethra or anogenital lesion, or demonstration of virus by antigen detection technique in clinical specimens from cervix, urethra or anogenital lesion, or demonstration of multinucleated giant cells on a Tzanck smear of scrapings from an anogenital lesion;

3.5.d.~~6~~7. HIV (Human Immunodeficiency Virus) Type 1 or 2, confirmed antibody or virus detection test (serology, culture, antigen, PCR, DNA, RNA probe, etc.) (in time frame noted in HIV legislative rules)[3];

3.5.d.~~7~~8. ~~Lead poisoning (blood concentration greater than or equal to 10 micrograms per deciliter);~~ Lead, all blood lead test results;

3.5.d.~~8~~9. Mycobacterium tuberculosis from any site (include drug susceptibility patterns) (within 24 hours);

3.5.d.~~9~~10. Neisseria gonorrheae (drug resistant) from any site** (within 24 hours);

3.5.d.~~10~~11. Neisseria gonorrheae from female upper genital tract** (within 24 hours);

3.5.d.~~11~~12. Neisseria gonorrheae from the eye of a newborn** (within 24 hours);

3.5.d.~~12~~13. Neisseria gonorrheae**, culture or other positive laboratory evidence, (all other);

3.5.d.~~13~~14. Syphilis**, serologic evidence;

3.5.d.~~14~~15. Treponema pallidum, positive dark-field examination** (within 24 hours); and

3.5.d.~~15~~16. Other laboratory evidence suggestive of current infection with any of the diseases or conditions listed in Category III.A.

3.5.e. Reports of Category III.B diseases and conditions marked with two (2) asterisks (**) are made on the appropriate sexually transmitted disease report forms provided by the division.

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

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

§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, are 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 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. 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. Administration of immunization against the following diseases are reportable: 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. All immunizations administered to children of ages six (6) and under are reported to the immunization registry within ~~one (1) week~~

two (2) weeks of the administration of the immunization.

6.4. 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.

6.5. Immunization data that must be reported to the Department is confidential, except it may be shared with other health care providers, or other entities with a legally defined access to the data, who are enrolled in the system, without the specific consent of the parent or patient. It shall only be used for the ongoing care of the patient to assess immunization status, to determine immunization coverage rates, to assist in outbreak investigations or other purposes determined by the Director.

§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, except a Category III disease or condition. The State registrar shall report Category III diseases 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.

8.1.a 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 Subdivisions 3.3.b., 3.4.b., 3.5.b., or elsewhere in this rule shall:

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

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

8.1.a.3. 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.a.4. If the disease or condition is communicable, advise, in consultation with State and local public health officials, the patient, and as necessary, members of the patient's household and other patient contacts regarding the precautions to be taken to prevent further spread of the disease. In cases of sexually transmitted diseases, HIV, and tuberculosis, the division 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.a.5. 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.a.6. 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, shall report evidence of current infection with the diseases or conditions listed in Subdivisions 3.3.d., 3.4.d., and 3.5.d. of this rule and shall otherwise comply with the requirements of this rule.

8.2.b. The laboratory which receives a specimen yielding Mycobacterium tuberculosis shall submit the first isolate to the Office of Laboratory Services, Division of Health. Additionally, any isolate of M. tuberculosis from a patient collected ninety (90) days after the initial specimen shall also be forwarded to the Office of Laboratory Services. The laboratory shall perform (or arrange for) drug susceptibility testing on the initial isolate from each patient from whom M. tuberculosis was isolated and report the results of that drug susceptibility testing to the local health department in the county where the patient resides, within one working day from the time the person or agency who submitted the specimen is notified. If any subsequent culture of *M. tuberculosis* is found to have developed new patterns of resistance, an additional culture or subculture of the resistant isolate shall be submitted to the Office of Laboratory Services. Clinical laboratories that identify acid fast bacillus (AFB) on a smear from a patient shall culture and identify the AFB, or refer these to another laboratory for those purposes.

8.2.b.1. 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 Office of Laboratory Services.

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

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

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

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

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

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

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

8.2.b.2.G. 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.

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

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

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

8.3.a.3. 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.a.4. If the disease or condition is communicable, advise, in consultation with State and local public health officials, the patient, and

as necessary, members of the patient's household and other patient contacts regarding the precautions to be taken to prevent further spread of the disease. In cases of sexually transmitted diseases, HIV, and tuberculosis the division 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.a.5. Assist the local health officer by promoting implementation of the control method for the disease or condition specified in the protocol with the patient, and, as applicable, members of the patient's household, facility staff, and other involved individuals.

§64-7-9. Distribution of Rule.

9.1. The division and health care professional licensing boards and agencies may distribute this rule to licensed health care professionals who have a duty under this rule. Local health departments may copy and distribute this rule to local health care providers at no cost.

§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, look for undetected and unreported cases, and 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; 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 are 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 Subsections 3.3, 3.4, 3.5, 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 reportable suggested disease or condition until a definitive diagnosis is established. If the disease diagnosed does not require the control measures initiated, then these measures are 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 shall 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 are designated as potentially sexually transmittable: chlamydia trachomatis, gonorrhea, herpes simplex virus type 2, syphilis (all stages), chancroid, lymphogranuloma venereum, human immunodeficiency virus, hepatitis B virus, and any other diseases the director determines sexually transmittable, by order filed with the Secretary of State. The director may, by order filed with the Secretary of State, also remove the designation of diseases he or she has, by order, previously designated.

§64-7-14. 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 Subsection 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 determined 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 shall be kept confidential by the manager of the licensed facility to whom a disclosure was made; and

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

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 determined 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 they are 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 for which isolation is required for the control of the disease, the local health officer may initiate and 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 another health hazard. In addition, no person shall conceal, mutilate or remove any 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 or her authorized representative stating that the individual is no longer liable to transmit the disease to others. The return is subject to compliance with jointly developed 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 shall satisfy the local health officer that the training of management personnel will result in suitable training for the other food service workers within that particular food service establishment.

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

17.4. 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; 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 or her 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 §§16-2-4 or 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 §§16-2-4 or 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.

COMMENTS AND RESPONSES
64CSR7

§64-7-6.1

COMMENT: The West Virginia Statewide Immunization Information System (WVSIIS) should have received legislative approval prior to being operational.

RESPONSE: The provision in 64CSR7 that establishes WVSIIS underwent an extensive public comment period during the summer of 1998, was approved by the West Virginia Legislature during the 1999 legislative session, and went into effect July 1, 1999. Development work for WVSIIS began after that date

COMMENT: The public has not been adequately notified of the creation of WVSIIS.

RESPONSE: Great care went into publicity related to the development of WVSIIS. When 64CSR7 was revised in 1998 to include WVSIIS, a one month public comment period was held. After the system's approval, numerous informational meetings were held around the state to inform providers and the public of WVSIIS and its related requirements.

COMMENT: Reporting of immunization data creates a breech in physician/patient confidentiality and may lead people who are opposed to being entered in the registry to avoid seeking medical care.

RESPONSE: All information shared with WVSIIS is treated as confidential and is not disclosed in ways that are inconsistent with the understanding that exists between physicians and patients. Studies of immunization registries in other states reveal that patients view immunization registries as positive contributors to health and wellness, and do not view immunization registries as a reason to not seek medical care.

COMMENT: Information collected in the system could be used to deny a number of privileges to individuals who choose to not be vaccinated.

RESPONSE: The sole purposes of WVSIIS are to inform parents of when their child is due for immunizations, to inform health care providers of the immunization status of each child seen, and to assess immunization coverage in practices and clinics.

COMMENT: §64-7-6.1 could result in the harassment and punishment of parents and health-care providers who do not comply with the nationally recommended vaccine schedule.

RESPONSE: There are no provisions for such action in 64CSR7

§64-7-6.4

COMMENT: 64CSR7 should explicitly state what information will be collected and maintained in the WVSIIS database.

RESPONSE: Information to be included in the WVSIIS database is explicitly identified in §64-7-6.4. The phrase "any other information required by the director" allows WVSIIS the flexibility only to include additional information that is related to the tracking of compliance with nationally recommended immunization schedules and the monitoring of vaccine use.

§64-7-6.5

COMMENT: Safeguards must be provided and guaranteed to individuals who do not want their medical records accessible to any government agency or database.

RESPONSE: WVSIIS is by no means the first program requiring the report of confidential medical information to a government agency. In order to ensure a healthy population, statistics related to many diseases and health conditions are studied and analyzed by government health agencies.

COMMENT: Information should not be obtained from private medical records and shared with undisclosed third parties without the informed consent of patients or their parents.

RESPONSE: It would be costly, unwieldy, and time consuming to obtain the written consent of patients to report immunization information to WVSIIS. Information maintained in WVSIIS is only used for the purposes of tracking compliance with nationally recommended immunization schedules and for monitoring vaccine use.

COMMENT: WVDHHR should be required to explicitly state who is entitled to receive information from the vaccine registry.

RESPONSE: §64-7-6.5 specifically states that information reported to WVSIIS can only be shared with health care providers defined by 64CSR7 and

other entities with a legally defined access to the data, which refers to individuals who are responsible for the administering of vaccines to patients.

COMMENT: The language stating for what purpose the data will be used is vague and could lead to private medical information being shared with unknown third parties without their knowledge and informed consent.

RESPONSE: §64-7-6.5 specifically states that information in WVSIIS shall only be used "to assess immunization status, to determine immunization coverage rates, to assist in outbreak investigations, or other purposes determined by the Director." These "other purposes" must be consistent with the purposes of WVSIIS established under §64-7-6.

COMMENT: There is no way to absolutely guarantee that information contained in a database will be safe from unauthorized access and use.

RESPONSE: WVSIIS has numerous technical safeguards, including encryption, passwords, and firewalls, that protect the security of immunization data. WVSIIS also has extensive confidentiality policies and security plans in place, which are consistent with standards relating to protecting the privacy and confidentiality of sensitive information.

COMMENT: Any individual recognized by the state as an adult should have the right to request that information contained in the database be permanently deleted.

RESPONSE: Immunization data that is maintained by WVSIIS will be useful well into one's adulthood, especially when adult vaccines are needed.

From:
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July 19, 2001

To:
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Attn: Beth Marquart, Director

I am writing in response to the West Virginia Department of Health and Human Resources – Bureau for Public Health's request for public comment on the proposed amendment to Title 64 Legislative Rule Series 7 (64CSR7). I ask that this letter in its entirety be made part of the official public record and that official response be made in writing. I am also forwarding copies of this letter plus supporting documents to all members of the Legislative Rule-Making Review Committee.

My concerns are related to §64-7-6. Other Reportable Events: Administration of Immunizations. This legislative rule has been cited as authority to develop the West Virginia Statewide Immunization Information System (WVSIIS), a government database that tracks vaccine use of private citizens using personally identifiable information. While I find troubling the inherent loss of privacy with the establishment of yet another government database, I find it absolutely unacceptable that information is being obtained from private medical records and shared with undisclosed third parties without the informed consent of patients or their parents. Considering the low-profile manner in which notice was given of this proposed rule change, I maintain that the public has not been adequately notified of the creation of this database (WVSIIS). I find it reprehensible that WVSIIS is operational and expanding prior to receiving legislative approval of this final rule especially in light of the fact that it deals with confidentiality.

Physicians and other health care providers are required to report the administration of a familiar list of vaccines plus any additional immunizations required by the Director to the government database. According to the DHHR those who do not report immunizations can be punished with a fine of $200 per instance of immunization not reported. There are no provisions in the rules for patients to opt out of the registry which in essence forces health care providers to become agents of the state. This creates a breech in physician/patient confidentiality and may lead people who are opposed to being entered in the registry to avoid seeking medical care. I am also concerned that follow-up activities will harass and punish parents and health-care providers who do not comply with the nationally recommended vaccine schedule.

The language stating what information is to be submitted to the State is unacceptable, (6.4 *...and any other information required by the director for development, maintenance, and use of the immunization registry and vaccine tracking system.*). The DHHR should be required to explicitly state what information will be collected and maintained in the database.

I am concerned about confidentiality. Personally identifiable information including name, address, date of birth, mother's maiden name plus any other information required by the director will be transmitted electronically and maintained in the database. Other information suggested by the Center for Disease Control/National Immunization Program (CDC/NIP) could include the Social Security number of the patient, mother and father; race; primary language; birth order; birth registration number and Medicaid number. Mother's maiden name is frequently used as vouching information to verify access to bank accounts and credit card accounts. There is no way to absolutely guarantee that information contained in a database will be safe from unauthorized access and use. A child who comes of legal age (e.g. is recognized by the State as an adult) as well as any other adult should have the right to request that information contained in the database be permanently deleted.

The language stating with whom the information will be shared is unacceptable, (6.5 "*...except it may be shared with other health care providers, or other entities with a legally defined access to the data, who are enrolled in the system...*"). Citizens should have the right to know who is privy to information taken from their medical record. The DHHR should be required to explicitly state who is entitled to receive information from the vaccine registry.

The language stating for what purpose the data will be used is alarmingly vague, (6.5 "*...or other purposes determined by the Director*"). This open-ended statement gives the Director authority to use the data for any other purpose he chooses. As more research is conducted on vaccine injury it is likely to lead to genetic connections. It is alarming to think that government research could be conducted in the name of public health in which the most personal and private medical information of citizens, including genetic information, could be collected and shared with unknown third parties without their knowledge and informed consent.

While the Rules imply that data will be collected on children, nowhere do the rules specify an age limit. Information from the DHHR suggests that the registry will not be limited to children. West Virginia Epi-log, Second Quarter/2001, Vol. 20 No. 2 states,

"A fully mature immunization registry is one that records all shots for all."

Note this quote from the DHHR website 2/3/01:

> *"The system design has the capacity for all immunization data, regardless of age, to be stored and shared electronically. This feature will provide future expansion capabilities with other health information systems."*

While the Rule currently only applies to immunization data there is no guarantee the rules will remain unchanged. And given the low profile manner in which public notice was given of this potentially invasive issue I have little confidence that an effort will be made to actually make the general public aware of future amendments. Please note this quote from the DHHR website 2/3/01:

> *"WVSIIS will have the potential to expand and include additional health information as well as link to other existing Bureau for Public Health databases at the state level for use to develop public health indicators and outcomes."*

The information collected in the system could be used to deny a number of privileges including a public education, health insurance, and employment. Compliance with nationally recommended immunization schedules is already linked to government entitlement programs. Basic Constitutional liberties should not be denied due to an individual's conscientiously made health-care decisions.

Although the stated purpose of the vaccine registry is to track compliance with nationally recommended immunization schedules and monitor vaccine use, my concern is that the registry will be used to enforce compliance with nationally recommended immunization schedules without regard for the individual needs of the patient. There is ample evidence to suggest that the one-size-fits-all vaccination policy may not be safe for all individuals. All citizens should have the right to alter the vaccination schedule to take into account individual health needs and concerns. I am not opposed to the use of vaccines in general but I am opposed to citizens being forced to use biologicals of unknown toxicity especially in the absence of an epidemic.

I am assuming only the best intentions are held by the members of the advisory committee which developed these rules and that the members are truly acting out of a belief that this Rule is in the best interest of public health. If the true intent of this Rule is to create an innocuous childhood vaccine registry then the Rule should be rewritten to reflect that intent. At the very least the Rule should be rewritten to require the State to obtain voluntary, written, informed consent and allow individuals the right to opt out of the system at any time. Anything less is an inclination toward totalitarianism.

It is my belief that state-run vaccine registries will be part of a national surveillance and enforcement system and will serve as the "foot in the door" to federal control of health care choices of all citizens from cradle to grave. If a state-run vaccine registry is needed in West Virginia every effort should be made to limit it to that intended purpose.

Kathy C Heflin

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July 19, 2001

DWHR - Regulatory Support
State Capitol Complex
Building 3 Room 201
Charleston WV 25305

Attn: Beth Marquart, Director
RE: 64CSR7

We believe that safeguards must be provided and guaranteed to all parents and individuals who do not want their medical records accessible to any government agency. No one should have to surrender personal medical records to a government data base.

Please consider the rights of citizens to restrict their immunization and other medical records from being tracked, without their specific written consent.

Sincerely,
William L. Reuther
Carol L. Reuther

7-18-01

DHHR- REGULATORY SUPPORT
STATE CAPITOL COMPLEX
BUILDING 3 ROOM 201
CHARLESTON WV 25305

ATTN: BETH MARQUART, DIRECTOR

RE: G4CSR7

SAFEGUARDS MUST BE PROVIDED AND GUARANTEED TO INDIVIDUALS AND PARENTS WHO DO NOT WANT THEIR MEDICAL RECORDS ACCESSIBLE TO ANY GOVERNMENT AGENCY. NO ONE MUST SURRENDER PERSONAL RECORDS TO A GOVERNMENT DATA BASE.

PLEASE CONSIDER THE RIGHTS OF INDIVIDUALS AND PARENTS TO RESTRICT THEIR IMMUNIZATION OR OTHER MEDICAL RECORDS FROM TRACKING, WITHOUT SPECIFIC WRITTEN CONSENT

YUT

K B Gundlach
125 ELM
WHEELING, WV 26003