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)

Frequently Asked Questions

NJ Immunization Requirements

Q: What are the minimally required vaccines for preschool/child care and school entry in New Jersey?

A: Please visit http://nj.gov/health/cd/imm.shtml

- Age-Appropriate Vaccinations for Licensed Child Care Centers/Pre-School [word 25k] [pdf 20k]

- Minimum Immunization Requirements Table For School Attendance In New Jersey [word 34k] [pdf 29k]

Immunization Regulations can be accessed at: www.lexisnexis.com/njoal
Instructions for accessing NJ Immunization Requirements:
http://nj.gov/health/cd/documents/instructions_viewing_regulations.pdf

Q: Are NJ Immunization Requirements the same as the CDC/ACIP guidelines?

A: Yes, New Jersey's immunization requirements are in accordance with the guidelines of the American Academy of Pediatrics (AAP) and Advisory Committee on Immunization Practices (ACIP). However NJ establishes the minimum vaccine requirements for child-care centers, preschool, and school entry and attendance.

For example, NJ requires every child born on or after January 1, 1998 to receive one dose of a varicella virus containing vaccine. The CDC/ACIP schedule recommends 2 doses of varicella vaccine. The New Jersey Department of Health and Senior Services (NJDHSS) recommends following the CDC/ACIP schedule, as periodically revised, for optimal protection and additional vaccines or vaccine doses may be administered, although they are not required for school attendance. Therefore, a child would only be required to receive one dose of a varicella virus containing vaccine for attendance in NJ, but two doses would be recommended for optimal protection.

Child Care Pre-School Requirements

Influenza Vaccine

Q: Is the seasonal influenza vaccine a requirement for child care and preschool?

A: Yes, it is a requirement as per N.J.A.C. 8:57-4.19 unless the Commissioner or his or her designee temporarily suspends the requirement due to limited vaccine availability.

As per N.J.A.C. 8:57-4.19, 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.

Q: How many doses of the seasonal influenza vaccine are required for preschool/child care attendance?

A: Per NJAC 8:57-4.19, only 1 dose of seasonal flu vaccine is required for children 6-59 months of age attending child care/preschool. However, the Centers for Disease Control (CDC)/Advisory Committee on Immunization Practices (ACIP), recommends two doses given at least four weeks apart for children aged 6 months through 8 years of age who are getting a flu vaccine for the first time. Please see the "Vaccination Dosage" section for further guidance.

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

A: Flu seasons are unpredictable and can be severe. Over a period of 30 years, between 1976 and 2006, estimates of flu-associated deaths range from a low of about 3,000 to a high of about 49,000 people. 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 all children 6 months of age and older. However, annual vaccination of all children aged 6 months--4 years (59 months) and older children with conditions that place them at increased risk for complications from influenza should continue to be a primary focus of vaccination efforts.

With regard to the influenza vaccine, a study in The American Journal of Epidemiology supports the recommendation to vaccinate 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: 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. We also know that public requests for flu vaccine peaks around September to December. 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: Students who do not receive the vaccine by December 31st will be excluded from school for the duration of influenza season (through March 31st) or until they receive at least one dose of the influenza vaccine.

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

A: Students who have not received the flu vaccine by December 31st must be excluded from school for the duration of influenza season (through March 31st), until they receive at least one dose of the influenza vaccine or until they turn 60 months of age.

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 must provide documentation that your child received the flu vaccine prior to entering school.

Q: Is flu vaccine required after March?

A: No, students enrolling in school after March 31st are not required to get vaccinated; however, flu season may extend until May and therefore getting a flu vaccine even late in the season is still protective.

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: Children who get vaccinated with the seasonal flu vaccine prior to September 1, will be considered compliant and these vaccinations will be accepted to meet the requirement as long as the vaccine is for the respective flu season**.**

Please note most seasonal flu vaccines expire on June 30.

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

A: A: The influenza vaccine is now recommended for all individuals $\geq$ 6 months. Discuss with your health care provider (HCP) what plans are in

place to ensure an adequate supply of flu vaccine for all eligible clients at the practice.

If a national flu vaccine shortage has not been declared and your HCP cannot guarantee an adequate supply of flu vaccine, other alternatives must be sought by the family. Options include:
1. Asking your child's HCP to assist with arranging for vaccination through another healthcare provider
2. Seeking out another HCP who can administer flu vaccine to children;
3. Checking with your local health department to see if they will administer flu vaccine to children less than 18 years of age;
4. Contacting your local public health clinic/Federally Qualified Health care Centers (FQHCs): http://nj.gov/health/fhs/cphc/documents/locations.pdf
(Note: anyone is eligible to receive service at a local public health clinic);
5. Checking your local newspaper for flu clinic listings and verifying that they have flu vaccine available that is appropriate for your child's age. 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 the NJ VFC brochure for health care providers: https://njiis.nj.gov/njiis/docs/C1567.pdf
6. Check the Department's internet address for the Find a Flu Shot Locator at http://nj.gov/health/flu/findflushot.shtml, or to www.google.com/flushot for vaccine clinics.

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

A: The influenza vaccine regulation states that children six months through 59 months of age enrolling in or attending a child-care center or preschool facility on of 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.

As far as distribution and shortages are concerned, the NJ regulations 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 will be included in the 2011-2012 flu vaccine?

A: The seasonal flu vaccine protects against three influenza viruses that research indicates will be most common during the upcoming season. The 2011-2012 influenza vaccine will protect against the following 3 viruses:

- an A/California/7/2009 (H1N1)-like virus;
- an A/Perth/16/2009 (H3N2)-like virus; and
- a B/Brisbane/60/2008-like virus.

These are the same viruses that were selected for the Northern Hemisphere for the 2010-2011 influenza vaccine.

Q: If the influenza vaccine composition is the same for the upcoming season as it was last season, do I need to get vaccinated again?

A: Yes. People should get vaccinated every year because even if the viruses in the vaccine are the same as the year before, immunity to influenza viruses declines over time and may be too low to provide protection after a year. Several studies conducted over different flu seasons and involving different influenza viruses and types of flu vaccine have shown that a person's protection against influenza viruses declines over the course of a year after vaccination, particularly in the elderly. So, a flu shot given during one season may not provide adequate protection through later seasons. This fall, everyone 6 months and older should get vaccinated against the flu as soon as 2011-2012 influenza vaccines become available, even if they got vaccinated last season.

Q: What types of flu vaccines are available?

A: There are two types of flu vaccine available. 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). The flu shot is approved for use in people 6 months of age and older, including healthy people and people with chronic medical conditions.

The second is a live, attenuated (weakened) vaccine, which is sprayed into the nose and was licensed in 2003. 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. LAIV is approved for use in healthy people 2 through 49 years of age who are not pregnant.

Check with your health care provider to see if your child can receive the LAIV flu vaccine.

Q: What is the intradermal flu shot?

A: "Fluzone Intradermal®" was licensed by the Food and Drug Administration (FDA) for use in the United States for the 2011-2012 flu season. The intradermal flu vaccine is a shot that is injected into the skin instead of the muscle. The intradermal shot uses a much smaller needle than the regular flu shot, and it requires less antigen to be as effective as

the regular flu shot. Antigen is the part of the vaccine that helps your body build up protection against flu viruses. The intradermal vaccine has been approved by the FDA for use in adults 18 through 64 years of age.

For more information, please visit:
http://www.cdc.gov/flu/protect/vaccine/qa_intradermal-vaccine.htm

Q: What is the high dose flu vaccine?

A: Fluzone High-Dose is an influenza vaccine designed specifically for people 65 years and older. Fluzone High-Dose vaccines contain 4 times the amount of antigen (the part of the vaccine that prompts the body to make antibody) contained in regular flu shots. A higher dose of antigen in the vaccine is supposed to give older people a better immune response and therefore better protection against flu.

For more information, please visit:
http://www.cdc.gov/flu/protect/vaccine/qa_fluzone.htm

Q: How effective is the flu vaccine in children?

A: It is recommended that all individuals $\geq$ 6 months be vaccinated. The flu vaccine can prevent 66% or more influenza infections in young children, with even higher estimates for older children, when the vaccine strains are well-matched to the flu viruses causing illness. Vaccinating close contacts of children can also help decrease children's risk of getting the flu.
Children younger than 6 months of age are most at risk for having complications from the flu. However, they are too young to get the flu vaccine. In addition, vaccinated people who are elderly or ill may not develop antibody levels as well as healthy people. To protect these infants and other vulnerable individuals within our communities, it is very important that their household members, out-of-home caregivers and other close contacts be vaccinated against the flu.

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 with the peak occurrence during January and February. However, cases of influenza can be seen at any time of the year.

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. A listing of thimerosal content in seasonal flu vaccines, can be accessed at: http://www.cdc.gov/flu/protect/vaccine/vaccines.htm

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

A: Thimerosal is a mercury-containing preservative used in some vaccines and other products since the 1930s. There is no 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. Centers for Disease Control and Prevention:

http://www.cdc.gov/vaccinesafety/Concerns/Thimerosal/thimerosal_faqs.html

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

Q: Although the flu vaccine, Afluria, is licensed for those aged 5 years and older, why is the CDC/ACIP only recommending it for those who are aged 9 years and older?

A: The CDC/ACIP is recommending that Afluria not be used in children aged 5-8 years because of increased reports of febrile seizures in this age group. If no other age-appropriate, licensed inactivated seasonal influenza vaccine is available for a child aged 5-8 years who has a medical condition that increases the child's risk for influenza complications, Afluria can be used; however, providers should discuss with the parents or caregivers the benefits and risks of influenza vaccination with Afluria before administering this vaccine. Afluria may be used in persons aged ≥9 years.

A complete listing of all 2011-2012 influenza vaccines, can be accessed at the following website: http://www.cdc.gov/flu/protect/vaccine/vaccines.htm

If you suspect a severe side effect after receiving any type of vaccination, you may ask your health care provider to report the reaction to the Vaccine Adverse Event Reporting System (VAERS), a national vaccine safety

surveillance program co-sponsored by the CDC and the Food and Drug Administration (FDA).

Anyone can file a VAERS report, including health care providers, manufacturers, and vaccine recipients. You can find information about submitting a VAERS report at the following website:

http://vaers.hhs.gov/esub/index

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

A: The CDC/Advisory Committee on Immunization Practices (ACIP) currently recommends everyone 6 months and older to receive a flu vaccine each year. The purpose of "Universal" flu vaccination in the U.S. is to expand protection against the flu to more people. While everyone should get a flu vaccine each flu season, it's especially important that certain people get vaccinated either because they are at high risk of having serious flu-related complications or because they live with or care for people at high risk for developing flu-related complications.

Those who are at high risk for flu complications include:

- Children younger than 5, but especially children younger than 2 years old

- Adults 65 years of age and older
- Pregnant women
- American Indians and Alaskan Natives seem to be at higher risk of flu complications
- People who have medical conditions including:
    - Asthma (even if it's controlled or mild)
    - Neurological and neurodevelopmental conditions [including disorders of the brain, spinal cord, peripheral nerve, and muscle such as cerebral palsy, epilepsy (seizure disorders), stroke, intellectual disability (mental retardation), moderate to severe developmental delay, muscular dystrophy, or spinal cord injury]
    - Chronic lung disease (such as chronic obstructive pulmonary disease [COPD] and cystic fibrosis)
    - Heart disease (such as congenital heart disease, congestive heart failure and coronary artery disease)
    - Blood disorders (such as sickle cell disease)
    - Endocrine disorders (such as diabetes mellitus)
    - Kidney disorders
    - Liver disorders
    - Metabolic disorders (such as inherited metabolic disorders and mitochondrial disorders)

- Weakened immune system due to disease or medication (such as people with HIV or AIDS, or cancer, or those on chronic steroids)
- People younger than 19 years of age who are receiving long-term aspirin therapy
- People who are morbidly obese (Body Mass Index [BMI] of 40 or greater)

Other people for whom vaccination is especially important are:

- People who live in nursing homes and other long-term care facilities
- People who live with or care for those at high risk for complications from flu, including:
  - Health care workers
  - Household contacts of persons at high risk for complications from the flu
  - Household contacts and caregivers of children younger than 5 years of age with particular emphasis on vaccinating contacts of children younger than 6 months of age (children younger than 6 months are at highest risk of flu-related complications but are too young to get vaccinated)

Use of the Nasal Spray Seasonal Flu Vaccine

Vaccination with the nasal-spray flu vaccine is an option for healthy people 2 through 49 years of age who are not pregnant. Even people who live with or care for those in a high risk group (including health care workers) can get the nasal-spray flu vaccine as long as they are healthy themselves and are not pregnant. The one exception is health care workers who care for people with severely weakened immune systems who require a special protected hospital environment (like those who had a bone marrow transplant); these people should get the inactivated flu vaccine (flu shot).

Q: Who Should Not Be Vaccinated Against Seasonal Flu?

A: Some people should not get vaccinated or should wait:

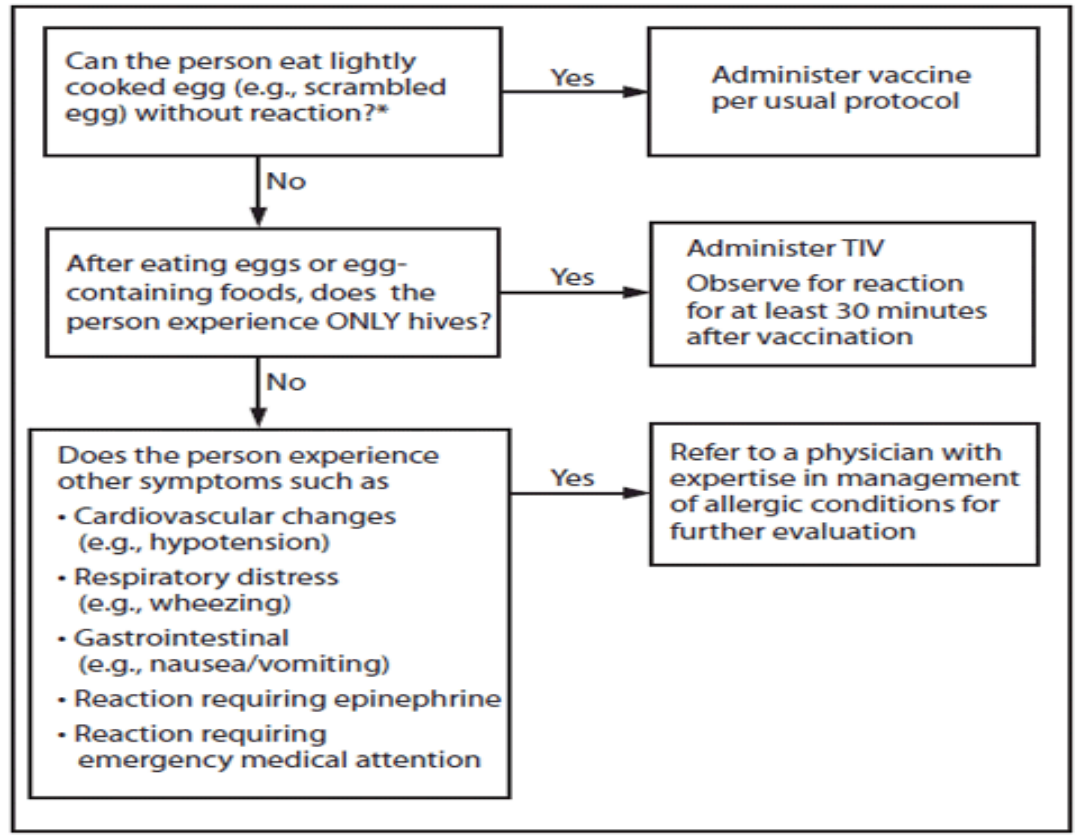
- People who have any severe (life-threatening) allergies, including a severe allergy to eggs. A severe allergy to any vaccine component may be a reason not to get the vaccine. Allergic reactions to influenza vaccine are rare.
- People who have had a severe reaction to an influenza vaccination in the past.
- People who have a history of Guillain-Barré Syndrome will need to be evaluated to determine if the vaccination is appropriate.

- Children younger than 6 months of age (influenza vaccine is not approved for use in this age group).
- People who are moderately or severely ill should usually wait until they recover before getting flu vaccine. People with a mild illness can usually get the vaccine.

Q: Can individuals with egg allergies now receive the flu vaccine?

A: A severe allergic reaction (e.g., anaphylaxis or a reaction involving angioedema (similar to hives but swelling is under the skin), respiratory distress, lightheadedness, or recurrent vomiting; or which required emergency medical care or epinephrine), no matter what component may have caused the reaction, should not receive the vaccine. However, several recent studies have documented safe receipt of TIV (flu shot) in people with egg allergy, particularly those with a history of less severe reactions to egg. Egg allergic people who experience mild reactions to egg —specifically, those who have only experienced hives — can and should receive the influenza vaccine with some additional safety measures: vaccine should be given by a health care provider who is familiar with the subject of egg allergy; TIV (flu shot) should be used rather than LAIV (nasal spray) because studies published to date involved TIV; and the recipient should be observed for at least 30 minutes (after the last dose, if vaccine is divided) by their health care provider to monitor for possible reactions.

Health care providers may use the following algorithm to determine if a patient can receive the flu vaccine:



* Persons with egg allergy might tolerate egg in baked products (e.g., bread or cake). Tolerance to egg-containing foods does not exclude the possibility of egg allergy.

Please contact your health care provider for more information.

Q: Who should NOT get the nasal mist flu vaccine?

A: The following people should receive the inactivated vaccine instead:

- Adults 50 years of age and older or children from 6 through 23 months of age (Children younger than 6 months should not get either influenza vaccine).
- Children younger than 5 years with asthma or one or more episodes of wheezing within the past year.
- Pregnant women
- Anyone with a long-term health problem such as:
    - Heart disease
    - Lung disease
    - Asthma
    - Kidney or liver disease
    - Metabolic disease such as diabetes
    - Anemia and other blood disorders
- Anyone with certain muscle or nerve disorders (such as cerebral palsy) that can lead to breathing or swallowing problems

- Anyone with a weakened immune system.
- Anyone in close contact with someone whose immune system is so weak they require care in a protected environment (such as a bone marrow transplant unit). Close contacts of other people with a weakened immune system (such as those with HIV) may receive LAIV. Healthcare personnel in neonatal intensive care units or oncology clinics may receive LAIV.
- Children or adolescents on long-term aspirin treatment

Please note:
Anyone with a nasal condition serious enough to make breathing difficult, such as a very stuffy nose, should get the flu shot instead.

Q: How long after I get a flu vaccine will I become immune to the flu virus?

A: Flu vaccines cause antibodies to develop in the body. These antibodies provide protection against infection with the viruses that are in the vaccine. Once you get vaccinated, your body makes protective antibodies in about two weeks.

Q: Does getting a flu vaccine early in the season mean that I will not be protected later in the season?

A: No. Flu vaccination provides protection against the influenza strains contained in the seasonal vaccine for the entire season. Vaccination can begin as soon as vaccine becomes available.

Q: Can flu vaccines be given at the same time as other vaccines?

A: Nasal mist (live) flu vaccines can be given at the same time as killed vaccines (e.g., pneumococcal or meningococcal vaccine) or any other live injectable vaccine (e.g., MMR, MMRV, varicella, yellow fever). If not given at the same time, nasal mist (live) flu vaccines and other live vaccines should be separated by at least 4 weeks. The injectable (killed) flu vaccine can be given at the same time as any other killed or live vaccine.

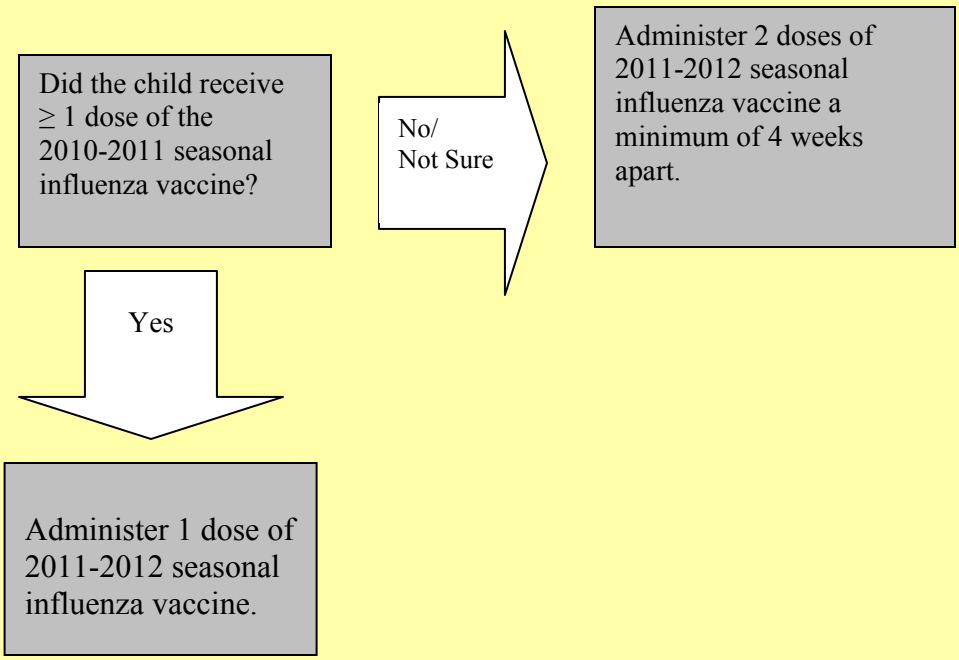
Tell your health care provider if you received any other vaccines within the past month or plan to get any within the next month.

Vaccination Dosage

Q: How do you determine the number of doses of 2011-2012 flu vaccine recommended for children 6 months through 8 years?

A: All children ages 6 months through 8 years who receive a seasonal influenza vaccine for the first time should be given 2 doses administered a minimum of 4 weeks apart to optimize immune response. Since the 2011-2012 vaccine strains are unchanged from the 2010-2011 season, children in this age group who received at least 1 dose of the 2010-2011 seasonal vaccine should receive only 1 dose of the 2011-2012 seasonal vaccine. Children in this age group who did not receive at least one dose of the 2010-2011 vaccine, or whom it is not certain whether the 2010-2011 vaccine was received, should receive 2 doses of the 2011-2012 seasonal vaccine. The following diagram will assist you in determining the number of doses required in this age group.

2011-2012 Influenza Vaccine Dosing Algorithm for Children 6 Months through 8 Years of Age



Q: Will it be necessary for the first and second dose to be given by the same provider?

A: No. Patients should be given written documentation of the doses administered that can be presented to any health care provider in the future.

Q: Can the first dose be nasal mist and the second dose be injectable (and vice versa)?

A: Yes, but when feasible, the same brand and type of vaccine (live attenuated or inactivated) should be used.

Q: Will it be necessary for the first and second dose to be the same product?

A: When feasible, the same brand of vaccine should be used in a two dose schedule, but any vaccine FDA-approved for the age of the patient can be used to complete the series.

Q: If my child gets the 2nd dose more than 4 weeks after the 1st one, how does that affect his protection against the flu? Is my child protected against the flu with just one dose?

A: The span of 4 weeks between doses is a minimum time. With just one dose, your child has some protection against the flu, but for full protection a second dose should be administered. The level of protective immunity will not be affected by a delay in receiving the 2nd dose.

Pneumococcal Conjugate Vaccine

Q: According to the regulations, your pneumococcal conjugate vaccine (PCV) 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 minimum 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: If a child entered pre-school/child care at the age of two and has received 4 doses of PCV before 12 months of age, does this child need additional doses?

A: Yes, even though PCV is a 4 dose series, children are still required by NJ Regulations to receive one dose after twelve months of age.

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

Q: If my child did not attend child care, preschool, or pre-kindergarten, is my child required to receive a dose of PCV when he/she enters kindergarten if my child did not receive these vaccines after his/her first birthday?

A: If your child is at least 5 years old, he/she is not required to receive PCV prior to entry into kindergarten. NJ does not require PCV after the age of 59 months.
(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

Hib Vaccine

Q: According to the regulations, the *Haemophilus influenzae* type b (Hib) conjugate vaccine 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 minimum 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 PCV as well).

Q: If a child entered pre-school/child care at the age of two and has received 4 doses of Hib vaccine before 12 months of age, does this child need additional doses?

A: Yes, even though Hib is a 3 or 4 dose series (depending on brand of vaccine), children are still required by NJ Regulations to receive one dose after twelve months of age.

(This answer also applies to the PCV as well).

Q: If my child did not attend child care, preschool, or pre-kindergarten, is my child required to receive a dose of Hib when he/she enters kindergarten if my child did not receive these vaccines after his/her first birthday?

A: If your child is at least 5 years old, he/she is not required to receive Hib prior to entry into kindergarten. NJ does not require Hib after the age of 59 months.
(This answer also applies to the PCV as well).

Hib Vaccine Shortage

Q: Is my child required to receive the Hib booster dose after the first birthday for preschool/child care attendance?

A: Yes, NJDHSS lifted the waiver and reinstated the Hib vaccine mandate effective September 2011.

Since it has been almost 2 years since the shortage has been lifted, NJDHSS is now enforcing the booster dose after the first birthday.

Please see the following link announcing the reinstatement of the Hib booster dose:
http://www.nj.gov/health/cd/vpdp/documents/hib_update.pdf

GRADE SIX REQUIREMENTS

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.

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.

Q: There are two vaccines for Tdap. 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 and older. Adacel by Sanofi Pasteur is licensed for ages 11-64. The Tdap vaccine provides protection from pertussis as immunity to pertussis wanes over time.

Q: Some 6th graders will not be 11 years old. I'm guessing that a 10 year old would not have to be in compliance with the 6th grade Tdap requirement until he or she reaches 11, is that correct?

A: Yes, a 10 year old would not be required to receive the Tdap vaccine until 11 years of age per NJ's Immunization Regulations. Note that while Boostrix is approved for 10 year olds, Adacel is not (11 to 64 years). 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 and this would fulfill NJ's school immunization requirements. However, either brands of Tdap vaccine may be administered at the same visit when they turn 11.

Q: NJ's regulations for Tdap states that a dose is required for students entering or attending Grade Six, or a comparable age level special education program with an unassigned grade. What if a child is 11 years old, but has the mental abilities of a 5-year-old, would he still need to receive the vaccine for Tdap?

A: Yes, the child would still need to follow NJ's immunization requirements and receive one dose of Tdap vaccine. The vaccine recommendations refer to the age-appropriate grade for the child's biological age, and not the child's mental capacity.

(This answer also applies to all NJ Immunization Requirements).

Q: If a student was inadvertently overlooked for the 6th grade Tdap requirement, would he/she still need to meet this requirement in the higher grade levels?

A: Yes, all children born after January 1, 1997 attending or transferring into a NJ school at grade six or higher grade level from another state or country are subject to the Tdap requirement provided at least five years have elapsed from the last documented Td dose.

(This answer also applies to the meningococcal vaccine requirement).

Q: Since the CDC/ACIP has new age recommendations for Tdap, will this effect NJ's immunization requirements?

A: In an effort to protect more people from pertussis, CDC/ACIP recently expanded the Tdap recommendations. For more information about the broadened recommendations, please visit:
http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6001a4.htm?s_cid=mm6001a4_w

NJ immunization regulations remain the same and reflect the minimum requirements for vaccines needed to attend school in NJ.

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. There is no licensed vaccine that just provides protection against pertussis at this time.

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, about 3,000 people in the U.S. get the disease. Adolescents die about 10 percent of the time, and one in four survivors has long-term disability, such as a loss of an arm or leg, deafness, nervous system problems, or even brain damage.

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

Q: There are three vaccines for meningococcal disease. Can you please clarify the difference between these vaccines?

A: The meningococcal vaccine protects against the bacterium *Neisseria meningitidis.* There are two types of meningococcal vaccines: the meningococcal polysaccharide (MPSV4, brand name, Menomune) and the meningococcal conjugate vaccine (MCV4, brand names, Menactra and Menveo). Although both are available, the MCV4 is currently preferred because it provides longer lasting immunity and can be used for all recommended groups.

Q: Some 6th graders will not be 11 years old. I'm guessing that a 10 year old would not have to be in compliance with the 6th grade meningococcal vaccine requirement until he or she reaches 11, is that correct?

A: Yes, a 10 year old entering sixth grade will not be required to receive the Meningococcal containing vaccine until they turn 11 years of age.

Q: If a child received a meningococcal containing vaccine earlier than 11 years of age, does NJ still require the child to receive the vaccine again when he/she enters grade six?

A: No, in the event the meningococcal vaccine was given earlier than age 11, it would still be valid as long as it was administered within the licensed age. However, NJDHSS does not require it until age 11.

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 at the sixth grade or higher grade level.

Q: If a student was inadvertently overlooked for the 6th grade meningococcal requirement, would he/she still need to meet this requirement in the higher grade levels?

A: Yes, all children born after January 1, 1997 attending or transferring into a NJ school at grade six or higher grade level from another state or country are subject to the meningococcal vaccine requirement.

(This answer also applies to the Tdap vaccine requirement).

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

A: Yes, the CDC/ACIP recently updated their recommendations for those who receive MCV4 at age 11 or 12 to receive a booster dose of MCV4 at age 16. Please see the question below for more information.

Q: I recently heard the CDC/ACIP updated recommendations for use of the MCV4. How will this impact NJ's Immunization Requirements?

A: CDC/ACIP updated recommendations for the use of MCV4 (Menveo, Novartis; and Menactra, Sanofi Pasteur) in adolescents and persons at high risk for meningococcal disease. CDC/ACIP recommends routine vaccination of persons with MCV4 at age 11 or 12 years, with a booster dose at age 16 years. A booster dose of MCV4, is expected to protect adolescents through the period of increased risk through age 21 years. For adolescents who receive the first dose at age 13 through 15 years, a one-time booster dose should be administered, preferably at age 16 through 18 years, before the peak in increased risk. Persons who receive their first dose of MCV4 at or after age 16 years do not need a booster dose. Routine vaccination of healthy persons who are not at increased risk for exposure to *N. meningitidis* is not recommended after age 21 years.

For additional information about the CDC/ACIP updated MCV4 recommendations, please visit:

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6003a3.htm?s_cid=mm6003a3_e

NJ immunization regulations remain the same. Therefore a child will not be required to receive booster dose MCV4 for attendance or entry into a NJ school. However, following CDC/ACIP recommendations would be optimal.

.**Q: A child transferred to a NJ school from out of the country. In the child's country, he received a vaccine for meningococcal disease, but the vaccine did not protect from all of the strains present in the US vaccine. Does the child need to revaccinated with a meningococcal vaccine licensed in the US to meet NJ Immunization Requirements?**

A: No, NJ immunization regulations state that you need to have documentation of one dose of meningococcal vaccine. The regulations do not specify which strains need to be included in the vaccine. Therefore, meningococcal containing vaccines received in other countries would be considered valid for school attendance in NJ. However, it is recommended that the child receive the additional dose to ensure protection against the additional vaccine strains.

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 child care. This is consistent with ACIP/ CDC recommendations. If the child does not start school until 4 years of age, then only the following conditions would be acceptable:

- A total of 4 doses of DTaP (or any combination of DTP, DTaP, and DT) with one of these 4 doses administered after the child's 4th birthday.

OR

- A total of any 5 doses of DTaP (or any combination of DTP, DTaP, and DT) even if a dose was not given after the fourth birthday as long as the minimum intervals were maintained.

The requirement to receive the fourth birthday booster does not apply while they are enrolled in child care/ preschool. They must receive the 4-6 year old booster dose once they enter kindergarten. So, if a child enters child care at 18 months, 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 documentation of having received a minimum of 3 doses of DTaP (or any combination of DTP, DTaP, and DT). Children 7 years of age and older, who have not been previously vaccinated with the primary DTaP series, should receive 3 doses of Td.

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 child care. This is consistent with ACIP/ CDC recommendations. If the child does not start school until 4 years of age, then only the following conditions would be acceptable:

- A total of 3 doses of polio vaccine with one of these 3 doses after the child's 4th birthday.

OR

- A total of any 4 doses of Polio

The requirement to receive the fourth birthday booster does not apply while they are enrolled in child care/ preschool. They must receive the 4-6 year old booster dose once they enter kindergarten. So, if a child enters child care at 18 months, 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.

Please note that the Polio vaccine is not required for students 18 years of age and older.

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: What are the minimum intervals between hepatitis B vaccine doses?

With the introduction of new vaccines and combination vaccines, it is becoming increasingly difficult for health care providers to keep track of minimum dosing intervals.

There has been confusion regarding the hepatitis B vaccine schedule for children.
NJDHSS supports the recommendation of the CDC to vaccinate children at birth.

Please note the following minimum intervals after the birth dose:

<u>The minimum interval between the first and second dose:</u>

 Weeks after first dose - 1 month or 4 weeks or 28 days

<u>There are three minimum intervals that must be met for the third dose:</u>

 Weeks after first dose - 4 months or 16 weeks or 112 days
 Weeks after second dose - 2 months or 8 weeks or 56 days
 Weeks after birth - 6 months or 24 weeks or 168 days.

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

Minimum Dose Spacing Intervals

Q: How do I determine the minimum dose spacing intervals between vaccinations?

A: NJ follows CDC/ACIP Recommend Catch-Up Immunization Schedule. Please see the following link for guidance: http://www.cdc.gov/vaccines/recs/schedules/downloads/child/catchup-schedule-pr.pdf

Grace Periods and Provisional Admission

Q: Can you please explain the Four-Day Grace Period?

A: 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: Can you please explain the 30-day grace period?

Students entering a NJ school from out of state or out of country are allowed up to 30 days to provide proof of immunization history before their provisional status begins.

Please review the following scenarios for further clarification:

If after the 30 days have elapsed and no documentation of previous vaccination is provided; the child may not attend school until one dose of all age-appropriate required vaccines are received before being provisionally admitted.

If schools are notified within the 30 days that documentation cannot be provided; the child may continue attending school since the 30 days have not elapsed. However, it is the responsibility of the school nurse or person in charge of the school to inform the parents that their child must receive one dose of all age-appropriate required vaccines before provisional status begins.

Please reference below for clarification of provisional admission.

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.

Q: What is Provisional Admission?

Provisional admission allows a child to enter/attend school after having received a minimum of one dose of each of the required vaccines. Pupils must be actively in the process of completing the series. Pupils <5 years of age, must receive the required vaccines within 17 months in accordance with the ACIP recommended minimum vaccination interval schedule. Pupils 5 years of age and older, must receive the required vaccines within 12 months in accordance with the ACIP recommended minimum vaccination interval schedule.

Seventeen months and twelve months for completion apply only to those who have never been vaccinated and are starting their vaccination series for the first time. All others should follow the minimum interval schedule.

Exclusions and Exemptions

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.

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.

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.

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-508.pdf

Q: Do medical exemptions have to be renewed annually?

A: Medical exemptions need to be reviewed, but not necessarily updated, annually. Per NJAC 8:57-4.3 (c), when a child's medical condition permits immunization, this exemption terminates and the child will be required to obtain the immunization(s) from which he/she has been exempted. A medical exemption must indicate a specific period of time in which the child cannot receive specific vaccinations.

For example if a child was granted a medical exemption because he/she was on medication that was contraindicated for one or more vaccines, that child would not be required to receive those specific vaccinations until the specified time period has elapsed. If the child is still medically contraindicated and the time period has elapsed, a new medical exemption would need to be submitted.

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.

All schools, child care centers, and local health officers may be advised that the religious exemption extends to private, parochial, and public institutions. When a parent or guardian submits their written religious exemption to immunization, which contains some religious reference, those persons charged with implementing administrative rules at N.J.A.C. 8:57 – 4.4, should not question whether the parent's professed religious statement or stated belief is reasonable, acceptable, sincere and bona fide. In practice, if the written statement contains the word "religion" or "religious" or some reference thereto, then the statement should be accepted and the religious exemption of mandatory immunization(s) granted. Please note, religious-affiliated schools cannot be challenged on their decision.

Q: Do religious exemptions have to be renewed annually?

A: Religious exemptions do not need to be updated yearly. However, if children receive vaccines after a religious exemption has been granted, the exemption would become null and void.

<u>The following example may provide some clarification</u>: In the beginning of the school year, a child was granted a religious exemption so he/she did not have to receive any of the required vaccines. Later on in the school year, the child provides documentation of receiving one dose of Tdap (or another

required vaccine). Since the child now has received a vaccine from which he was previously exempted, the religious exemption is now null and void. This means he would now be responsible for receiving all of the required vaccines from which he was previously exempted.

If a religious exemption was granted for a specific vaccine (i.e. varicella), the child would only be exempted from that particular vaccine and would be responsible for meeting all other vaccine requirements to continue attending school.

Q: Are there any forms parents can complete for religious and medical exemptions?

A: The New Jersey Department of Health does not have religious and medical exemption forms. Please refer to the above questions to see what constitutes a valid religious or medical exemption.

Q: Are philosophical or moral objections now acceptable in New Jersey?
A: No, currently the only 2 exemptions allowed in New Jersey are religious and medical exemptions.

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 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 BSAb 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.

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.
- Diptheria, 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.
- *Haemophilus influenzae* type b, pneumococcal, meningococcal and influenza
  There is no serology alternative to vaccination.
- Hepatitis B
  Hepatits 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) 826-4861.

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) 826-4860. 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, statewide immunization registry that can help parents and health car providers keep track of immunizations given from birth through adulthood. NJIIS is managed by the New Jersey Department of Health and Senior Services, Vaccine Preventable Disease Program and has been operating since 1997. **For more information about joining NJIIS, go to: http://njiis.nj.gov/njiis/**

Q: What is the new NJIIS mandate for physicians?

A: Effective December 31, 2011, every health care provider administering vaccine to children less than seven years of age shall register as an NJIIS site and authorized user and commence online reporting of vaccinations (N.J.A. C. 8:57-3.16a)

Q: Is NJIIS only for providers who vaccinate children under the age of seven?

A: No, NJIIS can be used for entering all vaccine doses administered regardless of patient age. Clinicians who administer vaccines to adolescents and adults are strongly recommended to become NJIIS users to ensure that the database is as robust as possible.

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.aap.org/immunization/pediatricians/pdf/RefusaltoVaccinate.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. For further information about the National Childhood Vaccine Injury Act (NCVIA) please see the following link: http://www.immunize.org/catg.d/p2027.pdf

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 http://www.cdc.gov/vaccines/pubs/vis/default.htm and the Immunization Action Coalition http://www.immunize.org/vis/ . You can also order single hard copies of the VISs using NIP's Online Order Form: http://wwwn.cdc.gov/pubs/ncird.aspx 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

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

A: Go to the CDC's "Epidemiology and Prevention of Vaccine Preventable Diseases, 12th edition Appendix B:

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/us-vaccines.pdf

Another source is the "Childhood and Adolescent Recommended Vaccines" booklet which can be found at: http://nj.gov/health/cd/imm.shtml

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: I received a foreign immunization record. Is this acceptable?

A: Yes, it is acceptable as long as the record contains proper written documentation with a seal or a stamp from the facility where the vaccine was administered or signed and dated by a physician.

You should be skeptical when reviewing the record. Match the record with the CDC/ACIP recommended schedule and more specifically NJ's Immunization requirements.

If unsure about vaccination status, revaccination may be simpler or do serology if appropriate. Please see the section on serology to see what is acceptable.

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.