

**WEST VIRGINIA
SECRETARY OF STATE
BETTY IRELAND
ADMINISTRATIVE LAW DIVISION**

Form #2

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WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF A COMMENT PERIOD ON A PROPOSED RULE

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

RULE TYPE: Interpretive CITE AUTHORITY: WV Code §§5-16-9, 16-1-4, 16-1-6, 16-3-4 and 16-3-5.

AMENDMENT TO AN EXISTING RULE: YES NO

IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: 95

TITLE OF RULE BEING PROPOSED: Immunization Requirements and Recommendations for New School Enterers

IN LIEU OF A PUBLIC HEARING, A COMMENT PERIOD HAS BEEN ESTABLISHED DURING WHICH ANY INTERESTED PERSON MAY SEND COMMENTS CONCERNING THESE PROPOSED RULES. THIS COMMENT PERIOD WILL END ON January 7, 2008 AT NOON ONLY WRITTEN COMMENTS WILL BE ACCEPTED AND ARE TO BE MAILED TO THE FOLLOWING ADDRESS:

Ann Spaner, Director
Public Health Regulations
Bureau for Public Health
350 Capitol Street, Room 702
Charleston, WV 25301

OR
Loretta Haddy, PhD.
State Epidemiologist
Bureau for Public Health
350 Capitol Street, Rm. 125
Charleston, WV 25301

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THIS PROPOSED RULE.


Authorized Signature

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Immunization Requirements and Recommendations for New School Enterers

Type of Rule: Legislative X Interpretive Procedural

Agency: HEALTH AND HUMAN RESOURCES

Address: Building 3, Room 206
Capitol Complex
Charleston, West Virginia 25305

Phone Number: 558-2971 Email: annspaner@wvdhhr.org

Fiscal Note Summary

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

This rule will have no impact on costs or revenues of state government.

Fiscal Note Detail

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

Effect of Proposal	Fiscal Year		
	2008 Increase/Decrease (use "-")	2009 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services			
Current Expenses			
Repairs and Alterations			
Equipment			
Other			
2. Estimated Total Revenues			

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

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

The Bureau for Public Health receives vaccine preventatives from the Centers for Disease Control. The vaccines are made available to local health departments and other providers free of charge in accordance with state law, §16-3-5(b). At the current and historic rates of vaccination for all of the immunizations required by this rule, there will be no additional costs to the Bureau for Public Health in the implementation of this rule.

If the number of children seeking the recommended vaccines, such as influenza and human papillomavirus (HPV), increases significantly then other state agencies, which pay medical costs for children, may be affected by the rule in the future.

Memorandum

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


Currently, there will be no financial impact from this proposed rule. The Bureau for Public Health currently provides free, universal access to all of the vaccines which are required by this rule. Similarly, the Certificate of Immunization which would be required for school entry under this rule is already available through local health departments at no cost to parents. If a parent or guardian chooses to present another form of documentation for their child's immunization record, that is also acceptable under the rule.

Date

Agency

Authorized Representative

Department of Health and Human Resources



Martha Yeager Walker
Secretary

**Department of Health and Human Resources
Bureau for Public Health
Interpretive Rule
Title 64, Series 95**

**IMMUNIZATION REQUIREMENTS AND RECOMMENDATIONS
FOR NEW SCHOOL ENTERERS**

BRIEF SUMMARY OF PROPOSED RULE

The proposed rule interprets the statutes governing the immunization requirements for school children in West Virginia. It gives clear and specific guidance to medical providers, local health officials, school nurses and other school officials as to the appropriate age and dosage requirements for each vaccine. The rule sets forth the procedure for requesting a medical exemption from vaccination(s). It authorizes the Commissioner of the Bureau for Public Health to modify, add or delete vaccines by Order in a manner similar to the method in the Reportable Diseases, Events and Conditions rule, 64CSR7, which allows for the addition or deletion of diseases to be reported by Order of the Commissioner, filed with the Secretary of State. The rule adds mumps, hepatitis B and varicella vaccine to the list of school entry requirements.

STATEMENT OF CIRCUMSTANCES

There is a state law on compulsory immunization §16-3-4. This section is written broadly and it lists six diseases for which vaccines were available when the law was passed in 1987. In 1994 a bill was passed adding new vaccines to be distributed for free to children and recognizing the authority of the Commissioner of the state Bureau for Public Health to make decisions with respect to additional vaccines, §16-3-5. Similar laws followed as recently as 2006. For many years both the Bureau for Public Health and the West Virginia Department of Education have been writing a rule to define and explain the details of immunizations required to be given to children before entering West Virginia schools.

A lot has changed in the development of vaccines for children in the past 20 years. New vaccines are available and universally recommended for children (e.g., Hepatitis B vaccine and Varicella vaccine). The importance of assuring a safe and protected school environment is as critical as ever. Old diseases have presented new and resurging threats (e.g., mumps, pertussis and flu). Outbreaks of chickenpox continue to occur in the school setting. The close proximity of people in schools results in this setting being a place where diseases can spread easily. Some of the children and staff who work and study in the schools every day have medical conditions which increase their risk of disease, or complications from disease. Immunizations are a vital means of protecting those most vulnerable individuals.

This rule is necessary for the Commissioner of the Bureau for Public Health to inform the public and protect the health of school children and staff by keeping up with current medical science in requiring and recommending immunizations as effective disease prevention measures reasonably calculated to promote public health and reduce the incidence and severity of disease.

TITLE 64

INTERPRETIVE RULE
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR PUBLIC HEALTH

OFFICE OF THE SECRETARY OF STATE

SERIES 95

IMMUNIZATION REQUIRMENTS AND RECOMMENDATIONS
FOR NEW SCHOOL ENTERERS

§64-95-1. General.

1.1. Scope - This rule establishes immunization requirements for enrollment as a new school enterer in a West Virginia School. Additionally, the rule includes recommendations for immunizations to promote public health.

1.2. Authority - WV Code §§ 5-16-9, 16-1-4, 16-1-6, 16-3-4 and 16-3-5.

1.3. Filing Date -

1.4. Effective Date -

1.5 Applicability - This rule applies to all new school enterers and to students transferring into a West Virginia school from out of state. This rule supersedes the legislative rule, Immunization Criteria for Transfer Students, 64CSR58.

1.6. Purpose - The purpose of this rule is to clearly define the requirements and recommendations for immunizations for new school enterers.

1.7. Standards - The standards of medical practice used in this rule incorporate

the most current recommendations issued by the U.S. Department of Health and Human Services, Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP) and the American Academy of Family Physicians (AAFP).

§64-95-2. Definitions.

2.1. Bureau - means the Bureau for Public Health in the Department of Health and Human Resources.

2.2. Child - means any person between the ages of birth and eighteen years or up to twenty-one years of age when that child is attending school.

2.3. Commissioner - means the Commissioner of the Bureau for Public Health as that term is defined in WV Code §16-1-2, or his or her designee.

2.4. Contraindication - means a medical condition which renders an immunization improper for a particular individual. Contraindications for each vaccine are found in statements written and published by the Advisory Committee on Immunization

Practices (ACIP) as *Recommendations of the Immunization Practices Advisory Committee* and in Vaccine Information Statements (VIS) from the Centers for Disease Control and Prevention (CDC). The recommendations of the ACIP and VIS regarding contraindications can be found at www.cdc.gov.

2.5. Delinquent - means lacking age appropriate immunization(s) which are required to have been completed prior to school entry.

2.6. Local Health Officer - means the individual physician, with a current West Virginia license to practice medicine, who supervises and directs the medical activities of a local health department and is appointed by the local board of health with approval from the Commissioner.

2.7. Medical exemption - means an exemption from any of the requirements for compulsory immunization due to a contraindication or precaution to any or all of the vaccines required by law and this rule.

2.8. New School Enterer – means any child entering a school building housing kindergarten through twelfth grade students to attend classes or programs or to participate in extracurricular activities taking place in the school building and includes children entering for pre-school programs as well as all students in grades kindergarten through twelfth grade and students who transfer into a West Virginia school from another state.

2.9. Precaution – means a condition defined under the current standards of immunization practice that might increase the

chance or severity of an adverse vaccine reaction or compromise the ability of the vaccine to produce immunity.

2.10. State Health Officer - means the person appointed to serve as State Health Officer who is a licensed physician authorized to practice medicine in accordance with West Virginia Code §16-1-5.

§64-95-3. Recommended Immunization Schedules.

The recommended immunization schedule for childhood immunization is the schedule jointly approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians. This schedule is issued annually and can be found at www.cdc.gov by searching under “Immunization Schedules”. Recommended schedules for children birth to age 6 as well as for children age 7 through 18 may be found at this website.

§64-95-4. Immunizations Required for School Entry and Specifics of Each Immunization Requirement.

4.1. All new school enterers attending a West Virginia school for the first time shall show proof of immunization against the following diseases:

4.1.a. DIPHTHERIA;

4.1.b. HEPATITIS B;

4.1.c. MUMPS;

64CSR95

- 4.1.d. PERTUSSIS (whooping cough);
- 4.1.e. POLIOMYELITIS;
- 4.1.f. RUBELLA;
- 4.1.g. RUBEOLA (measles);
- 4.1.h. TETANUS; and
- 4.1.i. VARICELLA (chickenpox).

4.2. Dosage and interval schedule for diphtheria, pertussis and tetanus vaccines are as follows:

4.2.a. Before being admitted to school, each child shall show proof that he or she has received a minimum of four doses of DIPHTHERIA, TETANUS, acellular PERTUSSIS (DTaP) vaccine, with the last dose having been received on or after the child's fourth birthday and prior to school entry; and

4.2.b. The interval between the third and fourth or final dose shall be at least six months; and

4.2.c. Children seven years of age and older may receive tetanus, diphtheria (Td) vaccine in lieu of DTaP vaccine. A single dose of Tdap vaccine should be considered in the series if age appropriate.

4.2.d. Occurrence of prior disease may be used as evidence of immunity for pertussis in accordance with subsection 6.4 of this rule.

4.3. Children entering school shall show proof that they have received at least three doses of HEPATITIS B vaccine with at least one dose having been given on or after six months of age. The second and third doses should be separated by at least two months. Occurrence of prior disease may be used as evidence of immunity in accordance with subsection 6.4. of this rule.

4.4. Children entering school shall show proof that they have received two doses of RUBEOLA (MEASLES) vaccine, the first dose on or after the first birthday and the second dose no less than one month after the first dose. Alternatively, immunity may be proven through laboratory testing. Occurrence of prior disease may be used as evidence of immunity in accordance with subsection 6.4. of this rule.

4.5. Children entering school shall show proof that they have received at least two doses of MUMPS vaccine, the first dose on or after the first birthday and the second dose no less than one month after the first dose. Alternately, immunity may be shown through laboratory testing. Occurrence of prior disease may be used as evidence of immunity in accordance with subsection 6.4. of this rule.

4.6. Dosage and interval schedule for the POLIO vaccine is as follows:

4.6.a. Before being admitted to school each child shall show proof that he or she has received a minimum of three doses of trivalent polio vaccine (PV) with the last dose having been received on or after the child's fourth birthday and prior to school entry.

64CSR95

Although less desirable, immunity may be shown through laboratory testing showing immunity to all 3 poliovirus strains included in the vaccine. The impact on duration of immunity given an incomplete series but positive titers is not known.

4.7. Children entering school shall show proof that they have received at least two doses of RUBELLA vaccine, the first dose on or after the first birthday and the second dose no less than one month after the first dose. Alternately, immunity may be proven through laboratory testing. Occurrence of prior disease may be used as evidence of immunity in accordance with subsection 6.4. of this rule.

4.8. Children entering school shall show proof that they have received two doses of VARICELLA (CHICKENPOX) vaccine, the first dose on or after the first birthday and the second dose no less than one month after the first. Alternately, immunity may be shown through the written or verbal statement of a parent or legal guardian attesting to the fact of their child's history of chickenpox. A third alternative is to show immunity through laboratory testing.

4.9. For preschool children entering a school housing other children in grades kindergarten through twelfth, the above immunization requirements hold to the extent that they are age appropriate in accordance with the immunization schedules referenced in section 3 of this rule.

§64-95-5. Compliance with the Law.

5.1. A child shall be considered to be in compliance with the law requiring compulsory immunizations of school children prior to school entry when that child has a complete certificate of immunization, or similar medical record of immunizations.

5.2. If a child has been determined to be medically exempt from receiving one or more vaccinations, in accordance with the provisions of section nine of this rule, the certificate of immunization shall note specifically which vaccine the child is exempt from, the reason for the exemption, and whether or not the reason for the exemption is permanent or temporary. If the exemption is temporary, a notation shall be made as to the future date at which the exemption should be reevaluated.

5.3. A student who does not have a completed certificate of immunization or other similar medical record of immunizations shall show proof that he or she has received at least one dose of each of the required vaccines in order to be provisionally enrolled in school.

5.4. Provisional enrollment may continue for up to seven months from school entry. After attending school for a maximum of seven months, all provisionally enrolled students shall show proof to the school that they have completed all of the required immunizations.

5.5. Children who are delinquent for any required vaccinations, or who have exceeded the seven month provisional enrollment period, will be considered to be out of compliance with the law and may be required to stop attending school until the

appropriate vaccine(s) are received and the records are amended.

§64-95-6. Proof of Immunity.

6.1. Proof that a child has received the immunizations required by law and this rule, in the correct number and spacing of doses, shall be recorded on a completed document, such as a certificate of immunization, for all new school enterers.

6.2. A Certificate of Immunization form has been developed by the West Virginia Department of Health and Human Resources, Bureau for Public Health, Immunization Program. This form is available to appropriate health care providers electronically through the West Virginia Statewide Immunization Information System (WVSIIS) <http://www.wvdhhr.org/immunizations/wvsiis1.asp>. The form is also available from:

ATTN: WVSIIS
Bureau for Public Health
Immunization Program
350 Capitol Street, Room 125
Charleston, WV 25301

6.3. The documentary evidence of immunizations shall contain the day, month and year of each vaccine received by the child or sufficient information of the time interval between doses to enable verification that the minimum intervals required or suggested by this rule have been observed.

6.4. Proof of prior measles, mumps, rubella, pertussis or hepatitis B disease being used in lieu of vaccination requires a document signed by a physician indicating, at

a minimum, the name of the patient, the date of the illness and any obtained laboratory evidence of the diagnosis. If the historical disease diagnosis is in question, current laboratory evidence of immunity may be required.

6.5. The verbal or written statement of the parent or legal guardian of a child shall suffice to prove that a child has had chickenpox and is considered to be proof of immunity.

§64-95-7. Commissioner's Authority to Change Immunization Requirements for New School Enterers.

The Commissioner may, by order filed with the Secretary of State, modify, add or delete vaccines to be required for new school enterers. The Commissioner's orders shall be made after consultation with the State Health Officer and shall be consistent with the immunization schedules referenced in section 3 of this rule. The Commissioner's orders shall not exceed those recommendations.

§64-95-8. Recommended Vaccines.

The following vaccines are recommended, though not required, for children attending West Virginia schools:

8.1. INFLUENZA VACCINE.

8.1.a. Any child aged six months or older may be vaccinated against influenza. Children from six to twenty-three months are at substantially increased risk for influenza-related hospitalizations and children ages twenty-four to fifty-nine months are at

increased risk for influenza-related clinic and emergency room visits. Children and school personnel with certain medical conditions and school personnel who are older are at increased risks of influenza complications and death.

8.1.b. An annual flu vaccine is recommended in accordance with annually released ACIP recommendations.

8.2. MENINGOCOCCAL VACCINE

8.2.a. Meningitis caused by *Neisseria meningitides*, termed meningococcal meningitis, is one of the leading causes of bacterial meningitis in the U.S. While children less than 1 year of age are at highest risk of the disease, children ages 11-18 are at increased risk compared to the general population. College freshmen housed in dormitories or other settings where adolescents and young adults are housed in close quarters also are at higher risk. Ten to fourteen percent of those contracting meningococcal meningitis die. Meningococcal disease can also result in significant disability. While the vast majority of cases are sporadic, localized outbreaks of this disease do occur. Given disease severity and the challenges managing this disease in the institutional or school setting, vaccination of all children is now recommended.

8.2.b. Meningococcal Vaccination is recommended at age 11-12. It is also recommended for previously unvaccinated children at high school entry.

8.3. Tdap VACCINE

8.3.a. Diphtheria and tetanus boosters are typically recommended throughout one's lifetime. Pertussis is a disease that has been increasing in West Virginia and the United States. Protection from the pertussis component of the primary DTaP series wanes over time. While pertussis disease is less severe in older children and young adults, they can readily pass the disease to younger children at high risk of severe disease or death from pertussis. The Tdap vaccine offers an opportunity to boost immunity to not only diphtheria and tetanus, but also to pertussis.

8.3.b. Tdap vaccine is recommended for children age 11-12 years who have completed the recommended childhood DTP/DTaP vaccine series and have not already received a tetanus and diphtheria (Td) booster dose. Adolescents age 13-18 who missed the 11-12 year old Tdap/Td dose and who have completed the primary DTP/DTaP series should also be given a dose of Tdap vaccine.

8.4. HUMAN PAPILLOMAVIRUS VACCINE - HPV Vaccine.

8.4.a. Approximately twenty million people in the United States are infected by genital human papillomavirus (HPV) and about six million more become infected each year. HPV can cause cervical cancer in women. Every year in the United States about ten thousand women get cervical cancer and three thousand seven hundred die from it. It is the second leading cause of cancer deaths among women worldwide. HPV is also associated with several less common types of cancer in both men and women and

causes genital warts and warts in the upper respiratory tract. More than fifty percent of sexually active men and women are infected with HPV at some time in their lives. The HPV vaccine works against the four types of the virus which are responsible for seventy percent of cervical cancer cases and ninety percent of genital warts cases.

8.4.b. The best way to ensure disease prevention is to give the series of three shots prior to the individual becoming sexually active.

8.4.c. The HPV vaccine is currently licensed for use in females ages nine to twenty-six. It consists of a three dose series. The first dose is recommended for girls at age eleven to twelve. It is also recommended for girls ages 13-18 who have not previously been vaccinated.

8.5. Other vaccines recommended for various high risk populations in the school setting may be found on the immunization schedules jointly approved by the Advisory Committee on Immunization Practices, the American Academy of Pediatrics, and the American Academy of Family Physicians at www.cdc.gov by searching under "Immunization Schedules".

§64-95-9. Medical Exemptions.

9.1. The provisions of this rule may not apply if a child has a valid medical contraindication or precaution to a particular vaccine. To obtain a medical exemption the child's parent or guardian shall present a written request for an exemption from a physician who has treated or examined the

child to the local health officer in the county where the child attends school.

9.2. The physician's request for exemption from immunization shall state specifically which vaccine or vaccines the child should be exempt from receiving, an explanation of the medical contraindication or precaution relied upon to make the request, and whether the reason for the exemption is permanent or temporary. If the medical exemption is temporary, the request shall also provide the future date or time when the exemption should be reevaluated.

9.3. Requests for medical exemption from vaccine requirements shall be reviewed and approved or denied initially by the local health officer in the county where the requestor attends school. Approval or denial of a request shall be in writing and a copy of the response shall be sent to the State Health Officer.

9.4. Local health officials shall verify that immunization exemptions are entered into the West Virginia Statewide Immunization Information System -- WVSIS-- to enable ready support of individuals at increased risk of disease in an outbreak and to aid in disease control and surveillance.

9.5. The local health officer's decision on a request for a medical exemption from immunization may be reviewed by the State Health Officer. The request for state level review and the State Health Officer's decision on such requests shall be in writing.

9.6. Appeal from the ruling of the State Health Officer may be made through the

64CSR95

administrative review procedure described in section ten of this rule.

9.7. All requests for medical exemption from immunization shall be reviewed, and determinations made, based on current medical science and recommendations from the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP).

§64-95-10. Administrative Due Process.

Any person 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 the manner prescribed in the bureau procedural rule, Rules for Contested Case Hearings and Declaratory Rulings, 64CSR1.