

New Jersey Department of Health and Senior Services, Vaccine Preventable Disease Program

Questions and Answers on Immunization Regulations Pertaining to Children Attending School/ Higher Education

Immunization of Pupils in Schools (New Jersey Administrative Code Citation 8:57-4.1 to 8:57-4.24)

<http://www.lexisnexis.com/njoal/>

8:57-4.1 Applicability

This subchapter shall apply to all children attending any public or private school, child care center, nursery school, preschool or kindergarten in New Jersey.

8:57-4.2 Proof of Immunization

A principal, director or other person in charge of a school, preschool, or childcare facility shall not knowingly admit or retain a child whose parent or guardian has not submitted acceptable evidence of the child's immunization.

8:57-4.23 Optimal Immunization Recommendations

The specific vaccines and the number of doses required under this subchapter are intended to establish the minimum vaccine requirements for child care center, preschool, or school entry and attendance in New Jersey. Additional vaccines, vaccine doses, and proper spacing between vaccine doses are recommended by the Department in accordance with the guidelines of the American Academy of Pediatrics (AAP) and the Advisory Committee on Immunization Practices (ACIP) for optimal protection. Additional vaccines or vaccine doses may be administered, although they are not required for school attendance unless otherwise specified in this subchapter.

8:57-4.24 Penalties

N.J.S.A. 26:1A-10. Violation of State Sanitary Code, penalty

Each violation of any provision of the State Sanitary Code shall constitute a separate offense and shall be punishable by a penalty of not less than \$50 nor more than \$1,000. Each such penalty shall be sued for and recovered in a civil action, in any court of competent jurisdiction, by and in the name of the State Department of Health or by and in the name of the local board of health of the municipality in which the violation occurred. Any penalty recovered in any such action shall be paid to the plaintiff therein. When the plaintiff is the State Department of Health, the penalty recovered shall be paid by the department to the State Treasurer. When the plaintiff is a local board of health, the penalty recovered shall be paid by the local board into the treasury of the municipality within which the local board has jurisdiction.

L.1047,c.177,s.10; amended 1953, c.26,s.1; 1993,c55.

Q: What are the minimally required vaccines for school entry in New Jersey?

A: Refer to <http://nj.gov/health/forms/imm-7.pdf> for a copy of the document, 'MINIMAL IMMUNIZATION REQUIREMENTS FOR SCHOOL ATTENDANCE IN NEW JERSEY'

2008 Amended Immunization Requirements

The New Jersey Department of Health and Senior Services (DHSS) has recently revised the administrative rules N.J.A.C. 8:57-4 with substantive changes to include the requirement of four new vaccines for school, preschool and licensed child-care center attendance beginning in September 2008. We encourage both private and Vaccines For Children (VFC) Program providers who provide care to commercially insured children to order enough vaccine to meet the higher demand anticipated due to the new vaccine requirements.

The rule changes include a four day grace period for all childhood vaccines which became effective on January 7, 2008. These changes were formally adopted by the New Jersey Public Health Council on October 9, 2007 and published in the *New Jersey Register* on January 7, 2008. The amended regulations in N.J.A.C 8:57-4 state the following:

8:57-4.10 Diphtheria and tetanus toxoids and pertussis vaccine

- (h) Every child born on or after January 1, 1997, and entering or attending Grade Six, or a comparable age level special education program with an unassigned grade on or after September 1, 2008, shall have received one dose of Tdap (Tetanus, diphtheria, acellular pertussis) given no earlier than the 10th birthday.
- (i) Children entering or attending Grade Six on or after September 1, 2008, who received a Td booster dose less than five years prior to entry or attendance shall not be required to receive a Tdap dose until five years have elapsed from the last DTP/DTaP or Td dose.
- (j) Children born on or after January 1, 1997, and transferring into a New Jersey school from another state or country after September 1, 2008, shall have received one dose of Tdap, provided at least five years have elapsed from the last documented Td dose.

8:57-4.18 Pneumococcal conjugate vaccine

- (a) Every child two months through 11 months of age enrolling in or attending any licensed child-care center or preschool facility on or after September 1, 2008, shall have received a minimum of two age-appropriate doses of pneumococcal conjugate vaccine (PCV), or fewer as medically appropriate for the child's age according to the ACIP recommendations.
- (b) Every child 12 months through 59 months of age enrolling in or attending a licensed child-care center or preschool facility on or after September 1, 2008, shall have received at least one dose of PCV on or after their first birthday.

8:57-4.19 Influenza vaccine

Children six months through 59 months of age attending any licensed child-care center or preschool facility on or after September 1, 2008, shall annually receive at least one dose of influenza vaccine between September 1 and December 31 of each year.

8:57-4.20 Meningococcal vaccine

(a) Every child born on or after January 1, 1997, and entering or attending Grade Six or a comparable age level special education program with an unassigned grade on or after September 1, 2008, shall have received one dose of a meningococcal-containing vaccine, such as the medically-preferred meningococcal conjugate vaccine.

**Please note: This applies to students when they turn 11 years of age and attending Grade Six.*

(b) Every child born on or after January 1, 1997, and transferring into a New Jersey school from another state or country on or after September 1, 2008, shall have received one dose of meningococcal vaccine.

8:57-4.23 Optimal immunization recommendations – 4 Day Grace Period

(b) All vaccine doses included within, and mandated by, this subchapter that are administered less than or equal to four days before either the specified product label minimum age or dose spacing interval shall be counted as valid and shall not require revaccination in order to enter or remain in a school, preschool, or licensed child-care facility. Schools are encouraged to send a notice home to parents informing them of the new requirements to assure compliance at the beginning of the 2008-2009 school year.

INFLUENZA VACCINE

Q: Why did the state health department make the influenza vaccine requirement only apply to preschool and licensed childcare facilities?

A: Influenza is responsible for approximately 200,000 hospitalizations and 36,000 deaths each year in the United States. Hospitalization rates for influenza for children 12 months of age and younger are comparable to rates of persons 65 years and older. Among children 0 to 4 years of age, hospitalization rates due to influenza have varied from 100 per 100,000 healthy children to as high as 500 per 100,000 for children with underlying medical conditions. To reduce the risk of hospitalization from complications of influenza, the American Academy of Pediatrics (AAP) and the Centers for Disease Control and Prevention (CDC) recommend routine annual influenza vaccination of children 6 to 59 months of age.

With regard to the influenza vaccine, a study in the October 2005 issue of the *American Journal of Epidemiology* supported the idea of vaccinating all preschool children. The study tracked influenza cases by age groups and found that preschoolers were the first to be seen in flu-related doctor visits, with sick adults following about 29 days later. The findings revealed that flu like illness in children under age five, compared with all other age groups, was the most predictive of pneumonia and influenza deaths in the general population.

Q: Is the flu vaccine required after January 1st for children coming in at that time or had not gotten it between Sept. 1- Dec. 31 of the prior year?

A: Yes, the flu vaccine is still required for children after January 1. As we all know, the flu season may not peak until February. The flu season can also extend until May in some cases. So getting a flu vaccine even late in the season is protective.

Q: Why then do the regulations specify a specific time frame?

A: 1. Most flu vaccine is distributed to health care providers (HCPs) by October and November each year so most HCPs should have their supplies at that time. 2. We also know that public requests for flu vaccine peaks around September to December. 3. If we can get a majority of children immunized within that four month timeframe, it will make monitoring the immunization status of a large number of children more manageable by the school or public health agency.

Q: How much time after December 31 of a given year do I have to get my child vaccinated with the flu vaccine?

A: The state is recommending to school administrators/ school nurses that two weeks is a sufficient amount of time to produce a documented receipt of dose or produce an appointment slip indicating that they are in the process of receiving at least one dose of flu vaccine, as appropriate. Depending on individual circumstances, a scheduled appointment outside the two week period may be acceptable. The Department's goal is not to exclude anyone, but if the child does not receive the vaccine in a reasonable period, he/ she will be asked to leave school.

Q: How should a school enforce the flu vaccine regulation for those students who have not received the flu shot after December 31st?

A: After December 31st, a majority of students should already have received the required one dose of the flu vaccine. For those students who have not received the flu vaccine by December 31st, they should be flagged in January of the following year, and parents should be notified by the school indicating that they have two weeks to have their child vaccinated with one dose of the flu vaccine.

Q: What if I am enrolling my child in January of the following year, is my child exempt from getting the mandatory flu vaccine?

A: No, the flu vaccine is still required for children after January 1. Flu season may not peak until February and can also extend until May in some cases. Getting a flu vaccine even late in the season is still protective. If you enroll your child after December 31st, you will have two weeks to provide a documented receipt of the flu vaccine or produce an appointment slip indicating that they are in the process of receiving at least one dose of flu vaccine, as appropriate.

Q: Is it acceptable for a child to receive flu vaccine in August when the regulations specifically state to receive one flu dose between September 1 to December 31 of each year?

A: The Department is not encouraging parents to get their child vaccinated before September 1 but if they do get vaccinated prior to September 1 it would be accepted. The rationale behind this is that depending on the flu vaccine, the average coverage duration is four to six months. Therefore, receiving the flu vaccine earlier than this timeframe could mean that the protection wanes at the height of flu season.

Another important note is that unlike the other new requirements, the flu vaccine has a window between Sept.1- Dec.31 to receive the flu vaccine so a child does not need the flu vaccine to enter school in September; the Department is recommending that a child be vaccinated during that time (Sept- Dec) to provide the most protection during the flu season.

Q: Where can a family go to get the flu vaccine if the pediatrician does not have any more flu vaccine?

A: If your pediatrician/ healthcare provider (HCP) cannot provide the flu vaccine for you within the given time frame of September 1- December 31st, documentation within that time frame stating that you have an appointment to receive the flu vaccine from your HCP would be acceptable.

Barring that there is no national flu vaccine shortage and your HCP cannot guarantee an adequate supply of flu vaccine, other alternatives must be sought by the family. Options include:

1. Seeking out another HCP who can administer flu vaccine to children;
2. Checking with your local health department to see if they will administer flu vaccine to children less than 18 years of age;
3. Contacting your local public health clinic <http://nj.gov/health/fhs/cphc/documents/locations.pdf> (Note: anyone is eligible to receive service at a local public health clinic);
4. Checking your local newspaper for flu clinic listings and verifying that they have flu vaccine available.

As a reminder, local health departments and FQHCs purchase flu vaccine through the Vaccine for Children (VFC) Program. A child must qualify to receive VFC vaccine; to

view those eligibility requirements, go to
<http://www.cdc.gov/vaccines/programs/vfc/projects/faqs-doc.htm>

Q: What if there is a flu vaccine shortage or a flu vaccine distribution problem?

A: The amended regulations for Influenza vaccine state that children six months through 59 months of age enrolling in or attending a child-care center or preschool facility on or after September 1, 2008, shall annually receive at least one dose of influenza vaccine between September 1 and December 31 of each year. After December 31, a student will be considered delinquent. If the physician has not received their supply by December 31, they can provide a letter/script notifying the school nurse that the student will receive the vaccine once they have it in stock.

As far as distribution and shortages are concerned, the amended regulations now state the following: In the event of a national or state vaccine supply shortage, as determined by the Centers for Disease Control and Prevention and Commissioner, respectively, the Commissioner or his or her designee may temporarily suspend the immunization requirement for the particular immunization affected by the supply shortage, after provision of notice to the public via print and electronic news media, NJLINCS, electronic posting on the Department's website, etc.

Q: What types of flu vaccines are available for children?

A: There are two types of flu vaccine available for children. The first is an inactivated (killed) vaccine given as a shot, which has been used for many years. It is also known as a trivalent influenza vaccine (TIV). There are many vaccine products for TIV available. It can be given to anyone six months of age and older. The second is a live, attenuated (weakened) vaccine, which is sprayed into the nose and was licensed in 2003. It is not licensed for children less than two years old. It is also known as a live, attenuated, influenza vaccine (LAIV). The brand name for the LAIV is FluMist™. The LAIV is not for everyone. Check with your healthcare provider to see if your child can receive the LAIV flu vaccine.

Q: What is the effectiveness of these flu vaccines?

A: Because influenza viruses change from year to year, new vaccines must also be formulated each year, and annual vaccination is recommended. The inactivated influenza vaccine is 70-90% effective in healthy children, and the live, intranasal vaccine is over 84% effective among healthy children less than seven years of age.

Q: How is the 'flu season' defined?

A: Based on trend analysis of influenza seasons in New Jersey over the past five years, influenza and/ or influenza-like illness (ILI) have been confirmed to be present during the months of November through to the end of March.

Q: Is there flu vaccine available that does not contain the preservative, thimerosal?

A: Most single dose vials or syringes of influenza vaccine do not contain the preservative, thimerosal. The live, attenuated, influenza vaccine, (Brand Name: FluMist) given intra-nasally, is thimerosal-free. For a listing of thimerosal content in U.S. licensed vaccines, go to: <http://www.vaccinesafety.edu/thi-table.htm>

Q: Should I be concerned about thimerosal in my child's vaccines?

Thimerosal is a mercury-containing preservative used in some vaccines and other products since the 1930s. There is no convincing scientific evidence of harm caused by the low doses of thimerosal in vaccines, except for minor reactions like redness and swelling at the injection site. However, in July 1999, the Public Health Service agencies, the American Academy of Pediatrics, and vaccine manufacturers agreed that thimerosal should be reduced or eliminated in vaccines as a precautionary measure.

Since 2001, with the exception of some influenza (flu) vaccines, thimerosal is not used as a preservative in routinely recommended childhood vaccines.

For more information about vaccine safety and thimerosal, go to:

U.S. Food and Drug Administration: <http://www.fda.gov/cber/vaccine/thimerosal.htm>

U.S. Centers for Disease Control and Prevention:
<http://www.cdc.gov/vaccinesafety/concerns/thimerosal.htm>

Q: Aside from the flu vaccination requirement for children 6-59 months, who else should get vaccinated for flu?

A: See boxes of information below, Source: CDC MMWR ACIP Recommendations for the Prevention and Control of Influenza July 18, 2008

<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr57e717a1.htm>

BOX 1. Summary of Influenza vaccination recommendations, 2008: children and adolescents aged 6 months–18 years

Vaccination of all children aged 6 months–18 years should begin before or during the 2008–09 influenza season if feasible, but no later than during the 2009–10 influenza season. Vaccination of all children aged 5–18 years is a new ACIP recommendation.

Children and adolescents at high risk for influenza complications should continue to be a focus of vaccination efforts as providers and programs transition to routinely vaccinating all children and adolescents. Recommendations for these children have not changed. Children and adolescents at higher risk for influenza complication are those:

- aged 6 months–4 years;
- who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- who are immunosuppressed (including immunosuppression caused by medications or by human immunodeficiency virus);
- who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- who are receiving long-term aspirin therapy who therefore might be at risk for experiencing Reye syndrome after influenza virus infection;
- who are residents of chronic-care facilities; and,
- who will be pregnant during the influenza season.

Note: Children aged <6 months should not receive influenza vaccination. Household and other close contacts (e.g., daycare providers) of children aged <6 months, including older children and adolescents, should be vaccinated.

BOX 2. Summary of influenza vaccination recommendations, 2008: adults

Annual recommendations for adults have not changed. Annual vaccination against influenza is recommended for any adult who wants to reduce the risk for becoming ill with influenza or of transmitting it to others. Vaccination also is recommended for all adults in the following groups, because these persons are either at high risk for influenza complications, or are close contacts of persons at higher risk:

- persons aged ≥ 50 years;
- women who will be pregnant during the influenza season;
- persons who have chronic pulmonary (including asthma), cardiovascular (except hypertension), renal, hepatic, hematological or metabolic disorders (including diabetes mellitus);
- persons who have immunosuppression (including immunosuppression caused by medications or by human immunodeficiency virus);
- persons who have any condition (e.g., cognitive dysfunction, spinal cord injuries, seizure disorders, or other neuromuscular disorders) that can compromise respiratory function or the handling of respiratory secretions or that can increase the risk for aspiration;
- residents of nursing homes and other chronic-care facilities;
- health-care personnel;
- household contacts and caregivers of children aged < 5 years and adults aged ≥ 50 years, with particular emphasis on vaccinating contacts of children aged < 6 months; and,
- household contacts and caregivers of persons with medical conditions that put them at high risk for severe complications from influenza.

Q: What is the recommended dosing schedule for influenza vaccine?

A: According to the CDC recommended immunization schedule 2008, administer 2 doses (separated by 4 weeks or longer) to children younger than 9 years who are receiving influenza vaccine for the first time or who were vaccinated for the first time last season but only received one dose. Only one dose is recommended thereafter for children 6 months and over. (See above for full recommendation guidelines). The NJDHSS regulation minimally requires 1 dose of influenza vaccine for school entry into a licensed child care or preschool facility, each year between September 1-December 31.

PNEUMOCOCCAL CONJUGATE VACCINE

Q: According to the regulations, your pneumococcal requirements of 1-2 doses (depending on age) does not provide sufficient protection from the disease with the current available formulation. Can you explain this?

A: Our regulations reflect the minimal requirements for vaccines needed to attend school in NJ. They do not however, comprise the full immunization series recommended by the CDC. It is the state's intention that parents will seek to meet their vaccination requirements for school and then begin a dialogue with their HCP who would educate them about the importance of completing the full vaccination series to achieve full protection from vaccine preventable diseases and set up subsequent appointments with the intention of giving them the age-appropriate vaccines at the next visit.

(This answer also applies to the haemophilus Influenzae b (Hib) vaccine as well).

Q: Why is pneumococcal vaccination required for child care/ preschool entry?

A: The pneumococcal conjugate vaccine protects against the bacterium *Streptococcus pneumoniae*. This bacteria is the most common cause of: lung infections (pneumonia), blood infections (bacteremia) and infection of the covering of the brain and spinal cord (meningitis). Two to five percent of children who get pneumococcal meningitis will die. Of those who survive, 25% to 35% will have hearing loss, mental retardation or paralysis. *Streptococcus pneumoniae* is also the most common cause of ear infections (otitis media) in young children. Children under two years of age average more than one middle ear infection each year, many of which are caused by *Streptococcus pneumoniae* infections. Young children are much more likely than older children and adults to get pneumococcal disease. Children in child care settings are two- to-three times at greater risk for pneumococcal disease.

For more pneumococcal vaccine information, go to: www.cdc.gov/vaccines/vpd-vac/pneumo/default.htm

[GRADE SIX REQUIREMENTS]

TETANUS, DIPHTHERIA, ACELLULAR PERTUSSIS (Tdap) & MENINGOCOCCAL VACCINES

Q: There are two different types of vaccines for Tdap and for meningococcal disease. Can you please clarify the difference between these vaccines?

A: The Tdap vaccines are made by two different manufacturers and are licensed for different age groups. Boostrix by Glaxo Smith Kline is licensed for ages 10-18 years of age. Adacel by Sanofi-pasteur is licensed for ages 11-64. The Tdap vaccine provides protection from pertussis as immunity to pertussis wanes over time.

The meningococcal vaccine protects against the bacterium *Neisseria meningitidis*.

There are two meningococcal vaccines: the meningococcal polysaccharide (MPSV4, brand name, Menomune) and the meningococcal conjugate vaccine (MCV4, brand name, Menactra). Although both are available, the MCV4 is currently preferred because it provides longer lasting immunity and can be used for all recommended groups. PSV4 was used before 2005 and can still be used for high-risk children ages two to 10 years.

Tdap VACCINE

Q: Why did the state health department make Tdap a requirement for sixth grade entry?

A: Acellular pertussis antigen is given as part of the Tetanus toxoid, reduced diphtheria toxoid vaccine. Pertussis, an acute, infectious cough illness, remains endemic in the United States despite routine childhood pertussis vaccination for more than half a century and high coverage levels in children for more than a decade. A primary reason for the continued circulation of *Bordetella pertussis* is that immunity to pertussis wanes approximately 5–10 years after completion of childhood pertussis vaccination, leaving adolescents and adults susceptible to pertussis. Among the diseases for which universal childhood vaccination has been recommended, pertussis is the least well-controlled reportable bacterial vaccine-preventable disease in the United States. Since the 1980s, the number of reported pertussis cases has been steadily increasing, especially among adolescents and adults. Possible reasons for the increase in reported pertussis cases include a true increase in the burden of disease and an increase in the detection and reporting of cases; the relative contribution of each of these factors to the increase observed is unclear.

During 2004, a total of 8,897 (34%) of the 25,827 reported U.S. cases occurred among adolescents aged 11–18 years (incidence for adolescents: 30 per 100,000 population); 17 states each reported >100 pertussis cases in adolescents (CDC unpublished data, 2005*). The age distribution of the other pertussis cases reported in 2004 was 3,357 (13%) among infants aged <1 years, 5,441 (21%) among children aged 1–10 years, and 7,481 (29%) among adults aged >19 years (the age was unknown for 2.5% of the cases).

B. pertussis is primarily transmitted from person to person through large respiratory droplets generated by coughing or sneezing. Persons with pertussis are most infectious during the catarrhal and early paroxysmal phases of illness. The disease is highly communicable, with attack rates as high as 80%–90% among nonimmune household contacts. Adolescents with pertussis can transmit the disease to infants. A study conducted using enhanced pertussis surveillance during 1999–2002 investigated the source of pertussis among infants aged <12 months. On the basis of parental interview, a source was identified among 264 (43%) of 616 infant cases. An adolescent (defined in the study as a person aged 10–19 years) was identified as the source for 43 (7%) of the 616 infants. Infants aged <12 months with pertussis are more likely than older age groups to have complications or be hospitalized during their illness

Source: <http://www.cdc.gov/mmwr/PDF/rr/rr5503.pdf>

Q: Some 6th graders will not be 11 years old. Note that while Boostrix is approved for 10 year olds, Adacel is not (11 to 64 years). Menactra (MCV4) is approved for 11 year olds as well. I'm guessing that a 10 year old would not have to get the vaccine booster until he or she reaches 11- is that correct?

A: A 10 year old entering sixth grade will not be required to receive the preferred Meningococcal Conjugate Vaccine, Menactra until they turn 11 years of age. That holds true for the Tdap vaccine as well. If the child's physician only carries Adacel then the child will not be required to receive it until 11 years of age. If the physician carries Boostrix then we encourage them to use it for their 10 year olds so they can be in compliance by September 1, 2008.

Q: I understand the importance of the pertussis booster. But why should I give a Tetanus toxoid and diphtheria toxoid booster?

A: Just as with pertussis, immunity to tetanus and diphtheria wanes with time so it is important to get regularly scheduled vaccines, such as receiving the Tdap vaccine to maintain protective immunity.

Q: If a child is medically contraindicated from receiving pertussis vaccine, would receiving the Td vaccination suffice for the new 6th grade Tdap requirement?

A: The New Jersey immunization requirement is for all sixth graders to receive the Tdap vaccine. The purpose of this requirement is to provide protection to this age cohort whose immunity to pertussis wanes from their last DTaP vaccination at 4-6 years of age. If a child cannot receive the pertussis component then they cannot receive Tdap and therefore would need to provide a medical exemption from their health care provider.

In this circumstance, the Td vaccine is not a required vaccine for sixth grade entry; the Td vaccine is recommended to be given 10 years after their last DT as long as they have received at least three doses of DT.

MENINGOCOCCAL VACCINE

Q: Why did the state health department make meningococcal disease a requirement for sixth grade entry?

A: Meningococcal disease is a severe infection of the blood or the meninges (the covering of the brain and spinal cord). It is caused by a bacterium (germ) called *Neisseria meningitidis*. Each year, up to 2,800 people get the disease. Even when they are treated with antibiotics, 10-15% of these people die. Of those who survive, another 11-19% lose their arms or legs, become deaf, have problems with their nervous systems, become mentally retarded, or suffer seizures or strokes.

Anyone can get meningococcal disease, but pre-teens and teens are at greater risk of contracting the disease. According to the CDC, pre-teens and teens account for nearly 30 percent of all cases of reported meningococcal infection in the U.S. and death rates are up to five times higher among 15-to 24-year olds compared with other age groups.

The disease is spread by exchange of respiratory droplets and close, personal contact with infected persons, such as through kissing, uncovered face-to-face coughing and sneezing, sharing eating utensils, food or drink or living in the same household or living quarters, such as a sleep-away camp or dormitory.

The ACIP goal is routine vaccination of all adolescents with MCV4 beginning at age 11 years. ACIP and partner organizations, including the American Academy of Pediatrics, American Academy of Family Physicians, American Medical Association, and Society for Adolescent Medicine, recommend children aged 11--12 years receive the recommended vaccinations and indicated preventive services at that adolescent health care visit. This visit is the optimal time for adolescents to receive MCV4. In addition, because the incidence of meningococcal disease increases during adolescence, health-care providers should vaccinate previously unvaccinated persons aged 11--18 years with MCV4 at the earliest possible health-care visit. College freshmen living in dormitories are at increased risk for meningococcal disease and should be vaccinated with MCV4 before

college entry if they have not been vaccinated previously. Because of difficulties in targeting freshmen in dormitories, colleges may elect to target their vaccination campaigns to all matriculating freshmen (1).

Source: <http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5631a3.htm>

Q: I have a transfer student who is in kindergarten this year. He/ she was born after January 1997. How does the meningococcal vaccine regulation apply in this case?

A: With regard to transfer students, the requirement to receive the meningococcal conjugate vaccine applies to all students born on or after January 1, 1997 and attending/transferring into a New Jersey school, regardless of grade but must be age eligible to receive this vaccine. Eleven to 55 years of age are the recommended ages to be immunized as enumerated by the ACIP and the CDC. Although Menactra is licensed for persons 2-55 years of age, it is recommended to only be given to children ages 2-10 years if they are considered high-risk individuals susceptible to meningococcal disease (e.g. immunocompromised, terminal complement deficiencies or anatomic or functional asplenia). Assessment of the child's place of origin and their risk status for meningococcal disease would determine if they need to receive the meningococcal vaccine younger than 11 years of age.

For more information, go to the CDC MMWR, "Report from the Advisory Committee on Immunization Practices (ACIP): Decision Not to Recommend Routine Vaccination of All Children Aged 2--10 Years with Quadrivalent Meningococcal Conjugate Vaccine (MCV4)"

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5717a4.htm?s_cid=mm5717a4_e

Q: Should a child or teen who received MCV4 (Menactra) at age 12 years receive a second dose if they will be a freshman in a college dorm?

A: No, at this time only 1 dose of Menactra (MCV4) is recommended. More data will likely become available within the next few years to guide recommendations on revaccination for persons who were previously vaccinated with MCV4.

Source: IAC http://www.immunize.org/askexperts/experts_men.asp

Other Vaccines

DTaP VACCINE

Q: How many doses of DTaP are required for school entry in NJ?

A: As a clarification to the DTaP requirements, a child needs 4-5 doses of DTaP however it is dependent on when the child enters school. If the child is 18 months up to 4 years of age, they will be required to have 4 doses of DTaP in order to enter childcare. This is consistent with ACIP/ CDC recommendations. If the child does not start school until 4 years of age, then they must have 4 doses with the option of the fourth dose on or after the fourth birthday. The requirement to receive the fourth birthday booster does not apply while they are enrolled in childcare/ preschool. They must receive the 4-6 year old booster dose once they enter kindergarten. So, if a child enters childcare at 18 mos, by kindergarten they should have a total of five DTaP doses. If a child first enters the

school system at 4 years of age, they could technically have 4-5 doses of DTaP by kindergarten entry.

Children 7 years of age and older attending school must have a minimum of 3 doses of DTaP.

For the full ACIP recommended schedule for DTaP, go to <http://www.cdc.gov/vaccines/recs/schedules/child-schedule.htm#printable>

POLIO VACCINE

Q: How many doses of polio are required for school entry in NJ?

A: As a clarification to the polio requirements, a child needs 3-4 doses of polio however it is dependent on when the child enters school. If the child is 18 months up to 4 years of age, they will be required to have 3 doses of polio in order to enter childcare. This is consistent with ACIP/ CDC recommendations. If the child does not start school until 4 years of age, then they must have 3 doses with the option of the fourth dose on or after the fourth birthday. The requirement to receive the fourth birthday booster does not apply while they are enrolled in childcare/ preschool. They must receive the 4-6 year old booster dose once they enter kindergarten. So, if a child enters childcare at 18 mos, by kindergarten they should have a total of 4 polio doses. If a child first enters the school system at 4 years of age, they could technically have 3-4 doses of polio by kindergarten entry.

Children 7 years of age and older attending school must have a minimum of 3 doses of polio.

VARICELLA (CHICKENPOX) VACCINE

Q: Is the varicella vaccine required for children entering a licensed child care and less than 19 months of age?

A: According to the ACIP recommendations, the first dose of varicella vaccine can be given between the ages of 12-15 months of age. However, for requirements for school entry into a licensed child care facility in New Jersey you do not need a varicella vaccination until 19 months of age.

Q: Is the second dose of varicella vaccine a requirement for school entry?

A: No, the second dose of varicella vaccine is not a requirement but a strong recommendation by NJDHSS. The ACIP recommends a second dose of varicella vaccine to be given between four to six years of age for optimal protection.

Q: According to New Jersey immunization regulations, who needs the varicella vaccine?

A: All children, born on or after January 1, 1998 and is at least 19 months of age or older and attending a New Jersey school is required to receive one dose of varicella vaccine. This applies to all transfer students, both out of state/ out of country and those transferring from another school district within the state.

HEPATITIS B VACCINE

Q: How many doses of hepatitis B are required for school entry?

A: According to New Jersey immunization regulations, the three-dose hepatitis B series is not required until a child enters kindergarten. By kindergarten entry, a child must enter school with three doses of hepatitis B vaccine. Previously unvaccinated adolescents, between the ages of 11-15 years, can receive the two-dose hepatitis B vaccine adolescent series (Recombivax).

Q: Can an adolescent receive the two-dose adolescent series outside the licensed age?

A: No, the two-dose adolescent series is only licensed for persons 11-15 years of age. Talk with your health care provider for further guidance.

Other vaccine requirement questions

Timing of vaccination schedule

Q: Explain the new Four-Day Grace Period:

A: Effective January 7, 2008 all vaccine doses administered less than, or equal to, four days before either the specified minimum age or dose spacing interval, shall be counted as valid and revaccination would not be required.

Q: To whom does the 30-Day Grace Period apply?

A: According to the New Jersey immunization regulations, the 30-day grace period only applies to transfer students, coming from out of state/out of country. This does not apply to *in-state* transfer students.

Exclusion from school

Q: When would a child need to be excluded from school?

A: There are two situations in which a child would be excluded from school:

1. *Non-compliance with vaccine requirements.*

A child must be in compliance with vaccination requirements by the time they enter school. In the instance of sixth grade entry, where a child is younger than the licensed age to be given a vaccine, the child can wait until they are age eligible to receive the adolescent vaccine. The child should be given two weeks to comply with vaccination requirements by either providing documentation that they received the vaccine, or a note from the health care provider with an appointment date to receive the vaccine. This documentation needs to be provided to the school nurse to include in their immunization record. Depending on individual circumstances, a scheduled appointment outside the two-week period may be acceptable. The Department's goal is not to exclude anyone, but if the child does not receive the vaccine in a reasonable period, he/she will be asked to leave school.

2. *In the event of an outbreak.*

8:57-4.19 Emergency powers of the Commissioner of Health and Senior Services
(a) In the event that the Commissioner, Department of Health and Senior Services or his or her designee determines either that an outbreak or threatened outbreak of disease or other public health immunization emergency exists, the Commissioner or his or her designee may issue either additional immunization requirements to control

the outbreak or threat of an outbreak or modify immunization requirements to meet the emergency.

(b) All children failing to meet these additional requirements shall be excluded from a school, preschool, or child care center until the outbreak or threatened outbreak is over.

(c) These requirements or amendments to the requirements shall remain in effect until such time as the Commissioner, Department of Health and Senior Services or his or her designee determines that an outbreak or a threatened outbreak no longer exists or the emergency is declared over, or for three months after the declaration of the emergency, whichever one comes first. The Commissioner, Department of Health and Senior Services or his or her designee may re-declare a state of emergency if the emergency has not ended.

3. 8:57-4.4 *Religious exemptions*

(d) Those children with religious exemptions from receiving immunizing agents may be excluded from the school, preschool, or child care center during a vaccine-preventable disease outbreak or threatened outbreak as determined by the Commissioner, Department of Health and Senior Services or his or her designee.

4. 8:57-4.3 *Medical exemptions*

(d) Those children with medical exemptions to receiving specific immunizations may be excluded from the school, preschool, or child care facility during a vaccine-preventable disease outbreak or threatened outbreak as determined by the Commissioner, Health and Senior Services or his or her designee.

Exemptions

Q: What type of health care provider can write an acceptable medical exemption?

A: According to the NJDHSS Vaccine Preventable Disease Program, only a physician licensed to practice medicine/ osteopathic medicine and a nurse practitioner can write a medical exemption.

Q: What is considered grounds for filing a medical exemption?

A: A medical exemption must indicate a specific period of time in which the child cannot receive specific vaccinations. Reason(s) for medical contraindication must be enumerated by the Advisory Committee on Immunization Practices (ACIP) and the American Academy of Pediatrics (AAP). Precautions to receiving a vaccine are not contraindications but a provider must take into consideration:

http://www.cdc.gov/vaccines/recs/vac-admin/downloads/contraindications_guide.pdf

Q: What should be included in an acceptable religious exemption?

A: A religious exemption is not the same as a philosophical, moral or conscientious exemption. A religious exemption does not have to include the name of the religion, nor does it need to be notarized nor does it need to be signed by a religious leader. It can be filed by a parent or guardian of a minor or by an adult individual. The religious exemption must explain how immunizing agents conflict with exercise of bona fide practice of their religious tenets.

The school administrator/ principal makes the decision to accept or reject. A school or local health department may choose to challenge the credibility of the filed exemption for

those children attending a public school. The local health department who conducts the immunization audits cannot challenge a religious exemption that is accepted by a private/ parochial school. However, a private/ parochial school can challenge a filed religious exemption if they believe it is an inappropriate interpretation and use of the tenet or religious belief.

Serology Titers

Q: Are serology titers acceptable as laboratory evidence of immunity in lieu of completing a vaccination series?

A: The subchapter 8:57-4 on immunization requirements specifically addresses the acceptance of serology titers. According to the amended New Jersey Administrative Code 8:57-4.6(c):

“Laboratory evidence of protective immunity, as enumerated by the Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service, shall be accepted as evidence of immunization if a parent or guardian cannot produce a documented history of immunization.”

In addition, The Antibody Titer Law (Holly’s Law, NJSA 26:2N-8-11), passed on January 14, 2004, requires the New Jersey Department of Health and Senior Services (NJDHSS) to accept serologic evidence of protective immunity to measles, mumps and rubella in lieu of the second ACIP recommended measles, mumps and rubella vaccine. The tests used to document immunity must be approved by the U.S. Food and Drug Administration (FDA) for this purpose and performed by a laboratory that is CLIA certified. The reference ranges and interpretation must be included with the laboratory results and the documentation must be placed in the record. Borderline, equivocal and negative titers necessitate vaccination/re-vaccination.

The use of serology to evaluate exposure or immunity to infectious diseases is complicated and is the topic of a great deal of medical literature. There are considerations that need to be addressed when one considers serology titer results. For example, the time interval from receiving the last vaccination and when the serology titer sample is drawn may produce a false sense of security that an individual is fully protected (as immune levels may initially peak immediately after receiving a dose but taper down over time). Likewise for some vaccines, the ACIP and NJDHSS do not recognize serology as an alternative to vaccination since serologic correlates for protection do not exist for some diseases (e.g. *Bordetella pertussis*).

NJDHSS does not support the use of serology to “abort” a vaccine schedule as approved by the US Food and Drug Administration and recommended by the ACIP (e.g., check serology after 1 dose of hepatitis B vaccine). However, NJDHSS recognizes that serology is useful for individuals to:

- Document natural infection to certain diseases.
- Document immunity in an individual who received a complete vaccination series but lacks documentation – and revaccination is not practical (e.g., refugees).
- Document immunity in an individual who received a complete vaccination series but vaccination practices were questionable – and revaccination is not practical (e.g., vaccination with expired vaccine).

- Document post-vaccination response in those individuals who are at high risk of infection with a particular disease (hepatitis BSAg in infants born to Sag positive mothers, health care workers).

As more reliable data on serology titers becomes available from the ACIP, we will incorporate that into our consideration of the use of serology titers for acceptable laboratory evidence of immunity.

<http://www.cdc.gov/vaccines/pubs/surv-manual/chpt22-lab-support.htm>

Q: What serology titer tests are currently available for mandatory vaccines and how will the serology results be evaluated?

- Measles, Mumps and Rubella
In most cases, an antibody level considered protective is a good indicator of immunity and must be accepted in lieu of a second MMR vaccine as per Holly's Law. Serology does not need to be repeated once an antibody level in the protective range is documented or the individual receives 2 MMR vaccines.
- Varicella
In most cases, an antibody level in the protective range is a good indicator of immunity and may be accepted in lieu of vaccination. Serology does not need to be repeated once an antibody level in the protective range is documented or the individual receives 2 varicella vaccines.
- Inactivated Polio Vaccine
Serologic testing for protective antibody to poliovirus types 1, 2, and 3 can be obtained commercially. The ACIP states, "Children with protective titers against all three types do not need revaccination and should complete the schedule as age appropriate." Positive titers cannot be used to abort the FDA approved/ACIP recommended vaccine series.
- Diphtheria, Tetanus and Pertussis
Serologic testing for protective antibody to tetanus and diphtheria can be obtained commercially. No established serologic correlates exist for protection against pertussis. The ACIP states, "If a protective concentration is present, recorded doses can be considered valid and the vaccination series completed as age-appropriate. Positive titers cannot be used to abort the FDA approved/ACIP recommended vaccine series.
- *Haemophilus influenzae* type b, pneumococcal, meningococcal and influenza
There is no serology alternative to vaccination.
- Hepatitis B
Hepatitis B serology and the interpretation is complicated and is beyond the scope of this document. *Pre-vaccination* testing is not routinely recommended for infants or children. *Pre-vaccination* testing is recommended only for
 - all persons born in Africa, Asia, the Pacific Islands, and other regions with HBSAg prevalence of $\geq 8\%$;
 - household, sex, and needle-sharing contacts of HBSAg-positive persons; and
 - persons with HIV infection.

Pre-vaccination testing can be considered for groups with high risk of HBV infection (i.e., men who have sex with men, intravenous drug users and incarcerated persons).

Post-vaccination serology is not routinely recommended for infants, children, adolescents and most adults. *Post-vaccination* serology is only recommended

for those whose medical management is based on knowledge of antibody status. Individuals for whom post-vaccination serology is recommended include, chronic hemodialysis patients, other immunocompromised patients, persons with HIV infection, sex partners of HBSAg-positive persons, infants born to HBSAg-positive women and certain health care workers. Vaccine is 80-100% effective in preventing infection or clinical hepatitis in those who receive the complete course of vaccine (3 doses or 2 doses of the adolescent formulation). Antibody levels might wane with time. However, individuals who demonstrate an anti-HBs antibody titer of 10mIU/ml or higher at least 1-2 months after completing the series are considered protected for life even if detectable antibody levels wane. Serum antibody titer cannot be used in lieu of completing the FDA-approved/ACIP-recommended vaccine series.

Q: What are considered acceptable values for serology titer results?

A: The titer results depend on the specific test used and the reference ranges applicable to that particular test. Equivocal and/ or borderline results are not acceptable and require vaccination/revaccination. Negative results require vaccination/revaccination. NJDHSS recommends that they discuss ACIP revaccination guidelines and follow-up serology with their health care providers, as appropriate.

Q: If a family is requesting a serology titer to circumvent the required immunizations and the family has health insurance which covers immunizations but the insurance does not cover serology titers, whose responsibility is it to pay for the serology titers?

A: It is not a recommendation or acceptable practice by the ACIP to use serology titers in lieu of completing a vaccination series or to avoid receiving subsequent vaccinations within a series. Additionally, in this circumstance it would be the family's responsibility to pay for the serology titer tests since they are choosing not to vaccinate their child as medically appropriate.

Q: What happens if a person receives a complete vaccine series and for some reason has a titer done that shows the person is not immune?

A: NJDHSS and the Advisory Committee on Immunization Practices (ACIP) do not recommend routine serology titer tests to document immunity. Once a person has received the complete series of a recommended vaccination, he/she is assumed to have produced the needed immunity level to protect them from the disease. The ACIP has identified specific scenarios when the use of serology titer testing is recommended. A serology test done without a specific public health or medical reason can be difficult to interpret and can sometimes lead to a person receiving extra vaccines. However, a negative or equivocal serology titer might mean that the individual is susceptible to the disease even if he/she completed the full series of vaccines. Therefore, the NJDHSS recommends that these individuals with negative or equivocal serology titers discuss ACIP revaccination guidelines and follow-up serology with their health care providers. Please also refer to the question, **“Q: Are serology titers acceptable as laboratory evidence of immunity in lieu of completing a vaccination series?”**

Enforcement of Immunization Regulations

Q: Where can a parent get a personal immunization record card for their child?

A: Anyone wishing to obtain a personal immunization record card (IMM-9 yellow, tri-fold document) can contact the New Jersey Department of Health and Senior Services, Vaccine Preventable Disease Program at (609) 588-7512.

Q: Where can a school nurse obtain the Standard School/ Child Care Center Immunization Record (IMM-8) or the A45 (Health and Appraisal Record) for school records?

A: Anyone wishing to obtain a Standard School/ Child Care Center Immunization Record (IMM-8) can contact the New Jersey Department of Health and Senior Services, Vaccine Preventable Disease Program at (609) 588-7512. To obtain the A45 Health and Appraisal Record, please contact your local board of education.

New Jersey Immunization Information System e.g. 'Immunization Registry' (NJiIS)

Q: What is NJiIS?

A: The New Jersey immunization Information System (NJiIS) is a secure, computerized immunization registry that keeps a permanent immunization record for your child, doctors, schools, day care centers, colleges and parents. For more information refer to : <http://njiis.nj.gov/njiis/>

For more information on NJiIS, go to: <http://njiis.nj.gov/njiis>

Clinician Resources

Q: Where can I obtain the Vaccine Declination ("Refusal to Vaccinate") form?

A: Clinicians may refer to the American Academy of Pediatrics website http://www.cispimmunize.org/pro/pdf/RefusaltoVaccinate_revised%204-11-06.pdf

Q: What is required of a health care provider before giving a vaccination?

A: By Federal law, all vaccine providers must give patients, or their parents or legal representatives, the appropriate Vaccine Information Statement (VIS) whenever a vaccination is given.

Q: Where can I obtain the latest Vaccine Information Statements (VIS)?

A: All current VISs are available on the internet at two websites — the CDC's Vaccines & Immunizations site (www.cdc.gov/vaccines) and the Immunization Action Coalition (www.immunize.org/vis/). You can also order single hard copies of the VISs using NIP's Online Order Form (at www.cdc.gov/vaccines/pubs). VISs from these sites can be downloaded as pdf files and printed. For more information on VIS, go to: <http://www.cdc.gov/vaccines/pubs/vis/vis-facts.htm#get>

Q: Where can I get a list of combination vaccinations?

A: Go to the CDC's "Epidemiology and Prevention of Vaccine Preventable Diseases, 10th Edition, 2nd Printing: <http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/table-of-contents.pdf>; see page 12.

Q: I receive several patients/ students from other countries. Where can I find a resource on vaccination schedules, by country?

A: Search by country of origin and scroll down to the country's recommended immunization schedule.

<http://www.who.int/vaccines/globalsummary/immunization/countryprofileselect.cfm>

Q: Is it a violation of HIPAA to include the date that a child will be given a vaccine dose needed for school, to be submitted by the parent to the school for their records?

A: No it is not a violation of HIPAA to include the appointment date that a child plans to receive a vaccine to show documentation for the child's immunization record.