

New Jersey Department of Health (NJDOH), Vaccine Preventable Disease Program

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

Frequently Asked Questions

New/updated questions are highlighted in yellow.

Please note that throughout this document, we will be referring to the Centers for Disease Control and Prevention as the CDC and the Advisory Committee on Immunization Practices as the ACIP.

NJ Immunization Requirements

Q: What are the minimum immunization requirements for preschool/child care, school, and college entry in NJ?

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

- Vaccination Requirements—Information for Schools and Parents
 - o Child Care/Preschool [pdf 114k]
 - K-12/Parents [pdf 76k]

Immunization of Pupils in School (N.J.A.C. 8:57-4) and Higher Education Immunization (N.J.A.C. 8:57-6) can be accessed at: www.lexisnexis.com/njoal.

Instructions for accessing NJ Immunization Requirements: http://nj.gov/health/cd/documents/instructions_viewing_regulations.pdf

1 | P a g e

Q: Are NJ Immunization Requirements in accordance with the CDC/ACIP guidelines?

A: Yes, NJ's immunization requirements are in accordance with the guidelines of the American Academy of Pediatrics (AAP), the American Academy of Family Physicians, and CDC/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. 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. The NJDOH recommends following the CDC/ACIP schedule, as periodically revised, for optimal protection.

Q: When do children need to show proof of immunization?

A: Immunization records must be presented on the first day of school or at the time of registration. Updates to immunization records must be provided to the school as the child receives his/her immunizations. The only exception to this rule is the 30-day grace period (see the "Grace Periods and Provisional Admission" section for further information).

Vaccine administration dates should be listed by month, day and year. However, if only a month and year are provided then you would need to assess if the minimum age and dose spacing intervals can be determined.

For example:

- 1. An immunization record indicating a child born on January 15, 2013 received his MMR vaccine in January 2014 would not be acceptable because you cannot determine if the vaccine was administered prior to the first birthday or if it was within the four-day grace period.
- 2. An immunization record indicating a child born on January 15, 2013 received his MMR vaccine in February 2014 would be acceptable because the vaccine was administered after the first birthday.

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 N.J.A.C. 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 CDC/ACIP recommends children 6 months through 8 years who are receiving influenza vaccine for the first time, and some in this age group who have previously been vaccinated, require 2 doses of vaccine administered ≥4 weeks apart.

Q: Is the flu vaccine required after January 1 for children coming in at that time or had not gotten it by December 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: Is there a document to help child care/preschool directors keep track of students who need to receive the flu vaccine?

A: NJDOH recognizes the challenges in implementing the flu vaccine requirement; therefore, the *Flu Vaccine Tracking* form has been developed to assist child care/preschool staff. This form can be used to list the names of students who have not received the flu vaccine by December 1. Completing this form will allow child care/preschool directors to have ample time to send a reminder notice to parents of students who still need to receive the vaccine by the December 31 deadline.

For more information, please visit http://nj.gov/health/cd/imm.shtml and access the following documents from the "Tools for Best Practice" section:

- Cover letter—flu vaccine tracking form
- · Flu vaccine tracking form

Q: Is the flu vaccine still required in child care/preschool, if a child already was sick with the flu?

A: Yes, the flu vaccine is still required even if the child was previously sick with the flu. Since there are more than 100 viruses that can cause "cold and flu" symptoms, a clinical diagnosis may not be the best indicator of what made the child sick. Only laboratory confirmation would prove the child actually had the flu. Even if the diagnosis is confirmed as flu, there is more than one strain of flu virus. Therefore, the child would still be required to receive the flu vaccine as it may protect him/her from the other common strains that are circulating. The seasonal flu vaccines protect against three or four different types of flu viruses (depending on the type of vaccine you receive).

Q: When should children be excluded for not satisfying the flu vaccine requirement?

A: Flu vaccine is a requirement for child care/preschool attendance for those who are 6 through 59 months of age. At least one dose of flu vaccine is due by December 31 of each year. Children who do not have documentation of receiving the flu vaccine or don't have a valid medical or religious exemption by December 31 will need to be excluded from school until the end of flu season, which is up until March 31 in NJ. Such students may return to school sooner than March 31 if they...

 Submit documentation of receiving the flu vaccine or submit a religious/medical exemption

• They can also "age out" of the requirement. This means that once they turn 5 years old (or 60 months), they are no longer subject to the requirement.

Q: Is the flu vaccine required for children who just turned 6 months of age in January since they were not age-eligible to receive the vaccine during September 1 through December 31 of the prior year?

A: Yes, once the child becomes age-eligible the flu vaccine is still required until the end of flu season in NJ (through March 31). 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 should a five-year-old in preschool be exempt from flu requirement?

A: NJ's immunization requirements reflect the ACIP recommendations during the time the rules were written and are not updated as frequently as ACIP revises or updates their recommendations. Therefore you may see a discrepancy in the vaccines or dosing schedule that are recommended versus those that are required for school attendance in New Jersey. Although NJ requires the flu vaccine for those 6 through 59 months of age, the flu vaccine is recommended for everyone ages 6 months and older per the ACIP, unless a person has a medical contraindication (reason for not receiving) for the vaccine.

Q: What if a child enrolls in school in January of the following year, will he/she be 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.

Children enrolled after December 31, must show proof of documentation that they received the flu vaccine prior to entering school.

Q: Is flu vaccine required after March?

A: No, students enrolling in school after March 31 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 during September 1 through 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: 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 <u>not</u> 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://www.njpca.org/fqhc/directory.aspx
- 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, some 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/docs/VFCBrochure.pdf

6. Checking the HealthMap Vaccine Finder at http://flushot.healthmap.org/ for vaccine availability at local health departments, pharmacies, and other locations.

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

A: 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 CDC 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, NJ Local Information Network and Communications System (NJ LINCS), electronic posting on the Department's website, etc.

Q: How is the 'flu season' defined?

A: Based on trend analysis of influenza seasons in NJ 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: Yes. Flu vaccines are currently available in both thimerosal-containing and thimerosal-free versions. To produce enough flu vaccine for the entire country, some of it must be put into multi-dose vials. These vials have very tiny amounts of thimerosal to safeguard against possible contamination of the vial once it is opened. Children can safely receive flu vaccine that contains thimerosal. Flu vaccine that does not contain thimerosal is available in single-dose units. The single-dose units are made without thimerosal as a preservative because they are intended to be opened and used only once. Additionally, the live-attenuated version of the vaccine (the nasal spray vaccine), is produced in single-dose units and does not contain thimerosal.

A listing of thimerosal content in seasonal flu vaccines, can be accessed at: http://www.cdc.gov/flu/protect/vaccine/vaccines.htm
For more information about vaccine safety and thimerosal, visit: http://www.cdc.gov/vaccinesafety/Concerns/thimerosal_faqs.html

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

A: This season, vaccine options are available for the following:

- Persons with a history of egg allergy who have experienced only hives after exposure to egg
- Persons with a history of severe reaction to egg
- Persons with no known history of exposure to egg, but who are suspected of being egg-allergic

All vaccines should be administered in settings in which personnel and equipment for rapid recognition and treatment of anaphylaxis are available. A previous severe allergic reaction to influenza vaccine, regardless of the component suspected to be responsible for the reaction, is a contraindication to future receipt of the vaccine.

For more information, please visit http://www.cdc.gov/flu/index.htm

Q: Will NJ continue to accept an allergy to eggs as a valid medical exemption for receiving the flu vaccine?

A: The NJDOH has received numerous inquiries from school health officials and parents regarding vaccination of persons with egg allergies. The current ACIP recommendation includes an algorithm for healthcare providers to manage patients with egg allergies. Since egg allergies range in severity, school health officials may find it difficult to determine the validity of influenza vaccine medical exemptions.

After careful consideration, the NJDOH has made a decision to continue to accept egg allergy as a valid medical contraindication. If the physician's/APN's written medical exemption states that the child has an egg allergy and cannot receive flu vaccine for that reason, we would encourage schools to accept this as a valid exemption. NJDOH will continue to evaluate the feasibility of implementing this ACIP recommendation in the future. In the interim, we continue to encourage healthcare providers to follow ACIP's guidelines and screening protocols to determine whether their patient can receive flu vaccine.

For more information, please visit http://www.cdc.gov/flu/index.htm

Q: What will be included in the current flu vaccine?

A: For more information about the current flu season, please visit http://www.cdc.gov/flu/index.htm

Q: What types of flu vaccines are available?

A: The single best way to prevent the flu is to get a flu vaccination each fall. There are two types of vaccines:

• The "flu shot" is an inactivated vaccine (containing killed virus) that is given with a needle. It can be given in the muscle or just under the skin. The flu shot that is given in the muscle is approved for use in people older than 6 months, including healthy people and people with chronic medical conditions. Most flu shots are given with a needle. One flu vaccine also can be given with a jet injector which uses a high-pressure, narrow stream of fluid to penetrate the skin instead of a hypodermic needle. There is also an intradermal flu vaccine, which is injected into the skin instead of the muscle and uses a much smaller needle than the regular flu shot.

8 | P a g e

 The nasal-spray flu vaccine is a vaccine (sometimes called LAIV for "Live Attenuated Influenza Vaccine") made with live, weakened flu viruses that do not cause the flu. LAIV is approved for use in healthy people 2 years to 49 years of age who are not pregnant.

Talk to your provider to find out which vaccine is right for you and your family.

Q: Why do I need to receive a flu vaccine every year?

A: A flu vaccine is needed every year because flu viruses are constantly changing. It's not unusual for new flu viruses to appear each year. The flu vaccine is formulated each year to keep up with the flu viruses as they change.

In addition, multiple studies conducted over different seasons and across vaccine types and influenza virus subtypes have shown that the body's immunity to influenza viruses (acquired either through natural infection or vaccination) declines over time.

Getting vaccinated each year provides the best protection against influenza throughout flu season.

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 type b (Hib) vaccine as well).

Q: If a child entered pre-school/child care with 4 doses of PCV vaccine administered before 12 months of age, does this child need an additional dose?

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 type b (Hib) vaccine as well).

Q: If a child did not attend child care, preschool, or prekindergarten, is he/she required to receive a dose of PCV before entering kindergarten?

A: If a 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 type b (Hib) vaccine as well).

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: NJDOH 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 with 4 doses of Hib vaccine administered before 12 months of age, does this child need an additional dose?

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.

10 | P a g e

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

Q: If a child did not attend child care, preschool, or prekindergarten, is he/she required to receive a dose of Hib before entering kindergarten?

A: If a 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).

Grade Six Requirements

Tdap Vaccine

Q: There are two vaccines for tetanus, diphtheria, acellular pertussis (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 GlaxoSmithKline is licensed for ages 10 and older. Adacel® by Sanofi Pasteur is licensed for ages 10 through 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. Although both Tdap vaccines, Boostrix® and Adacel®, are licensed for use beginning at age 10, NJ would not require Tdap for school attendance under the child is 11 years of age. The Department recommends the dose be received within two weeks of the 11th birthday.

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?

11 | Page

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, the 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: If a child receives the Tdap vaccine at 7 years old, will another dose of Tdap be required once he/she turns 11 years old?

A: In 2010, the ACIP expanded their recommendations stating that persons aged 7 years and older who are not fully immunized with diphtheria, tetanus and acellular pertussis (DTaP) vaccine should receive Tdap vaccine preferably as the first dose in the catch-up series; if additional doses are needed, use tetanus-diphtheria (Td) vaccine. For children 7 through 10 years who receive a dose of Tdap as part of the catch-up series, an adolescent Tdap vaccine dose at age 11 through 12 years should NOT be administered.

Q: If a dose of DTaP or Tdap is inadvertently given to a patient for whom the product is not indicated (e.g., wrong age group), how do we rectify the situation?

12 | P a g e

A: The first step is to inform the parent/patient that you administered the wrong vaccine. Next, follow these guidelines:

- Tdap given to a child younger than age 7 years as either dose 1, 2, or 3, is NOT valid. Repeat with DTaP as soon as feasible.
- Tdap given to a child younger than age 7 years as either dose 4 or 5 can be counted as valid for DTaP dose 4 or 5.
- DTaP given to patients age 7 or older can be counted as valid for the one-time Tdap dose.

Please see the Immunization Action Coalition's website for further information, http://www.immunize.org/askexperts/experts_diph.asp

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

A: There are two different kinds of vaccines available in the United States that protect against *Neisseria meningitidis* serogroups (strains) A, C, Y, and W: meningococcal polysaccharide vaccine (Menomune), and meningococcal conjugate vaccine (Menactra, Menveo).

 Meningococcal conjugate vaccine (MCV4) is the preferred vaccine for people 55 years of age and younger.

 Meningococcal polysaccharide vaccine (MPSV4) has been available since the 1970s. It is the only meningococcal vaccine licensed for people older than 55 years of age.

MenHibrix is a conjugate vaccine that protects against *Haemophilus influenzae* type b (Hib) and 2 strains (C and Y) of *Neisseria meningitidis*. This vaccine is licensed for use in children 6 weeks through 18 months of age.

In 2014, Trumenba [®] and Bexsero [®] were licensed for use in the United States. These vaccines only protect against serogroup B and are licensed for use in persons 10 through 25 years of age. *Please see the question below for further information about these vaccines*).

Q: Is the serogroup B meningococcal vaccine (Trumenba [®] and Bexsero [®]) required for school attendance?

A: No. The serogroup B meningococcal vaccine is not required for school attendance. The NJDOH requires vaccines that are recommended for general use by the ACIP.

At its meeting in February 2015, the ACIP voted to recommend the use of serogroup B vaccines for people 10 and older in certain specific risk groups. These include:

- Persons who have persistent complement component deficiencies;
- Persons who have anatomic or functional asplenia, including sickle cell disease;
- Persons identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B; and
- Microbiologists who are regularly exposed to Neisseria meningitidis.

In June 2015, the ACIP declined to vote to approve routine use of serogroup B meningococcal vaccine in young people, instead leaving the decision to doctors and their patients. ACIP voted that a serogroup B meningococcal vaccine series may be administered to adolescents and young adults 16 through 23 years of age to provide short term protection against most strains of serogroup B meningococcal disease. This recommendation is labeled as "Category B" meaning that individual clinical decision making is recommended. This recommendation expands the ACIP recommendations set forth in February.

You should discuss with your healthcare provider whether you are a candidate for the serogroup B vaccine. If you get this vaccine, you still must

14 | Page

get the vaccine that covers serogroups A,C,Y, and W in order to attend school in New Jersey.

Q: Should schools provide information about serogroup B disease and the serogroup B vaccine to students?

A: There are currently statutes and regulations requiring distribution of meningococcal educational materials.

Summary of N.J.S.A. 18A:40-21.2 (P.L.2006, c.64):

The Commissioner of Health, in consultation with the Commissioner of Education, shall develop an educational fact sheet concerning meningococcal meningitis for distribution to parents or guardians of students grades 6 through 12. These fact sheets have been distributed in a manner prescribed by the Commissioner of Education since 2007. This is required for public schools and voluntary for private schools.

Summary of N.J.S.A. 18A:61D-7 (P.L.2000, c.025, amended P.L.2003, c.284):

Beginning with the 2000-2001 school year, each four year public or private institution of higher education, in a manner prescribed by the Commissioner of Health, shall provide information about meningitis and the vaccine, and shall develop a method for facilitating, receiving, and recording student responses to the material. The rules regarding the required educational materials are found at N.J.A.C. 8:57-6.10.

Educational material provided to students should include information about serogroup B meningococcal disease and the serogroup B vaccine. The VPDP has prepared a meningococcal educational brochure which is posted to our web site at

http://www.state.nj.us/health/cd/documents/faq/meningococcal_faq.pdf . This document was last updated November 2014 and includes information about MenB disease and the availability of licensed vaccines against MenB. This document meets the requirements stipulated in statute. Institutions of higher education are permitted to disseminate their own materials. In addition to this resource, there are additional educational materials available through our web site for healthcare and public health professionals as well as the general public at http://www.nj.gov/health/cd/meningo/index.shtml. These materials are updated as necessary.

Q: Is a specific type of meningococcal vaccine required for school attendance?

A: NJDOH requires that children be immunized against the four serogroups (A,C, Y, and W-135) that are present in the meningococcal-containing

vaccines licensed for use in the United States. Meningococcal conjugate vaccine (MCV4) is the preferred vaccine for people 55 years of age and younger.

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. The Department recommends the dose(s) be received within two weeks of the 11th birthday.

Q: A child received a meningococcal vaccine prior to 11 years of age. Would this satisfy NJ's Immunization requirement?

A: When meningococcal conjugate vaccine was licensed in January 2005, data were lacking on long-term efficacy and the need for additional vaccination. Therefore, NJDOH previously accepted doses given prior to 11 years of age without the need for revaccination. Since that time, studies have indicated that antibody levels decline. ACIP now recommends any meningococcal vaccination given prior to the tenth birthday (either MCV4 or MPSV4) does NOT count toward routinely recommended doses (ages 11 and older). Beginning the 2012-2013 school year, children who received the vaccine prior to the tenth birthday will need to be revaccinated for NJ school attendance.

However, there are exceptions to this rule. Meningococcal conjugate vaccine is recommended for certain children ages 2 months through 10 years. Students who travel to countries where meningococcal disease is endemic, have certain medical conditions such as complement component deficiencies and functional or anatomic asplenia (including sickle cell disease), or who are present during a meningococcal disease outbreak may have previously received meningococcal vaccine. These children may need to receive booster doses of vaccine and should consult with their physician to determine the appropriate vaccination schedule. According to the ACIP, eight weeks is the minimum interval between doses of meningococcal conjugate vaccine; however, a health care provider may determine the most appropriate interval based on his/her clinical assessment. Such students will satisfy the meningococcal vaccine requirement by submitting a medical exemption written by a health care provider. Please see "Meningococcal Vaccine Recommendations by Age and/or Risk Factor" for further information: http://www.immunize.org/catg.d/p2018.pdf

16 | P a g e

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 NJ 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 types 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: NJDOH is requiring that children be immunized against the four serogroups (A,C, Y, and W-135) that are present in the meningococcal-containing vaccines licensed for use in the United States. If any vaccines administered in foreign countries do not match the strains in US licensed vaccines, these vaccinations will not be accepted and will require revaccination to achieve optimal protection.

Other Vaccines

DTaP Vaccine

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

A: A child will need 4-5 doses of DTaP. The following two scenarios are acceptable:

 A total of 4 doses of a DTaP-containing vaccine with one of these 4 doses administered after the child's 4th birthday.

OR

 A total of any 5 doses of a DTaP-containing vaccine even if all doses were administered before the fourth birthday.

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. Please review the following examples:

Children who are 18 months and older will need 4 doses if attending/entering child care/preschool. The requirement to receive the fourth birthday booster dose (5th dose) will not apply until the child attends Kindergarten. Please note all other children must be age-appropriately vaccinated for child care/preschool entry.

18 | P a g e

Children who are first entering a preschool program at 4 years of age or older will also need 4 doses prior to entry. If one of these 4 doses was given on or after the 4th birthday, this child will <u>NOT</u> need an additional dose for Kindergarten.

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. For more information, please see the document, "Immunization Requirements—Implementation Guidance" at http://www.nj.gov/health/cd/imm.shtml

Polio Vaccine

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

A: Students will need 3-4 doses of a polio-containing vaccine depending upon the age of school entry. The following two scenarios are acceptable:

• A total of 3 doses of a polio vaccine with one of these 3 doses administered on or after the child's fourth birthday.

OR

• A total of 4 doses of polio-containing vaccine even if all doses were administered before the fourth birthday.

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. Please review the following examples:

Children who are 18 months and older will need 3 doses if attending/entering child care/preschool. The requirement to receive the fourth birthday booster dose (**4**th **dose**) will not apply until the child attends Kindergarten. *Please note all other children must be age-appropriately vaccinated for child care/preschool entry.*

Children who are first starting a preschool program at 4 years of age will also need 3 doses prior to entry. If one of these 3 doses was given on or after the 4th birthday, this child will <u>NOT</u> need an additional dose for Kindergarten.

Children 7 years of age and older attending school must have a minimum of 3 doses of polio. If these children do not have documentation of receiving at

least three doses, use the ACIP Recommended catch-up schedule to satisfy the requirement, http://www.cdc.gov/vaccines/schedules/hcp/child-adolescent.html

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

For more information, please see the document, "Immunization Requirements—Implementation Guidance" at http://www.nj.gov/health/cd/imm.shtml

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 NJ 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 NJDOH. 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 NJ 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 NJ 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 NJ immunization regulations, the three-dose hepatitis B series is not required until a child enters kindergarten. By kindergarten

20 | P a g e

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?

The introduction of new vaccines and combination vaccines can make it difficult for health care providers to keep track of minimum dose spacing intervals.

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

Please note the following minimum intervals after the birth dose:

The minimum interval between the first and second dose:

Weeks after first dose - 4 weeks (28 days)

There are three minimum intervals that must be met for the third dose:

- Weeks after first dose 16 weeks (112 days)
- ➤ Weeks after second dose 8 weeks (56 days)
- Weeks after birth 24 weeks (168 days)

Please use the ACIP's minimum age and dose spacing intervals table for further guidance,

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf. If the minimum interval or age is defined in terms of weeks, then use weeks to calculate the minimum interval or age. If the minimum interval or age is defined in terms of months, then use months to calculate the minimum age or interval. For hepatitis B, use weeks or days instead of months for calculating the minimum age and dose spacing intervals.

Q: I recently heard that the hepatitis B requirement, specifically the intervals between doses, has changed. What will happen with students that may have an incorrect interval?

A: The hepatitis b regulations have not changed but with the adoption of the four-day grace period in January 2008 schools need to make sure that all vaccines meet the recommended minimum age and dose spacing intervals. This applies to all vaccines—not just hepatitis B. Any child who

21 | Page

received hepatitis B vaccine after the four-day grace period was adopted must have proper minimum age and dose spacing intervals to be counted as valid doses.

Please see the "Minimum Dose Spacing Intervals" and "Grace Periods and Provisional Admission" sections of this document for further information.

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.

Q: A student's immunization record indicates that the first dose of hepatitis B vaccine was given "at Hospital" or "at Birth" rather than specifying a date of administration. Would this be an acceptable form of documentation?

A: Yes, you can accept "at Hospital" or "at Birth" as the date of administration for the first dose.

Other vaccine requirement questions

Minimum Dose Spacing Intervals

Q: What is meant by "minimum intervals" between vaccine doses?

A: Vaccination schedules are generally determined by clinical trials, usually prior to licensure of the vaccine. The spacing of doses in the clinical trial usually becomes the recommended schedule. A "minimum interval" is the shortest time between two doses of a vaccine series in which an adequate response to the second dose can be expected. The concern is that a dose given too soon after the previous dose may reduce the response to that dose.

Q: What is considered acceptable documentation for receipt of a vaccine?

A: Ideally all immunization dates should include a month, day, and year; however, NJ will accept a documented date of just month and year if the doses administered are determined to be in compliance with the minimum age or dose spacing intervals.

For example, a student born on August 20, 2011 received a dose of MMR vaccine in August 2012. Since you cannot determine when the MMR vaccine was administered, a documented date of just month and year would not be sufficient. This dose could have been administered on August 1, 2011, which would be prior to the child's first birthday.

Q: Why is it important to make sure vaccines meet the minimum age and interval?

A: Doses administered too close together or at too young an age can lead to a suboptimal (inadequate or poor) immune response.

Q: Where can I find the accepted minimum age and intervals? In some places I see the minimum age in months and in some places I see it written in weeks?

A: You should consult the ACIP/CDC documents located at http://www.cdc.gov/vaccines/schedules/downloads/child/catchup-schedule-pr.pdf or

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf when determining the minimum age and interval. If the minimum interval or age is defined in terms of weeks, then use weeks to calculate the minimum interval or age. If the minimum interval or age is defined in terms of months, then use months to calculate the minimum age or interval.

Q: For the purpose of vaccine spacing, what constitutes a month: 28 days (4 weeks), 30 days, or 31 days?

A: For intervals of 3 months or less, you should use 28 days (4 weeks) as a "month." For intervals of 4 months or longer, you should consider a month a "calendar month": the interval from one calendar date to the next a month later. This is a convention that was introduced on the childhood schedule in 2002 and discussed in the paper "Evaluation of Invalid Vaccine Doses" (Stokley S, Maurice E, Smith PJ, et al. *American Journal of Preventive Medicine*, 2004: 26[1]: 34–40).

Q: We sometimes have differences of opinion among our staff in determining the minimum interval or age for administering vaccines. Recommendations are sometimes written in months, weeks, or days. Can you help clarify?

A: Customarily, if the dosing interval is 4 months or more, it is common to use calendar months (e.g., 6 months from October 1 is April 1). If the interval is less than 4 months, it is common to convert months into days or weeks (e.g., 1 month = 4 weeks = 28 days).

23 | Page

Please use the ACIP's minimum age and dose spacing intervals table for further guidance,

http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/A/age-interval-table.pdf. If the minimum interval or age is defined in terms of weeks, then use weeks to calculate the minimum interval or age. If the minimum interval or age is defined in terms of months, then use months to calculate the minimum age or interval. For common questions about the scheduling of vaccine doses, visit the Immunization Action Coalition's webpage: http://www.immunize.org/askexperts/scheduling-vaccines.asp.

Q: Is there a tool that can help you calculate intervals between doses quickly?

A: There may be several date calculator tools available on the internet such as the time and date tool which is accessible at: http://www.timeanddate.com/date/duration.html. (Please note, NJDOH does not endorse, control, or guarantee the accuracy or completeness of information contained on the time and date website.)

Grace Periods and Provisional Admission

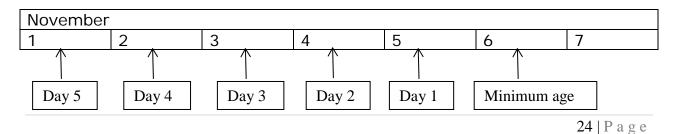
Q: Can you please explain the four-day grace period?

A: All vaccines administered less than or equal to 4 days before either the specified minimum age or dose spacing intervals shall be counted as valid and shall not require revaccination in order to enter or remain in a school, preschool, or child care facility.

Day 1 is the day before the minimum age or minimum interval for a vaccine. Doses of any vaccine administered ≥5 days earlier than the minimum interval or age should not be counted as valid doses and should be repeated as age appropriate. Please see the following example:

Example:

A child born on November 6, 2013 received the MMR vaccine on November 3, 2014. The minimum age for this vaccine is 12 months which would be November 6, 2014.



4 2015

Since November 6 is the minimum age, doses administered on or after November 2 would be considered valid (November 6 - 4 days = November 2). If the child received the dose on November 1, the dose would have been considered invalid.

Please note that ACIP does not recommend applying the four-day grace period for the dose spacing interval between two live vaccines. However, for school attendance and auditing purposes, this will be acceptable.

Q: We often find it confusing to determine the minimum intervals for hepatitis B vaccine doses. Will the four-day grace period make certain doses valid? Could you please provide an example?

A: In order to help with the calculation of minimum intervals, you may want to utilize tools on the internet such as the time and date tool accessible at http://www.timeanddate.com/date/duration.html for the example below. (Please note, NJDOH does not endorse, control, or guarantee the accuracy or completeness of information contained on the time and date website.)

Vaccine Administration Date	Minimum Interval	Comments	Acceptable (√) or Unacceptable (*)	
DOB: March 25, 2012 (given at birth)	The minimum age for the hepatitis B vaccine is at birth.	March 25, 2012 is the date of birth and the date of vaccine administration.	✓	
April 25, 2012	The minimum interval between the first and second dose is 4 weeks (28 days). NOTE: April 22 would mark the minimum interval.	March 25-April 25 4 weeks and 3 days (total of 31 days). This satisfies the minimum interval of 28 days (April 22).	✓	
There are three criteria for the third dose of hepatitis B vaccine. All criteria need to be met in order for the dose to be considered valid.				
September 1, 2012	The minimum interval between the second and third dose is 8 weeks (56 days).	April 25-September 1 18 weeks and 3 days (total of 129 days)	✓	
	NOTE: June 20 would mark the minimum interval.	This satisfies the minimum interval (June 20).		

25 | Page

The minimum interval between the first and third dose is 16 weeks (112 days). NOTE: July 15 would mark the	March 25—September 1. 22 weeks and 6 days (total of 160 days) This satisfies the minimum interval (July 15).	✓
minimum interval. The minimum age for the third dose is 24 weeks (168 days). NOTE: September 9 would mark	March 25 is the date of birth. March 25-September 1 22 weeks and 6 days (160 days) after birth	*
the minimum age.	This dose would be considered <u>invalid</u> because the third dose was given prior to 24 weeks (168 days) of age.*	

^{*}Since the dose was administered ≥5 days earlier than the minimum interval or age, the last dose is considered invalid. The dose would be considered valid if it were given on or after September 9 (the minimum age). If you applied the four-day grace period, you can accept doses administered on or after September 5 (September 9 - 4 days = September 5).

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

A: 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.

<u>Please review the following scenarios for further clarification:</u>

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 NJ 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?

A: 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 and on schedule to receive subsequent doses as rapidly as medically feasible. A school nurse or school administrator shall review the immunization status of a provisionally enrolled student every 30 days to ensure continued compliance in completing the required doses of vaccine(s).

Provisional status can only be granted one time to students entering or transferring into schools, preschools, or child care centers in New Jersey. Information on this status will need to be sent by the original school to the new school.

Students who are 4 months through 18 years whose vaccinations have been delayed or who are more than one month behind, need to follow the minimum age and dose spacing intervals in accordance with the Advisory Committee on Immunization Practices (ACIP) Recommended Catch-Up Schedule, http://www.cdc.gov/vaccines/schedules/downloads/child/catchup-schedule-pr.pdf

Q: How do you define, "as rapidly as medically feasible"?

A: The phrase, "as rapidly as medically feasible" is in reference to meeting the minimum age and dose spacing intervals in accordance with the ACIP Recommended Catch-Up Immunization Schedule. Please see the following example:

Example: A child was provisionally admitted to Kindergarten because he had received one dose of hepatitis B vaccine (NJ requires three doses of hepatitis B vaccine for school attendance). The school nurse/administrator would need to assess when the next dose in the vaccine series is due by consulting the ACIP Recommended Catch-Up Immunization Schedule. According to this schedule, the minimum dose spacing interval between hepatitis B dose one and two is four weeks. Therefore, this child will need to receive the second dose of hepatitis B vaccine once four weeks has elapsed from his first dose. It would not be medically feasible for the child to receive this dose prior to four weeks. If the minimum interval has exceeded (i.e. the child has not

27 | Page

shown documentation of receiving the second dose after the four weeks have elapsed), this student would be considered out of compliance and may not be allowed to attend school until he receives this required dose.

Q: Is there a document that school nurses can use to keep track of students who are enrolled provisionally?

A: The NJDOH recognizes the challenge in keeping track of students who have been provisionally admitted; therefore, you may use the *Provisional Admission Student Tracking* form to streamline the process. For more information, please visit http://nj.gov/health/cd/imm.shtml and access the following documents from the "Tools for Best Practice" section:

- Cover letter—provisional admission student tracking form
- Provisional admission student tracking form

Q: When is a student considered out-of-compliance?

A student would be considered out of compliance if he/she:

- Does not have an immunization record (only those children 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).
- Does not have serology or proof of immunity for missing vaccines
- Does not have a religious or medical exemption on file
- Does not meet the provisional admission definition since the minimum age and dose spacing interval to receive the next dose in the vaccination series has been exceeded.

Q: How do you determine whether or not the student should be enrolled, excluded, admitted provisionally, or allowed a 30-day grace period?

A: Review the "Immunization Compliance Flow Charts" at the link, http://nj.gov/health/cd/imm.shtml to guide you through the process.

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

28 | Page

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.

29 | Page

8:47-4.5 Provisional admission

(g) Those children in provisional status may be temporarily 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.

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

A: According to the NJDOH 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 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.immunize.org/catq.d/p3072a.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

30 | P a g e

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.

The following example may provide some clarification: 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 NJ 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 NJ 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 NJ Administrative Code 8:57-4.6(c):

"Laboratory evidence of protective immunity, as enumerated by the 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 NJ Department of Health (NJDOH) 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 NJDOH do not recognize serology as an alternative to vaccination since serologic correlates for protection do not exist for some diseases (e.g. *Bordetella pertussis*).

NJDOH 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, NJDOH 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.
- 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.
- Haemophilus influenzae type b, pneumococcal, meningococcal and influenza
 - There is no serology alternative to vaccination.
- Hepatitis B
 Hepatitis B serology and the interpretation are complicated and
 beyond the scope of this document. Pre-vaccination testing is not

routinely recommended for infants or children. Pre-vaccination testing is recommended only for

- o all persons born in Africa, Asia, the Pacific Islands, and other regions with HBSAg prevalence of > 8%;
- o household, sex, and needle-sharing contacts of HBSAg-positive persons; and
- o 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. NJDOH recommends that they discuss ACIP revaccination guidelines and follow-up serology with their health care providers, as appropriate.

Q: What is the Antibody Titer (Holly's Law)?

A: The Antibody Titer Law (Holly's Law, NJSA 26: 2N-8-11), passed on January 14, 2004, requires the NJDOH to accept serologic evidence of protective immunity to measles, mumps and rubella in lieu of the second ACIP recommended measles, mumps and rubella vaccine. For more information, please visit:

http://nj.gov/health/cd/documents/antibody_titer_law.pdf.

Q: What is acceptable proof of varicella disease?

A: A physician /licensed medical professional's written statement of varicella diagnosis; a written statement from parent/guardian reporting varicella disease; a lab confirmation of protective varicella immunity are examples of proof of varicella disease.

Q: Is a diagnosis of shingles disease acceptable proof of varicella disease?

A: Since shingles disease occurs only in someone who has had varicella disease previously, diagnosis of shingles by a licensed medical practitioner would be evidence of proof of past varicella disease.

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: NJDOH and the 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 NJDOH 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?"

35 | Page

Enforcement of Immunization Regulations

Q: What are the responsibilities of schools for ensuring immunization compliance?

A: The NJ Immunization of Pupils in School (N.J.A.C. 8:57-4) regulations apply to all children attending any public or private school, child care center, nursery school, preschool or kindergarten in NJ. According to N.J.A.C. 8:57-2, a principal, administrator or person in charge of a school shall not knowingly admit or retain any child whose parents have not submitted acceptable evidence of immunizations unless, however, they have a valid exemption. Failure to do so would be a violation of the state sanitary code N.J.S.A. 26:1A-10 and the school may be subject to a fine. The statute stipulates that 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 \$1000.

Q: How do we know if a foreign immunization record is valid?

A: If you receive a foreign immunization record, you can accept it with proper written documentation. It should ideally have a seal or stamp OR at least signed and dated by a health care provider. You should check to see if the vaccines administered match New Jersey's vaccination requirements for school attendance. If the student has to be revaccinated, it should be done in accordance with the ACIP Recommended Schedule, which may be simpler or they can have blood work done to test for immunity(when possible) to prevent over vaccination.

If you receive records that need to be translated, the CDC has resources to decipher foreign vaccines. Please visit the website http://www.cdc.gov/vaccines/pubs/pinkbook/downloads/appendices/B/foreign-products-tables.pdf. For further guidance please refer to the American Academy of Pediatrics' Red Book or the ACIP.

Higher Education Regulations

Q: What are the immunization requirements for students entering institutions of higher education?

A: According to the Higher Education Rules, N.J.A.C. 8:57-6.1, the requirements within this subchapter apply to the following:

36 | P a g e

- (a) All new or continuing full- and part-time undergraduate and graduate students enrolled in a program of study leading to an academic degree at any public or independent institution of higher education in New Jersey.
- (b) Two-year institutions shall apply these rules only to those students entering the college for the first time and registering for 12 or more credit hours of course study per semester/term.
- (c) Four-year institutions shall apply the rules to all full- or part-time students enrolled in a program leading to an academic degree.
- (d) Two-year institutions and Thomas Edison State College shall not be required to apply the meningococcal rule at N.J.A.C. 8:57-6.6 and 6.7.

Below are the specific vaccination requirements for attendance:

<u>Hepatitis B</u>: Students entering a two- or four-year institution and enrolled with a course study of 12 or more credit hours per semester or term shall have received three doses of a hepatitis B containing vaccine, or alternatively any two doses of a hepatitis B vaccine licensed and approved for a two dose regimen administered to the student between 11 through 15 years of age.

<u>Measles, Mumps, Rubella</u>: Two doses of measles vaccine and 1 dose of mumps and rubella vaccine are required. Two MMR vaccines are also acceptable.

<u>Meningococcal</u>: One dose of meningococcal vaccine is required for students entering a four-year institution and who reside in a campus dormitory. Students attending two-year institutions and students who do <u>not</u> reside in a campus dormitory are exempt from this requirement.

All four-year institutions are required to provide information on meningococcal disease to all new students (including those students who are commuters) prior to matriculation. This information will need to include the nature and severity, causes, disease prevention and treatments, and the availability of a meningococcal vaccine to prevent disease.

Q: Are students 31 years of age and older subject to the immunization requirements set forth in N.J.A.C. 8:57-6.4 (b)1 since the Higher Education statute N.J.S.A. 18A:61D-1 states that the immunization requirements specifically apply to students 30 years of age and under?

A: The NJ Education Statute, N.J.S.A. 18A: 61D-1 states:

Every public and independent institution of higher education in this State shall, as a condition of admission or continued enrollment, require every graduate and undergraduate student who is 30 years of age or less and is enrolled full-time or part-time in a program or course of study leading to an academic degree, to submit to the institution a valid immunization record which documents the administration of all required immunizations against vaccine-preventable disease, or evidence of immunity from these diseases, in accordance with regulations promulgated by the Department of Health. The institution shall keep the records on file in such form and manner as prescribed by the department.

The NJDOH administrative code, N.J.A.C. 8:57-6.4, states that students born before 1957 are exempt from the measles, mumps, and rubella (MMR) vaccination requirement.

Since the Education Statute at N.J.S.A. 18A:61D-1 specifically states that only students 30 years of age or less must show proof of vaccination, NJDOH cannot require a college student <u>over</u> 30 years of age that meets all the other requirements set forth at N.J.S.A. 18A:61D-1 to present proof of vaccine or immunity for any of the required college vaccines. However, NJDOH still highly recommends that students are age appropriately immunized.

Q: Which of the meningococcal vaccines is required for attendance in institutions of higher education?

A: NJDOH requires that students be immunized against the four serogroups (A,C,Y, and W) that are present in the meningococcal-containing vaccines licensed for use in the United States.

There are two different kinds of vaccines available in the United States that protect against *Neisseria meningitidis* serogroups (strains) A, C, Y, and W: meningococcal polysaccharide vaccine (Menomune), and meningococcal conjugate vaccine (Menactra, Menveo).

- Meningococcal conjugate vaccine (MCV4) is the preferred vaccine for people 55 years of age and younger.
- Meningococcal polysaccharide vaccine (MPSV4) has been available since the 1970s. It is the only meningococcal vaccine licensed for people older than 55 years of age.

MenHibrix is a conjugate vaccine that protects against *Haemophilus* influenza type b (Hib) and 2 strains (C and Y) of *Neisseria meningitidis*. This vaccine is licensed for use in children 6 weeks through 18 months of age.

In 2014, Trumenba [®] and Bexsero [®] were licensed for use in the United States. These vaccines only protect against serogroup B and are licensed for use in persons 10 through 25 years of age. *Please see the question below for further information about these vaccines*).

Q: Is the serogroup B meningococcal vaccine (Trumenba [®] and Bexsero [®]) required for attendance institutions of higher education?

A: No. The serogroup B meningococcal vaccine is not required for attendance at an institution of higher education. The NJDOH requires vaccines that are recommended for general use by the ACIP.

At its meeting in February 2015, the ACIP voted to recommend the use of serogroup B vaccines for people 10 and older in certain specific risk groups. These include:

- Persons who have persistent complement component deficiencies;
- Persons who have anatomic or functional asplenia, including sickle cell disease;
- Persons identified to be at increased risk because of a meningococcal disease outbreak attributable to serogroup B; and
- Microbiologists who are regularly exposed to Neisseria meningitidis.

In June 2015, the ACIP declined to vote to approve routine use of serogroup B meningococcal vaccine in young people, instead leaving the decision to doctors and their patients. ACIP voted that a serogroup B meningococcal vaccine series may be administered to adolescents and young adults 16 through 23 years of age to provide short term protection against most strains of serogroup B meningococcal disease. This recommendation is labeled as "Category B" meaning that individual clinical decision making is recommended. This recommendation expands the ACIP recommendations set forth in February.

You should discuss with your healthcare provider whether you are a candidate for the serogroup B vaccine. If you get this vaccine, you still must get the vaccine that covers serogroups A,C,Y, and W in order to attend school in New Jersey.

Q: We have heard that there have been cases and outbreaks of serogroup B meningococcal disease on college campuses in the United States. Should institutions of higher education provide

39 | Page

information about serogroup B disease and the serogroup B vaccine to students?

A: There are currently statutes and regulations requiring distribution of meningococcal educational materials.

Summary of N.J.S.A. 18A:40-21.2 (P.L.2006, c.64):

The Commissioner of Health, in consultation with the Commissioner of Education, shall develop an educational fact sheet concerning meningococcal meningitis for distribution to parents or guardians of students grades 6 through 12. These fact sheets have been distributed in a manner prescribed by the Commissioner of Education since 2007. This is required for public schools and voluntary for private schools.

Summary of N.J.S.A. 18A:61D-7 (P.L.2000, c.025, amended P.L.2003, c.284):

Beginning with the 2000-2001 school year, each four year public or private institution of higher education, in a manner prescribed by the Commissioner of Health, shall provide information about meningitis and the vaccine, and shall develop a method for facilitating, receiving, and recording student responses to the material. The rules regarding the required educational materials are found at N.J.A.C. 8:57-6.10.

Educational material provided to students should include information about serogroup B meningococcal disease and the serogroup B vaccine. The VPDP has prepared a meningococcal educational brochure which is posted to our web site at

http://www.state.nj.us/health/cd/documents/faq/meningococcal_faq.pdf . This document was last updated November 2014 and includes information about MenB disease and the availability of licensed vaccines against MenB. This document meets the requirements stipulated in statute. Institutions of higher education are permitted to disseminate their own materials. In addition to this resource, there are additional educational materials available through our web site for healthcare and public health professionals as well as the general public at http://www.nj.gov/health/cd/meningo/index.shtml. These materials are updated as necessary.

NJ Immunization Information System e.g. 'Immunization Registry' (NJIIS)

40 | P a g e

Q: What is NJIIS?

A: The NJ Immunization Information System (NJIIS) is a secure, computerized, statewide immunization registry that can help parents and health care providers keep track of immunizations given from birth through adulthood. NJIIS is managed by the NJDOH, Vaccine Preventable Disease Program and has been operating since 1997. For more information about joining NJIIS, go to: https://njiis.nj.qov/njiis/

Q: What is the 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 there a requirement for a physician's office to input immunizations into NJIIS within a certain time frame?

A: It is the responsibility of the health care provider—not the entity in which he/she operates—to assure that the data are entered or sent to NJIIS. The health care provider shall report to the NJIIS vaccines administered to children less than seven years of age within 30 days of administration. Practices that participate in the Vaccines for Children (VFC) program are required to enter all VFC doses administered, regardless of the patient's age, into NJIIS to demonstrate accountability for all doses of VFC vaccine. The health care provider must report all doses administered to children less than seven years of age to NJIIS, regardless of the funding source of the vaccine (VFC or private).

Some facilities transmit data to NJIIS through an interface. Health care providers should check with their administrators to make sure that ongoing data submission to NJIIS via interface is in place. If the data is not submitted via interface within this time period, it is the responsibility of the health care provider to report this information into NJIIS.

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.

41 | Page

Q: Does the state immunization registry, NJ Immunization Information System (NJIIS), produce an official record that can be used for immunization record auditing?

A: Yes, the NJIIS produces an official immunization record of a child's immunization history for child care, preschool, school, camp and college enrollment and can be used for immunization record auditing. Other examples of acceptable documents of immunization are the Department of Health, Standard School/Child Care Immunization record (also known as the IMM-8 or yellow card) and the Department of Education, State Health History and Appraisal Form (A-45). Anyone wishing to obtain a Standard School/ Child Care Center Immunization Record (IMM-8) can contact the NJ Department of Health, Vaccine Preventable Disease Program at (609) 826-4860. To obtain the A45 Health and Appraisal Record, please visit, http://www.state.nj.us/education/students/safety/health/records/hha.shtml.

Q: Are school nurses able to put vaccines in the registry?

A: Most school nurses have read-only access, which does not allow you to enter vaccine doses. If school nurses would like to add history or previous vaccine doses, they should contact the regional trainer for their county available at the following link,

https://njiis.nj.gov/njiis/jsp/trainingschedule.jsp

Q: Will shots listed as history appear on the official NJIIS record?

A: Yes, vaccine doses entered as history will be added to the official immunization record.

Q: How can you combine children's records during name changes such as adoption?

A: In order to merge the records, you will need to complete the NJIIS Duplicate Patient form (IMM-40) available at https://njiis.nj.gov/njiis/html/forms.html. Fax the completed form to Central Maternal and Child Health Consortia (MCHC) – NJIIS QA Unit at 732-246-3102.

Q: Can vaccine doses that were entered incorrectly be deleted from NJIIS?

A: Only the Site Manager of the practice who administered and entered the vaccine in NJIIS can delete data entry errors such as entering the incorrect vaccine administration date. In contrast, vaccine doses that were administered outside of the ACIP recommended vaccination schedule will

42 | P a g e

remain in the system. Please note, NJIIS has a built in four-day grace period which allows all doses administered less than or equal to four days before either the specified minimum age or dose spacing interval to be counted as valid and revaccination would not be required.

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://www2.aap.org/immunization/pediatricians/pdf/refusaltovaccinate.pdf

Q: Does NJ Department of Health (NJDOH) require a signed consent form prior to administering a vaccination? What is required of a health care provider before giving a vaccination?

A: No, NJDOH does not require a signed consent form prior to administering vaccination. However, healthcare institutions and facilities may have their own policies and procedures which may require a signature as a form of consent prior to the administration of vaccine.

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/. 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:

43 | P a g e

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://apps.who.int/immunization_monitoring/globalsummary

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.

For further questions pertaining to school immunization requirements, please send an email to immschoolquestions@doh.state.nj.us.
Please include all of your contact information, including your phone number, so your inquiry can be addressed in a timely manner.

44 | Page