

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

Do Not Mark In This Box

FILED

2015 AUG -3 P 1:56

OFFICE WEST VIRGINIA
SECRETARY OF STATE

Form #5

**NOTICE OF AGENCY ADOPTION OF A PROCEDURAL OR INTERPRETIVE RULE
OR A LEGISLATIVE RULE EXEMPT FROM LEGISLATIVE REVIEW**

AGENCY: Department of Health and Human Resources/Bureau for Public Health TITLE NUMBER: 64

CITE AUTHORITY: W.Va. Code §§ 16-3-1, 16-3-4(c), 5-16-9(i) and 16-1-4.

RULE TYPE: PROCEDURAL _____ INTERPRETIVE X

EXEMPT LEGISLATIVE RULE _____

CITE STATUTE(S) GRANTING EXEMPTION FROM LEGISLATIVE REVIEW

AMENDMENT TO AN EXISTING RULE: YES X NO _____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 95

TITLE OF RULE BEING AMENDED: IMMUNIZATION REQUIREMENTS AND RECOMMENDATIONS FOR
CHILDREN ATTENDING SCHOOL AND ENROLLED IN
STATE-REGULATED CHILD CARE

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: _____

TITLE OF RULE BEING PROPOSED: _____

THE ABOVE RULE IS HEREBY ADOPTED AND FILED WITH THE SECRETARY OF STATE. THE
EFFECTIVE DATE OF THIS RULE IS September 3rd, 2015


Authorized Signature

TITLE 64

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

SERIES 95

IMMUNIZATION REQUIREMENTS AND
RECOMMENDATIONS FOR CHILDREN ATTENDING SCHOOL AND
ENROLLED IN STATE-REGULATED CHILD CARE

Brief Summary of Rule: The proposed amendments to the current interpretive rule series establishes dosages and interval schedules for vaccines mandated by law for admission to a public, private, or parochial school in this state, or a state-regulated child care center. Additionally, the rule includes recommendations for immunizations to promote public health. Finally, this rule establishes a process for requesting a medical exemption from compulsory immunizations required of children attending a public, private, or parochial school in this state, or a state-regulated child care center. These provisions apply to all persons requesting an exemption from the compulsory immunization requirements of *W.Va. Code* § 16-3-4, and establishes the mechanism for granting, renewing, conditioning, denying, suspending or revoking a request for a medical exemption from the compulsory immunization requirements of *W.Va. Code* § 16-3-4.

Statement of Circumstances: The Bureau for Public Health proposes to amend the current *interpretive* rule to implement the provisions of *W.Va. Code* § 16-3-4, as amended by S.B. 286(2015 RS). The amendments are intended to implement those provisions of S.B. 286 that authorize the Commissioner to employ an Immunization Officer to decide requests for medical exemptions that are currently decided by local health officers. The process contained in the proposed rule is substantially different from the process contained in the current interpretive rule.

Identification of Proposed Amendments: The contents of the proposed interpretive rule are substantially similar to the contents of the current interpretive rule. However, the rule is substantially reorganized and contains additional information supporting the Commissioner's interpretation of state law as it applies to the compulsory immunization of children entering schools or state-regulated child care. Further, the proposed amendments modify the current provisions related to the manner in which requests for medical exemptions to compulsory immunizations are evaluated.

Relevant Statutes or Regulations: The Secretary of the Department of Health and Human Resources is authorized to "adopt rules . . . to obstruct and prevent the introduction or spread of . . . communicable or infectious diseases into or within the state, and the [State Health Officer] shall have the power to enforce these regulations . . ." *W.Va. Code* § 16-3-1. A child may not be admitted or received in any of the schools of the state or a state-regulated child care center until he or she has been appropriately immunized against chickenpox, hepatitis-b, measles, meningitis,

mumps, diphtheria, polio, rubella, tetanus and whooping cough or produces a certificate from the commissioner granting the child or person an exemption from the compulsory immunization requirements. *W.Va. Code* § 16-3-4(c). The Commissioner is authorized to require additional immunizations for public health purposes. *W.Va. Code* § 5-16-9(i). Finally, the Secretary of the Department of Health and Human Resources generally authorized to propose legislative rules necessary and proper to effectuate the purposes of Chapter 16. *W.Va. Code* §16-1-4.

Drafting Note: This rule series has been completely rewritten; therefore, underscoring and strike-through have been omitted.

Summary of Public Comments: No public comments were received.

TITLE 64

FILED

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

2016 AUG -3 P 1:56

SERIES 95

OFFICE WEST VIRGINIA
SECRETARY OF STATE

IMMUNIZATION REQUIREMENTS AND
RECOMMENDATIONS FOR CHILDREN ATTENDING SCHOOL AND
ENROLLED IN STATE-REGULATED CHILD CARE

§64-95-1. General.

1.1. *Scope.* -- This rule establishes dosages and interval schedules for vaccines mandated by law for admission to a public, private, or parochial school in this state, or a state-regulated child care center. Additionally, the rule includes additional recommendations for immunizations to promote public health. Finally, this rule establishes the process for requesting a medical exemption from compulsory immunizations required of children attending a public, private, or parochial school in this state, or a state-regulated child care center.

1.2. *Authority.* -- Generally, the Secretary of the Department of Health and Human Resources is authorized to "adopt rules . . . to obstruct and prevent the introduction or spread of . . . communicable or infectious diseases into or within the state, and the [State Health Officer] shall have the power to enforce these regulations . . ." *W.Va. Code* § 16-3-1. The Commissioner is authorized to require additional immunizations for public health purposes. *W.Va. Code* § 5-16-9(i). Furthermore, the Secretary of the Department of Health and Human Resources is generally authorized to propose legislative rules necessary and proper to effectuate the purposes of Chapter 16. *W.Va. Code* §16-1-4.

More specifically, a child may not be admitted or received in any of the schools of the state or a state-regulated child care center until he or she has been appropriately immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough or produces a certificate from the Commissioner granting the child or person, an exemption from the compulsory immunization requirements. *W.Va. Code* § 16-3-4(c). Although, state law provides for the immunizations required of children attending the schools of the state or state-regulated child care centers, *W.Va. Code* § 16-3-4, does not include specific guidance regarding the manner in which compulsory immunization must be administered.

The Commissioner has the authority to provide information or guidance to the public regarding the agency's interpretations, policy or opinions upon the law enforced or administered by the Commissioner. *W.Va. Code* § 29A-1-2. This rule is not intended to be determinative of any issue affecting constitutional, statutory or common law rights, privileges or interests. Instead, the rule will provide the public with information and clearly define the requirements and recommendations for immunizations for all children enrolled in a public, private, or parochial school in this state, or a state-regulated child care center.

1.3. *Filing Date.* --

1.4. *Effective Date.* --

1.5. *Summary.* -- The Bureau for Public Health is promulgating this interpretive rule to set forth the Bureau's interpretation of the provisions of *W.Va. Code* § 16-3-4, which provides that "[n]o child or person may be admitted or received in any of the schools of the state or a state-regulated child care center until he or she has been immunized against chickenpox, hepatitis-b, measles, meningitis, mumps, diphtheria, polio, rubella, tetanus and whooping cough or produces a certificate from the Commissioner granting the child or person an exemption from the compulsory immunization requirements of this section." The Bureau interprets the provisions of *W.Va. Code* § 16-3-4, to 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), the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC).

1.6. *Applicability* -- This rule applies to all children enrolled in a public, private, or parochial school in this state, or a state-regulated child care center.

1.7. *Purpose* -- The purpose of this rule is to clearly define the requirements and recommendations for immunizations for all children enrolled in a public, private, or parochial school in this state, or a state-regulated child care center. Additionally, the rule series establishes the procedure for granting, renewing, conditioning, denying, suspending or revoking a request for a medical exemption from the compulsory immunization requirements of *W.Va. Code* § 16-3-4.

1.8. *Background* -- The Legislature has granted the Commissioner/State Health Officer extensive powers to protect the public health, i.e., restricting the liberty of persons through measures such as quarantine, enter upon and inspecting private property, asserting authority of any epidemic or endemic conditions, compelling physical examinations and compelling vaccination. Indeed, *W.Va. Code* § 16-3-1, provides, "the state board of health [now the Secretary] may adopt rules and regulations to obstruct and prevent the introduction or spread of smallpox or other communicable or infectious diseases into or within the State[.]"

The Legislature has declared as the public policy of this State:

- That early immunization for preventable diseases represents one of the most cost-effective means of disease prevention.
- the savings which can be realized from immunization, compared to the cost of health care necessary to treat the illness and lost productivity, are substantial. Immunization of children at an early age serves as a preventative measure both in time and money and is essential to maintain our children's health and well-being.
- the costs of childhood immunizations should not be allowed to preclude the benefits available from a comprehensive, medically supervised child immunization service.
- the federal government has established goals that require ninety percent of all children to be immunized by age two and provided funding to allow uninsured children to meet this goal. *W.Va. Code* § 16-3-5(a)

Consistent with this expressed public policy, the Legislature has mandated compulsory

immunization for all children enrolled in a public, private, or parochial school in this state, or a state-regulated child care center. *W.Va. Code* § 16-3-4. However, the legislature only mandated particular immunizations without providing any further guidance. This rule is intended to provide specific guidance with regard to dosage and interval schedules based upon 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), the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC).

Optimal response to a vaccine depends on multiple factors, including the type of vaccine, age of the recipient, and immune status of the recipient. Recommendations for the age at which vaccines are administered are influenced by age-specific risks for disease, age-specific risks for complications, age-specific responses to vaccination, and potential interference with the immune response by passively transferred maternal antibodies. Vaccines are recommended for members of the youngest age group at risk for experiencing the disease for which efficacy and safety have been demonstrated.

Certain products, including inactivated vaccines, toxoids, recombinant subunit vaccines, polysaccharide conjugate vaccines, and live vaccines, require ≥ 2 doses to elicit an adequate antibody response. Tetanus and diphtheria toxoids require booster doses to maintain protective antibody concentrations. Unconjugated polysaccharide vaccines do not induce T-cell memory, and additional doses (although they elicit the same or a lower antibody concentration) might increase the level of protection. Conjugation with a protein carrier improves the effectiveness of polysaccharide vaccines by inducing T-lymphocyte-dependent immunologic function. Many vaccines that stimulate both cell-mediated immunity and neutralizing antibodies (e.g., live, attenuated virus vaccines) usually can induce prolonged immunity, even if antibody titers decline over time. Subsequent exposure to such viruses usually results in a rapid anamnestic antibody response without viremia.

Approximately 90%–95% of recipients of a single dose of certain live vaccines administered by injection at the recommended age (i.e., measles, rubella, and yellow fever vaccines) develop protective antibodies, generally within 14 days of the dose. For varicella and mumps vaccines, 80%–85% of vaccinees are protected after a single dose. However, because a limited proportion (5%–15%) of measles, mumps, and rubella (MMR) or varicella vaccinees fail to respond to 1 dose, a second dose is recommended to provide another opportunity to develop immunity. Of those who do not respond to the first dose of MMR or varicella vaccine, 97%–99% respond to a second dose.

The recommended immunization schedule for Persons Aged 0 Through 18 Years 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 <http://www.cdc.gov/vaccines>.

1.9. *Revising immunization requirements.* -- Upon a finding of the existence of an emergency that may adversely affect the public health and safety, the Commissioner may modify the immunization requirements of this rule, to remove, modify or add a vaccine, in accordance with the requirements of the State Administrative Procedures Act (*W.Va. Code* §§ 29A-3-1 *et. seq.*).

§64-95-2. Definitions.

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

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

2.3. "Commissioner" means the Commissioner of the Bureau for Public Health, 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 <http://www.cdc.gov/vaccines>.

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

2.6. "Exemption" means an exemption for the compulsory immunization requirements of *W.Va. Code* § 16-3-4 and 64 C.S.R. 95.

2.7. "Immunization Officer" means the physician appointed and employed by the Commissioner to make a determination on an application for an exemption to the compulsory immunization requirements of *W.Va. Code* § 16-3-4, on a statewide basis.

2.8. "Local Health Officer" means the physician 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.

2.9. "Physician" means the child's personal licensed physician.

2.10. "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.

2.11. "State Health Officer" means the person appointed to serve as Commissioner and State Health Officer of the Bureau.

2.12. "Student" means any child who enters into a school building housing kindergarten through twelfth grade to attend classes or programs or to participate in extracurricular activities taking place in a school building, on school grounds or at a place where the school conducts extracurricular activities and includes children entering for preschool programs as well as children in grades kindergarten through twelfth grade and children who transfer into a West Virginia School from another state or who transfer from being home schooled or from a private

or alternative school.

§64-95-3. Interpretive Rule.

As it is the intent of *W.Va. Code* § 16-3-4, to provide for the compulsory immunization of all children enrolled in a public, private, or parochial school in this state, or a state-regulated child care center, and as it is consistent with the Commissioner's authority to (1) enforce the public health laws of this State; and (2) require additional immunizations for public health purposes, the Bureau for Public Health interprets *W.Va. Code* § 16-3-4, to include:

3.1. Dosage and interval schedules based upon 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), the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC), for the following immunizations:

3.1.a. Diphtheria – the specific dosage and interval schedules are contained in section 4;

3.1.b. Hepatitis B – the specific dosage and interval schedules are contained in section 5;

3.1.c. Mumps – the specific dosage and interval schedules are contained in section 7;

3.1.d. Pertussis (Whooping Cough) – the specific dosage and interval schedules are contained in section 4;

3.1.e. Poliomyelitis (Polio) – the specific dosage and interval schedules are contained in section 8;

3.1.f. Rubella– the specific dosage and interval schedules are contained in section 9 of this rule;

3.1.g. Rubeola (Measles) – the specific dosage and interval schedules are contained in section 6;

3.1.h. Tetanus– the specific dosage and interval schedules are contained in section 4;

3.1.i. Varicella (Chickenpox) – the specific dosage and interval schedules are contained in section 10; and

3.1.j. Meningococcal (meningitis) – the specific dosage and interval schedules are contained in section 11;

3.2. Dosage and interval schedules based upon 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), the American Academy of Family Physicians (AAFP) and the Centers for Disease Control and Prevention (CDC), for children entering state-regulated child care centers as contained in section 12;

3.3. Recommended, but not required, vaccines for children as contained in section 13;

3.4. Criteria for determining compliance with compulsory immunization requirements of *W.Va. Code* § 16-3-4, as contained in section 14;

3.5. Methods for documenting proof of immunity as contained in section 15;

3.6. Determining eligibility for a medical exemption from the compulsory immunization requirements of *W.Va. Code* § 16-3-4, as contained in section 16; and

3.7. The process for requesting a medical exemption from the compulsory immunization requirements of *W.Va. Code* § 16-3-4, and process for making a determination as to whether there is sufficient medical evidence that an immunization is contraindicated or there exists a specific precaution to a particular vaccine, as contained in section 17;

§64-95-4. Dosage and Interval Schedule for Diphtheria, Pertussis And Tetanus Vaccines

4.1. Prior to being admitted to school, a child must show proof that he or she has received a minimum of four doses of Diphtheria, Tetanus, Acellular Pertussis (DTaP) vaccine, with the fourth dose having been received on or after the child's fourth birthday and prior to school entry.

4.2. The interval between the third and fourth dose shall be at least six (6) months.

4.3. A fifth dose of DTaP between the ages of 4 and 6 is only necessary if the fourth dose was given either before the child's fourth birthday or if the interval between the third and fourth doses was less than six months.

4.4. A child between the ages of 11 and 12 must receive one dose of Tetanus, Diphtheria and acellular Pertussis vaccine (Tdap). Tdap can be administered regardless of the interval since the last tetanus and diphtheria toxoid containing vaccine (Td). This includes a child/student transferring into school or newly joining school who has not had the DTaP or Tdap prior. Inadvertent doses of Tdap given between the ages of 7 and 10 do not count as the 11-12 year old dose except as provided in subsection 4.6.

4.5. A student who becomes pregnant may receive one dose of Tdap during the pregnancy (preferred during 27-36 weeks gestation) regardless of the number of years since a prior Tdap or Td vaccination.

4.6. A student aged 7 – 10 years old who is not fully immunized with the childhood DTaP vaccine series must receive the Tdap vaccine as the first dose in the catch-up series and if additional doses are needed, the student should receive the Td vaccine. A child who receives the Tdap vaccine, is specifically excluded from the requirements of subsection 4.4.

§64-95-5. Dosage and Interval Schedule for Hepatitis B Vaccine.

5.1. Prior to entering school, a child must show proof that he or she has 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 first and second dose must be at least four (4) weeks apart. The second and third doses should be separated by at least eight (8) weeks. Additionally, the third dose should be at least sixteen (16) weeks after the first dose.

5.2. An unvaccinated student must complete a three (3) dose series. However, a two (2) dose series (with doses separated by a minimum of four (4) months) using the adult formulation Recombivax HB which is licensed for children aged 11 -15 years, is an acceptable alternative to the three dose requirement.

5.3. Occurrence of prior disease may be used as evidence of immunity.

5.4. A student may attend school and participate in extracurricular activities after he or she has received the first of the series of Hepatitis B vaccinations. The series must be completed within seven (7) months of the date of entry or the student will be excluded from school and all extracurricular activities until the student completes the Hepatitis B series. It is the responsibility of the student and his or her parents or legal guardians to ensure the timely completion of the Hepatitis B series and submit the acceptable proof to the school authorities.

§64-95-6. Dosage and Interval Schedule for Rubeola (Measles) Vaccine.

6.1. Prior to entering school, a child must show proof that he or she has received two doses of Rubeola (Measles) vaccine, the first dose on or after the first birthday and the second dose no less than four (4) weeks after the first dose. Alternatively, immunity may be proven through laboratory testing. Results of laboratory that prove immunity must be presented to the Local Health Officer for review and approval before the child may be admitted to school.

6.2. Occurrence of prior disease may be used as evidence of immunity.

§64-95-7. Dosage and Interval Schedule for Mumps Vaccine.

7.1. Prior to entering school, a child must show proof that he or she has received at least two doses of Mumps vaccine, the first dose on or after the first birthday and the second dose no less than four (4) weeks after the first dose. Alternately, immunity may be shown through laboratory testing. Results of laboratory that prove immunity must be presented to the Local Health Officer for review and approval before the child may be admitted to school.

7.2. Occurrence of prior disease may be used as evidence of immunity.

§64-95-8. Dosage and Interval Schedule for the Polio (IPV) Vaccine.

8.1. Four doses of trivalent inactivated polio vaccine (IPV) are recommended for routine immunization of all children with the fourth dose given on or after the child's fourth birthday and at least a six (6) month interval from the third dose. Prior being admitted to school, a child must show proof that he or she has received a minimum of three doses of IPV with the last dose given on or after the child's fourth birthday and at least six months after the second dose.

8.2. A child who has not received the recommended doses of IPV should receive a minimum

of three doses, with four (4) weeks between dose one and two, and six (6) months between doses two and three. Additionally, dose three must be received on or after the child's fourth birthday.

8.3. A student may attend school and participate in extracurricular activities after he or she has received the first of the series of IPV vaccinations. The series must be completed within seven (7) months of the date of entry or the student will be removed from school and all extracurricular activities until the IPV series is complete. It is the responsibility of the student and his or her parents or legal guardians to ensure the timely completion of the IPV series and submit the acceptable proof to the school authorities.

8.4. In the alternative, a child who has had three or more doses of an oral, live attenuated version of the Polio Vaccine (OPV), or a combination of OPV and IPV, the last dose of which was given on or after the child's fourth birthday with at least a six (6) month separation between the second and third dose, are in compliance with this section. Otherwise, subsection 8.2., applies but doses of OPV may be substituted in the record for IPV.

§64-95-9. Dosage and Interval Schedule for the Rubella Vaccine.

9.1. Prior to entering school, a child must show proof that he or she has 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. Results of laboratory testing that prove immunity must be presented to the Local Health Officer for review and approval before the child may be admitted to school.

9.2. Occurrence of prior disease may be used as evidence of immunity.

§64-95-10. Dosage and Interval Schedule for the Varicella (Chickenpox) Vaccine.

10.1. Prior to a child age 4 to 12 years entering school, he or she must show proof of having received two doses of Varicella (Chickenpox) vaccine, the first dose on or after the first birthday and the second dose no less than three month after the first.

10.2. A child age 13 years and older who is without proof of immunity, must receive two doses of the Varicella vaccine with at least 4 weeks between shots.

10.3. A student who has received only one dose of the Varicella vaccine is required to obtain a second dose. For a child between the ages of 4 to 12 years, the second dose must be given at least 28 days after the first dose.

10.4. 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 accompanied by laboratory testing showing immunity, if requested.

10.5. A student may attend school and participate in extracurricular activities after he or she has received the first of the series of Varicella vaccinations. The series must be completed within three (3) months of the date of entry for a child between ages 4 to 12 years and within one (1) month for a child 13 or older, or the student must be removed from school and all extracurricular activities until such time as the Varicella series is complete or laboratory evidence of immunity

is supplied. It is the responsibility of the student and his or her parents or legal guardian to ensure the timely completion of the Varicella series or laboratory testing and submit acceptable proof to the school authorities.

§64-95-11. Dosage and Interval Schedule for the Meningococcal (MCV4) Vaccine.

11.1. A student ages 11 or 12 must show proof of Meningococcal vaccination prior to entry into the 7th grade. Students will require a booster shot at age 16 or older, and will need to show proof of the MCV4 booster prior to entry into the 12th grade.

11.2. A student who is newly entering the school system at age 13, 14 or 15, and who has not been previously vaccinated with MCV4 must receive the MCV4 vaccination and must also show proof of a booster shot on or after age 16 and prior to entry into the 12th grade.

11.3. A student who is newly entering the school system at age 16 or older and who has not been previously vaccinated with MVC4 must receive a MCV4 vaccination and will not be required to show proof of a booster prior to entry into the 12th grade.

§64-95-12. Applicability of Dosage and Interval Schedules to Pre-School Students.

The dosage and interval schedules contained in sections 4 through 11 apply to children entering a state-regulated child care center and preschool children who enter a school building housing other children in grades kindergarten through twelfth, to the extent that they are age appropriate in accordance with those immunization schedules.

§64-95-13. Recommended Vaccinations.

The following vaccines are recommended, but not required, for all children attending a public, private, or parochial school in this state, or a state-regulated child care center:

13.1. Influenza Vaccine.

13.1.a. A child aged six months or older should be vaccinated annually 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.

13.1.b. An annual flu vaccine is recommended in accordance with annually released U.S. Department of Health and Human Services, Advisory Committee on Immunization Practices recommendations.

13.2. Human Papillomavirus Vaccine - HPV Vaccine. Most human papillomavirus (HPV) infections are inapparent clinically. However, HPVs can cause benign though disfiguring epithelial proliferation of the skin and mucous membranes and are associated with several cancers. The HPV vaccines are the only available vaccine that protects against certain cancers.

The American Academy of Pediatrics recommends that routine vaccination of females with the HPV2 or HPV4 starting at age 11 or 12, though the vaccine has been approved starting at age 9. The vaccine is a three dose series with a minimum of one month between doses one (1) and two (2) and dose three (3) given six months after dose one (1). The vaccine for females is approved from age 9 to 26. The vaccine is also recommended for males from age 13 to 26 with the same dosing schedule. HPV4 is the only HPV vaccine approved for males.

13.3. Other Vaccinations. 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".

§64-95-14. Compliance with the Law.

14.1. A child is considered to be in compliance with the law requiring compulsory immunizations and this rule, when the child has a complete certificate of immunization or similar medical record of immunizations, or when immunization is contraindicated or there exists a specific precaution to a particular vaccine.

14.2. If a child has been granted an exemption from receiving one or more vaccinations, the certificate of immunization must indicate the vaccine(s) for which the child is exempted, the reason for the exemption, and whether or not the reason for the exemption is permanent or temporary. If the exemption is temporary, it must be re-evaluated annually unless a longer period of time is indicated by the child's treating physician. A temporary exemption may not exceed a period of 24 months before re-evaluation.

14.3. A student who does not have a completed certificate of immunization or other similar medical record of immunizations must 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.

14.3.a. Provisional enrollment may continue for the time medically necessary to complete the missing vaccinations.

14.3.b. At no time should the provisional enrollment period exceed 8 months from school entry, the time medically necessary to complete all required childhood vaccine series under the standard catch up schedule.

14.3.c. After attending school for the provisional enrollment time period, all provisionally enrolled students must show proof to the school that they have completed all of the required immunizations or laboratory evidence of immunity.

14.4. A child who is delinquent for any required vaccination, or who has exceeded the provisional enrollment period, will be considered not to be in compliance with the law and this rule, and will be suspended from attending school until the appropriate vaccine(s) or laboratory evidence is received and the records are amended.

§64-95-15. Proof of Immunity.

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

15.2. 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 participation in the West Virginia Statewide Immunization Information System (WVSIIS) - - <http://www.dhhr.wv.gov/oeps/immunization/providers/Pages/WVSIIS.aspx>

The form is also available from:

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

15.3. The documentary evidence of immunizations must 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.

15.4. Proof of prior measles, mumps, rubella, varicella 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 laboratory evidence of immunity in the form of titers for measles, mumps and rubella and a Hepatitis B panel for Hepatitis B. If the historical disease diagnosis is in question, current laboratory evidence of immunity may be required.

§64-95-16. Eligibility for a Medical Exemption.

The Immunization Officer must determine that the child, on whose behalf his or her physician has made a request for an exemption, is eligible for and issue an exemption, upon sufficient medical evidence that an immunization is contraindicated or there exists a specific precaution to a particular vaccine.

§64-95-17. Eligibility Process.

17.1. *Request.* A physician must complete a "Request for Medical Exemption from Compulsory Immunization" form available at the Department of Health and Human Resources Medical Exemption Resource Center website. The form may be accessed at the following link: http://www.dhhr.wv.gov/oeps/immunization/requirements/Documents/WV_Med_Exempt_Request_Form%2011.20.13.pdf. The application must include:

17.1.a. The name of the child for whom the request is made;

17.1.b. The date of birth of child for whom the request is made;

17.1.c. The name of the school the child attends and the county where the school is located;

17.1.d. The name(s) of the child's parent or guardian;

17.1.e. The address of the child's parent or guardian;

17.1.f. The name, address and telephone number of the physician making the request;

17.1.g. The specific vaccine or vaccines for which an exemption is requested;

17.1.h. An explanation of the medical contraindication or precaution relied upon to make the request;

17.1.i. Whether the request is for a permanent or temporary exemption;

17.1.j. Certification by the physician that the physical condition of the child is such that immunization is contraindicated or there exists a specific precaution to a particular vaccine. This certification must be supported by medical signs and laboratory findings; and

17.1.k. If a temporary exemption is indicated, the physician's opinion as to the date or period of time after which the exemption should be reevaluated.

17.2. *Evidence.* In general, the physician, on behalf of the child, has the burden of proving that an exemption is necessary. This means that the physician must furnish medical and other evidence that the Immunization Officer can use to reach conclusions about the need for an exemption.

17.2.a. Evidence is anything the physician submits to the Immunization Officer or that the Immunization Officer obtains that relates to the request for an exemption. This includes, but is not limited to:

17.2.a.1. Objective medical evidence, that is, medical signs and laboratory results; and

17.2.a.2. Other evidence from medical sources, such as medical history, opinions, and statements about treatment the child has received.

17.2.b. *Physician's responsibility.*

17.2.b.1. The physician must provide medical evidence showing that an exemption is necessary. The Immunization Officer will make reasonable efforts to notify the physician of any deficiencies in the request but it remains the responsibility of the physician to assure that the request is complete; and

17.2.b.2. The physician must inform the child's parent or guardian of the process for obtaining an exemption and the status of the request.

17.2.c. *Immunization Officer's responsibility.* Before making a determination as to whether an exemption should be granted, the Immunization Officer will review the evidence obtained from the physician. The Immunization Officer will make every reasonable effort to obtain relevant medical evidence from the physician.

17.2.d. Every reasonable effort means that the Immunization Officer will make an initial request for evidence from the physician and, at any time between 10 and 20 calendar days after the initial request, if the evidence has not been received, the Immunization Officer will make one follow-up request to obtain the medical evidence necessary to make a determination. The physician will have a minimum of 10 calendar days from the date of the follow-up request to reply, unless the Immunization Officer's experience with that physician indicates that a longer period is advisable in a particular case.

17.3. *Preliminary Exemption.* The Immunization Officer may grant a child a preliminary exemption if it appears that there is a substantial likelihood that the child will be eligible for a medical exemption, but that the medical evidence sufficient to support a medical exemption cannot be timely developed through no fault of the physician.

17.3.a. *How a preliminary exemption is obtained.* A preliminary exemption may be requested by a physician or may be granted without a request, by the Immunization Officer if the Immunization Officer finds that the medical evidence is insufficient to make a determination.

17.3.b. *Findings necessary for preliminary exemption.* In order to grant an applicant a preliminary exemption, the Immunization Officer must find that:

17.3.b.1. Sufficient medical evidence is not available;

17.3.b.2. Additional relevant medical evidence is obtainable;

17.3.b.3. Additional effort must be made to obtain relevant medical evidence;

17.3.b.4. It is not the fault of the physician that sufficient medical evidence is not available;

17.3.b.5. Because of the delay in obtaining relevant medical evidence, the child will miss a significant number of educational days if the preliminary exemption is not granted;

17.3.b.6. It is likely that little or no harm will result to the public if the preliminary exemption is granted; and

17.3.b.7. There is a substantial likelihood that the child will be eligible for an exemption once the relevant medical evidence is obtained.

17.3.c. *Duration of a preliminary exemption.* If a preliminary exemption is granted by the Immunization Officer, the preliminary exemption will remain in effect until the Immunization Officer makes a determination on the application for an exemption.

17.4. *Determination of Eligibility.* The Immunization Officer must determine eligibility for an exemption in accordance with the eligibility standard specified in section 16 and grant the certificate of exemption to any applicant determined eligible.

17.4.a. After the Immunization Officer reviews all of the evidence relevant to the application, including medical opinions, the Immunization Officer will make findings about what the evidence shows. In some situations, the Immunization Officer may not be able to make these findings because the evidence in the case record is insufficient or inconsistent. Evidence will be considered to be insufficient when it does not contain all the information needed to make a determination or decision. Evidence is considered to be inconsistent when it conflicts with other evidence, contains an internal conflict, is ambiguous, or when the medical evidence does not appear to be based on medically acceptable clinical or laboratory diagnostic techniques. If the evidence in the record is insufficient or inconsistent, the Immunization Officer may need to take additional actions, as explained in subdivisions c. and d. of this subsection.

17.4.b. If all of the evidence received by the Immunization Officer, including all medical opinion(s), is consistent and there is sufficient evidence for a determination of whether to grant an exemption, the Immunization Officer will make a determination or decision based on that evidence.

17.4.c. If any of the evidence in the record, including any medical opinion(s), is inconsistent, the Immunization Officer will weigh the relevant evidence and see whether a determination can be made based on the evidence obtained.

17.4.d. If the evidence is consistent, but the Immunization Officer has insufficient evidence to determine whether an exemption may be granted, or if after weighing the evidence the Immunization Officer determines that a conclusion cannot be reached about whether an exemption should be granted, the Immunization Officer will determine the best way to resolve the inconsistency or insufficiency. The action(s) taken by the Immunization Officer will depend on the nature of the inconsistency or insufficiency. The Immunization Officer will try to resolve the inconsistency or insufficiency by taking any one or more of the actions listed in paragraphs 17.4.d.1, 17.4.d.2, and 17.4.d.3. The Immunization Officer might not take all of the actions listed below. The Immunization Officer may also grant the applicant a preliminary exemption as described in subsection 17.3 until sufficient medical evidence is obtained. The Immunization Officer will consider any additional evidence received together with the evidence already obtained.

17.4.d.1. The Immunization Officer may re-contact the physician. If the Immunization Officer obtains medical evidence over the telephone, the telephone report will be sent to the Physician for review, signature, and return;

17.4.d.2. The Immunization Officer may request additional existing records; or

17.4.d.3. The Immunization Officer may request that the physician seek the opinion of a specialist.

17.4.e. When there are inconsistencies in the evidence that the Immunization Officer cannot resolve or when, despite efforts to obtain additional evidence, the evidence is insufficient

to determine whether an exemption should be granted, the Immunization Officer will make a determination or decision based on the evidence available.

17.4.f. The Immunization Officer will make the determination or decision based upon the most recent guidance from the Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), and the American Academy of Family Physicians (AAFP) with respect to medical contraindications or precautions for each vaccine.

17.5. *Time Standards.* A determination on an application for an exemption will be made within 20 days of receipt of a complete request for an exemption. A request that remains incomplete for 45 days will result in the denial of the request.

17.6. *Notice of the Immunization Officer's Decision.* The Immunization Officer will mail a written notice of the determination to the physician and the child's parent or guardian, at their last known address. The written notice will explain in simple and clear language the Immunization Officer's decision and the reasons for and the effect of the determination. If the Immunization Officer's determination is in whole or in part unfavorable, the written notice also will contain in understandable language a statement of the case setting forth the evidence on which the determination is based. The notice also will inform the child's parent or guardian of the right to request a review of the Immunization Officer's decision by the State Health Officer.

17.7. *Documenting Exemptions.* The Immunization Officer will ensure that that any exemption granted by the Immunization Officer is entered into the West Virginia Statewide Immunization Information System, Medical Exemption Module.

17.8. *Review by the State Health Officer.* If the Immunization Officer's determination is in whole or in part unfavorable, the child's parent or guardian may request a review of the Immunization Officer's decision by the State Health Officer.

17.8.a. *How to request a review by the State Health Officer.* A child's parent or guardian may request a review of the Immunization Officer's determination by filing a written request. A request form is available at the West Virginia Division of Immunization Services (DIS) website at the following link:

<http://www.dhhr.wv.gov/oeps/immunization/Documents/Request%20for%20Appeal-ME-2013.pdf>. The request should include:

17.8.a.1. The name and age of the child for whom the exemption is requested;

17.8.a.2. The name and address of the child's parent or guardian;

17.8.a.3. The reasons you disagree with the previous determination or decision;
and

17.8.a.4. A statement of additional evidence to be submitted and the date you will submit it.

17.8.b. *When and where to file.* The request must be filed with the State Health Officer by U.S. Mail at 305 Capitol Street, Room 702, Charleston, West Virginia 25301; or email at VaccineExemption@wv.gov; or facsimile at 304-558-8736, within 30 days after the date the child's parent or guardian receives notice of the Immunization Officer's decision (or within the extended time period if an extension is granted as provided in paragraph 17.8.c.).

17.8.c. *Extension of time to request a review.* If the child's parent or guardian fails to request a review within 30 days after the date the child's parent or guardian receives notice of the Immunization Officer's determination or decision, the child's parent or guardian may ask for more time to make their request. The request for an extension of time must be in writing and it must give the reasons why the request for a review was not filed within the stated time period. A request for an extension may be filed by U.S. Mail, facsimile or email as provided by subdivision 17.8.b. If the child's parent or guardian shows that there is good cause for missing the deadline, the time period will be extended to permit the filing of a request for a review. In determining whether the applicant has shown good cause for missing a deadline to request for review the following will be considered:

17.8.c.1. What circumstances kept the child's parent or guardian from making the request on time;

17.8.c.2. Whether an action of the Bureau misled you; and

17.8.c.3. Whether the child's parent or guardian has any physical, mental, educational, or linguistic limitations (including any lack of facility with the English language) which prevented the child's parent or guardian from filing a timely request or from understanding or knowing about the need to file a timely request for review.

17.8.d. *Review procedures.* If a request for a review is made, the child's parent or guardian will be given an opportunity to present any additional written evidence to the State Health Officer. The State Health Officer will then make a decision based on all of this evidence.

17.8.e. *Review determination.* After the child's parent or guardian requests a review of the determination of the Immunization Officer, the State Health Officer will review the evidence that the Immunization Officer considered in making the initial determination and any other evidence the State Health Officer receives. The State Health Officer may request additional information of the child's parent or guardian or the physician to complete the review and provide a decision. The State Health Officer will make a determination based on the preponderance of the evidence.

17.8.f. *Time Standards.* A determination on a request for a review of the Immunization Officer's determination will be made within 30 days of receipt of the request for review or, in the event the State Health Officer requests additional information from the child's parent or guardian or the physician, 30 days from the receipt of the requested information. Failure of the child's parent or guardian to submit requested information within 45 days of the receipt of the State

Health Officer's request will result in the State Health Officer making a determination based on the evidence available.

17.8.g. *Effect of the State Health Officer's review of the Immunization Officer's determination.* The State Health Officer's review is binding unless the child's parent or guardian requests a hearing with 45 days of the receipt of the State Health Officer's notice of review, as required by the Rules for Contested Case Hearings and Declaratory Rulings, 64 CSR 1.

17.8.h. *Notice of the State Health Officer's Review.* The State Health Officer will mail a written notice of the Review of the Immunization Officer's determination to the applicant at their last known address. The State Health Officer will state the specific reasons for the determination and tell the child's parent or guardian of the right to a hearing.