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RULE ADOPTIONS

HEALTH AND SENIOR SERVICES
PUBLIC HEALTH SERVICES BRANCH
DIVISION OF EPIDEMIOLOGY, ENVIRONMENTAL, AND OCCUPATIONAL HEALTH
COMMUNICABLE DISEASE SERVICE
VACCINE PREVENTABLE DISEASE PROGRAM

40 N.J.R. 151(a)

Adopted Amendments: N.J.A.C. 8:57-4.5, 4.7, 4.8, 4.10, 4.11, 4.12, 4.15 and 4.16

Adopted New Rules: N.J.A.C. 8:57-4.18, 4.19, 4.20 and 4.24 and 8:57-4 Appendix

Communicable Diseases

Immunization of Pupils in School

Proposed: December 18, 2006 at 38 N.J.R. 5284(a).

Adopted: October 9, 2007 by Fred M. Jacobs, M.D., J.D., Commissioner, Department of Health and Senior Services in consultation with the Public Health Council, Herbert Yardley, M.A., Chair.

Filed: December 12, 2007 as R.2008 d.9, **with substantive changes** not requiring additional public notice and comment (see N.J.A.C. 1:30-6.3).

Authority: N.J.S.A. 26:1A-7 and 26:2-137.1b.

Effective Date: January 7, 2008.

Operative Date: September 1, 2008, except adopted new N.J.A.C. 8:57-4.23(b), which shall be operative January 7, 2008.

Expiration Date: September 25, 2008.

Summary of Hearing Officer Recommendations and Agency Responses:

The New Jersey Department of Health and Senior Services (Department) held a public hearing on the proposed amendments and new rules at N.J.A.C. 8:57-4 on January 26, 2007. The Department held the public hearing at the Health and Agriculture Building, First Floor Auditorium, 369 South Warren Street (at Market Street), Trenton, New Jersey. Notice of the public hearing appeared in the New Jersey Register at 38 N.J.R. 5284(a) (December 18, 2006). Angela Sorrells-Washington, Acting Program Manager of the Department's Vaccine Preventable Disease Program, served as the hearing officer.

Seventeen persons made verbal comments at the public hearing. The numbers in parentheses after each commenter serves to identify the commenter throughout the notice of adoption. The following three persons spoke in support of the proposed amendments and new rules: Sharon Clugston, RN, Hamilton Health Department (1), Larry Downs, New Jersey Medical Society (2), and John Surmay, Health Officer, City of Elizabeth and member, New Jersey Health Officer Association (3). The following 14 persons spoke in opposition to the proposed amendments and new rules: Sue Collins (NJ Alliance for Informed Choice in Vaccinations and parent) (4), Gayle DeLong, Ph.D.* (Advocates for Children's Health Affected by Mercury Poisoning and parent) (5), Hilary Downing* (parent) (6), Barbara Flynn (Children Having Everybody Upset Bout Shots (CHERUBS) and parent) (7), Amy Galaraowitz (Holistic Mom's Network and parent) (8), John Gilmore (Advocates for Children's Health Affected by Mercury Poisoning) (9), Bret Hartman (Doctor of Chiropractic) (10), Beth Hoffman* (parent, Councilwoman, Wenonah) (11), Richard Marzo, (Doctor of Chiropractic and parent) (12), Barbara Sachau (13), Brian Selfridge (parent) (14), Alan Seletsky (parent) (15), Christopher Stappas (16), and Karen Steinberg (parent) (17). Three persons who also submitted letters subsequent to giving verbal testimony at the public hearing are indicated by an asterisk (*).

After reviewing both the testimony presented at the public hearing and the written comments, the hearing officer recommended that the Department proceed with the adoption of the amendments and new rules with the changes discussed in the Summary of Public Comments and Agency Responses and the Summary of Agency-Initiated Changes. The record of the public hearing is available for inspection in accordance with applicable law by contacting:
Department of Health and Senior Services
Communicable Disease Service
Vaccine Preventable Disease Program
PO Box 369
Trenton, NJ 08625-0369

Summary of Public Comments and Agency Responses:

The Department received written comments from the following individuals on or before the close of the 60-day public comment period, which ended on February 16, 2007.

The following nine commenters support the proposed amendments and new rules and/or suggest some changes: Marlene Dolan, RN, Public Health Nurse, Madison Department of Health (18), Barbara Gantwerk, Acting Assistant Commissioner, Division of Student Health Services, New Jersey Department of Education (19), Susan Hodgson, M.D., Child Advocate, New Jersey Office of the Child Advocate (20), Robert L. Morgan, M.D., Chief Medical Officer, New Jersey Department of Children and Families (21), Danielle B. Peloquin, RN, Supervisor of Nurses, Middlesex County Health Department (22), Janice Prontnicki, M.D., President, American Academy of Pediatrics (AAP) - New Jersey Chapter (23), Sanofi Pasteur Corporation, Department of Public Policy (24), Carolyn Torre, RN, APN, Director of Practice, New Jersey State Nurses Association (25), and Sherry Workman, Executive Director, National Association of Child Care Professionals (26).

The following 55 commenters mainly oppose the proposed new vaccines, especially the influenza vaccine: Jane Armitsis (27), James Argullo, Jr. (28), Heather Balog (29), George Bancora (30), Terri Barnable (31), Michelle Bick (32), Melissa Breda (33), Charles Butman (34), Carla Crow, RN (35), Valerie DePascale (36), Rev. John den Hoed and Edward Nieuwenhuis, Ebenezer Netherlands Reformed Church (37), David den Hollander, Netherlands Reformed Congregation (38), Tanaz Dutia (39), Kathleen Estenes, RN (40), Brian Fennelly (41), Sam and Joan Garner (42), Sharon Harris (43), Elizabeth Hathaway and Christopher Muir (44), Ann Hirsh (45), Deirdre Imus, Deirdre Imus Environmental Center for Pediatric Oncology (46), Jean Mager Johnson (47), Paul G. King, Ph.D., Coalition for Mercury Free Drugs (48), Loretta Krause (49), Debra Kurtz (50), Gabriella Landman (51), Lucia Leivylah (52), Elaine and Michael Lyons (53), Mr. and Mrs. Kevin Lyons (54), Elizabeth Main (55), Holly Masclans (56), Donna Moscatello (57), Ralph Moscatello (58), Mr. and Mrs. Todd Mizenko (59), Nancy Nouel (60), Michelle O'Neill (61), Tom Petrie, New York (62), Jennifer Postiglone (63), Sal and Sandie Prestipino (64), Maria Quigley (65), Michaela Redden (66), Lawrence Rosen, M.D., Deirdre Imus Environmental Center for Pediatric Oncology (67), Robert and Mary Sabo (68), Alicia Salerno (69), Jane Silane (70), Laurie Sullivan (71), William Sullivan (72), Dana Tromeur-Nach (73), John Van Der Brink, Netherlands Reformed Christian School (74), Assemblywoman Charlotte Vandervalk (75), Mary Jane Venteerini (76), JoAnn Wilson (77), Janice Wolf (78), Wayne Yankus, M.D. (Committee on School Health, AAPNJ) (79), Leanna Zoilkowski (80), and Michael Lyons (81).

The Department received 26 form letters from commenters opposing mandatory vaccinations due to the presence of the preservative thimerosal in vaccines, including the influenza vaccine, and expressing their need to have a parental choice or philosophical exemption from the immunization rules: Stacy and Marc Balzano (82), Lisa Barklow (83), Diane Brewin (84), Nancy Burke (85), Bridget Cella (86), Simon and Jennifer Deutsch (87), Arlene Fikentscher (88), Michelle and Chris Fiordaliso (89), Wendy Huston (90), Karen Johns (91), Natalie Kautz (92), Joanne Kirschner (93), Beth Laliberte (94), Aisha Mir (95), Sharon Martucci (96), Nicole Neiser (97), Donna Peterson (98), Mary and Bruce Rudilosso (99), Geraldine Sharkey (100), Mr. and Mrs. William Sharkey (101), Jennifer Tomkow (102), Stella Tomkow (103), Lisa Weiss (104) and Michael Weiss (105). The Department received two of the same form letters from Sharon Begin (106) and Elizabeth Thompson (107), who reside in other states.

The Department received 13 form letters from the following commenters that oppose any new mandated vaccines for children, especially the influenza vaccine, expressed concern over the quality and safety of vaccines, and expressed the need for a parental choice exemption from the immunization rules: Margaret Anderson (108), Gail Burkett (109), Karen Feriana (110), Allison Fleck (111), Carol Hartl (112), Alda Joffe (113), Carmela Harrison (114), Grace Marino (115), Mr. and Mrs. Charles McCabe (116), John O'Connell (117), Janet Serafino (118), Ira Stein (119) and June Wingate (120).

A summary of the comments and the Department's responses follows.

1. COMMENT: Three commenters expressed support for the proposed amendments and new rules to N.J.A.C. 8:57-4. I have witnessed and been responsible for the follow up of vaccine preventable diseases. Vaccines provide protection for all to prevent disease morbidity and mortality and I support these proposed immunization rules. (1) As a licensed pharmacist and local health officer, I commend these proposed rules and we endorse that concept. (3) It is the policy of the Medical Society that the benefits of vaccines are immeasurable and outweigh the risks. There is no scientific evidence that vaccines cause autism. There's a greater risk of infectious disease than there is of vaccine associated risks. (2)

RESPONSE: The Department acknowledges and appreciates the support of the three presenters and the organizations they represent.

2. COMMENT: Public health nurses were not solicited for their comments relative to the proposed amendments and new rules. (18) Two other commenters stated that the proposal to mandate four new vaccines to the immunization rules was not widely publicized or known among the public. (4 and 10)

RESPONSE: The Department proposed amendments and new rules at N.J.A.C. 8:57-4 in accordance with the proposal procedures established in the rules for agency rulemaking at N.J.A.C. 1:30-5. On December 18, 2006, the Department published a notice of proposal for amendments and new rules in the New Jersey Register at 38 N.J.R. 5284(a). The Department held a public hearing on January 26, 2007. The public comment period ended on February 16, 2007. Additionally, the Department also provided the notice of proposal to at least 29 interested parties, including, but not limited to, professional physician and nursing organizations, public health organizations, other affected State Departments, and citizens known to oppose or support immunization requirements. The Department also provided notice of the proposal through a press release, by posting on the Local Information Network and Communications System (LINCS), and a posting on the Department's website. The Department believes that the public health nurses have had an opportunity to comment on the proposed amendments and new rules.

3. COMMENT: The commenter strongly requested that the Department strictly define valid doses based upon the Advisory Committee on Immunization Practices (ACIP) recommended minimum age at which each specific vaccine is to be administered and the minimum interval between each specific vaccine dose in a multiple dose series in the rules because a qualitative, not just a quantitative evaluation of vaccines given should be part of the auditing review when determining rule compliance. (18)

RESPONSE: The ACIP recommended immunization schedule in recent years has become more complex as new vaccines, different formulations, vaccine combinations, and different brands of the same vaccine have become licensed for use. If the Department were to strictly mandate the minimum age for each vaccine and the minimum spacing between the same vaccine series doses or different vaccine doses, the immunization record review for the purpose of assessing school records, would create additional technical and administrative difficulties for child care administrators and school nurses in their review, assessment, and school compliance reporting of pupil records. The Department has never deemed it necessary to specify a minimum age in the rules with the exception of measles, mumps, rubella, and varicella. The Department believes that there are already sufficient minimum age and interval specifications and other timing parameters within the existing rules, and that to add further specificity as to what constitutes a "valid dose" would only add more administrative work, repeat vaccinations, serologic tests to prove immunity, and other increased economic costs without realizing a significant improvement in the personal health of the pupil or the public health. The Department established the rules to ensure that minimum vaccine requirements are met before a child can attend a child care center or school as noted at N.J.A.C. 8:57-4.20, recodified as N.J.A.C. 8:57-4.23, Optimal immunization recommendations. The audit of pupil immunizations records in schools is conducted to assess a school's compliance with correctly interpreting and enforcing the existing immunization rules and to validate the accuracy of the school's Annual Immunization Status Report, rather than to retrospectively determine the degree of compliance of a pupil's immunization record with the ACIP recommended minimum ages and minimum intervals for each vaccine. The existing New Jersey immunization rules regarding ages and intervals are not unlike those found in most other states. The Department does not agree with the commenter that there should be a more rigorous, technical criteria regarding the minimum age and minimum interval for each

vaccine and dose of a vaccine series, through a definition of valid doses written into the immunization rules at this time.

4. COMMENT: The commenter objected to deletion of the language "appropriately spaced" at N.J.A.C. 8:57-4.10(e), diphtheria and tetanus toxoids and pertussis vaccine and N.J.A.C. 8:57-4.11(a), poliovirus vaccine since all vaccine doses should be evaluated according to the ACIP minimum age and minimum interval recommendations for vaccine administration. (18)

RESPONSE: The previous use of the term "appropriately spaced," without additional guidance, resulted in some misinterpretation and disagreement among physicians, schools, and local health departments. The words "appropriately spaced" in the existing rules only appear in the subsections related to the diphtheria, tetanus, and pertussis (DTP) and the poliovirus vaccine, and none other. The deletion of that language will make those two vaccines consistent with the other vaccine series, such as HIB, hepatitis B, and pneumococcal conjugate vaccine. The term "appropriately spaced" had only applied to the recommended interval between doses within a specific vaccine series, it was not meant to apply to a minimum age. The issue of interpreting "appropriately spaced" will become even less of an issue since the ACIP has stated that, with the four-day grace period, doses of DTP and poliovirus vaccine can be given as close as 24 days apart. The Department does not agree that the term "appropriately spaced" should be retained in the existing rules at this time.

5. COMMENT: The commenter asked the Department how MMR and varicella vaccines when given on or after 12 months of age would be handled when given at less than a 28-day interval. (18)

RESPONSE: The Department believes the commenter asks the question in relation to follow-up doses of the two vaccines. Two doses of varicella vaccine (Varivax(TM)) are not required at N.J.A.C. 8:57-4.17, therefore there is no need to specify a time interval to a second varicella dose at this time. Two doses of a measles-containing vaccine are required at N.J.A.C. 8:57-4.12(a), which specifies that the second dose be given no less than one month after the first dose. The four-day grace period established at N.J.A.C. 8:57-4.23(b) allows a second dose of a measles-containing vaccine to be given as soon as 24 days after the first measles-containing dose, which would satisfy the measles requirement for school auditing purposes. Specific vaccine requirements within this subchapter apply to each separate vaccine in isolation of the other vaccines within this subchapter. The Department has never established specific rules that scrutinize or address the dose interval relationships among the various live virus vaccines, such as oral polio, measles, mumps, rubella or MMR, varicella, or the measles, mumps, rubella and varicella vaccine (MMRV) for school auditing purposes.

6. COMMENT: The commenter appreciated that the Department has incorporated a four-day grace period for those vaccines where a minimum age is specified in the immunization rules and has also shortened the time permitted for a child to complete the hepatitis B immunization vaccine series. (18)

RESPONSE: The Department appreciates the support of the commenter for these proposed two amendments. The Department intends to make the four-day grace period at N.J.A.C. 8:57-4.23(b) effective upon publication of the notice of adoption, rather than waiting until September 1, 2008. The Department discusses the September 1, 2008 operative date in the Response to Comment 7 below. This action will serve to bring these rules into more immediate conformity with the practices of most pediatricians and physicians following the published ACIP and AAP recommendations, which allow for a four-day grace period. This action will eliminate friction between physicians, parents, and the existing immunization rules being enforced by schools and local health departments due to the current incongruity between the existing State rules and the recommendations of the major childhood vaccine advisory groups. Implementing the four-day grace period upon adoption rather than waiting until September 1, 2008 will eliminate the need for some children to receive unnecessary blood tests to demonstrate immunity or receive additional and unnecessary revaccinations. This action will also save both direct and indirect costs for parents and physicians alike as preschoolers are seen during their routine pediatric visits or as their immunization records are being reviewed for new admission into a child care center or school. The Department believes that making the four-day grace period operative upon adoption, rather than September 1, 2008, will be unanimously welcomed by physicians, clinics, schools, child care centers, and local public health departments alike.

7. COMMENT: The commenter advised the Department that a September 1, 2007 effective date for the proposed amendments and new rules appears unrealistic given the absence of adopted rules and insufficient time to effectively notify and educate physicians, parents, health care providers, child care facilities, schools, and local health departments. (18) Three other commenters also stated there is insufficient time to implement these four new vaccines requirements by September 1, 2007. (35, 40 and 79)

RESPONSE: The Department recognizes that it will not be possible to meet the tight timeline for completion of the rulemaking process and complete all the steps necessary to implement the proposed amendments and new rules by September 1, 2007. The Department has decided on adoption to postpone the operative date of the amendments and new rules and related enforcement actions, with the exception of N.J.A.C. 8:57-4.23(b), to September 1, 2008, realizing that there is insufficient time to complete the administrative rulemaking process and to notify and prepare the participating parties for significant changes, which will simultaneously add four new vaccines to the immunization rules. Although such a change on adoption is substantive, the change does not require additional notice and opportunity to comment because the substance and requirements of the rules, with the exception of the operative date remain the same. This change is necessary because by the time the notice of adoption is published in the New Jersey Register and the rules become effective, the original September 1, 2007 date will have passed and the school year will have already started. The Department has consistently only implemented new rules or amendments to N.J.A.C. 8:57-4 to coincide with the start of each new school year on September 1. A September 1 date enables children affected by the new rules to be vaccinated during the late winter and early spring "round-up" sessions held by schools as they begin to enroll prospective new pupils and advise parents of the various requirements, including health and immunizations, necessary to be met by the beginning of the new school year. Physicians also use the nine to 12 months leading up to school entry to have their pediatric patients catch up or complete the ACIP recommended or the State required vaccinations. To implement new vaccines in the middle of the school year creates unnecessary administrative complexity for parents, physicians, schools, child care centers, and local health departments. Historically parents, physicians, schools, child care centers, and local health departments have required approximately one year in advance of a new vaccine requirement to ensure smooth implementation and enforcement of the immunization rules for children in school. Physicians require sufficient advance notice of new vaccine requirements so they can make special plans to purchase more vaccines and adjust patient appointments to meet increased demand for vaccine and administration services in their offices. Influenza vaccine is only available for physicians to order up to May 1 of each year for the fall flu season. Schools and child care centers are required to submit an Annual Immunization Status Report to the Department, Vaccine Preventable Disease Program by January 1 of each year, which reports on the immunization status of all new pupils who entered school after September 1 of each year and it would be administratively difficult, duplicative, and confusing to submit this report based upon pupils who entered in mid-year under a different set of immunization rules than those who were in school around September 1. The extension of the operative date of these amendments and new rules would mean that the tetanus, diphtheria, and acellular pertussis vaccine (Tdap), pneumococcal conjugate vaccine (PCV), influenza, and meningococcal conjugate vaccine (MCV), requirements would apply uniformly to a later age cohort of children. This action to extend the operative date of these rules to September 1, 2008, is preferable to all concerned parties, rather than making it operative upon adoption in the middle of a school year.

8. COMMENT: The New Jersey Department of Education (NJDOE) generally supports the new rules but has concerns that a large number of children attending preschool programs in school settings will have difficulty accessing the pneumococcal conjugate vaccine (PCV) and the influenza vaccine, due to lack of medical insurance. NJDOE requests that the Department consider establishing short-term vaccination clinics in

schools to provide these vaccines at no cost to parents. (19)

RESPONSE: The Department recognizes and appreciates the work performed at local school districts to implement and enforce the immunization rules. While the Department cannot provide personnel, free vaccines, or direct support services, the local health departments and the Department can provide technical assistance and advice on implementation matters. Since the original implementation of the immunization rules in 1974 through 1975, the Department has not provided direct vaccination services to local schools or child care centers unless there was a vaccine preventable disease outbreak or other special circumstances. National vaccine coverage surveys conducted by the Centers for Disease Control and Prevention (CDC) for 2006, indicated that 85 percent of New Jersey's children 19 through 35 months of age had received PCV. It is anticipated that with the current physician and parental acceptance of the PCV and the already high levels of PCV vaccine coverage, additional effort to comply with the PCV requirement will be minimal. Provisional data from the Behavior Risk Factor Surveillance System for the 2004 to 2005 Influenza Season indicated that approximately 63 percent of children aged six through 23 months in New Jersey had received the annual influenza vaccination. Another survey, the 2005 National Immunization Survey (NIS) by CDC, estimated that about 37 percent of New Jersey children six through 23 months of age in 2004 had received at least one dose of influenza vaccine. The Department recognizes that the implementation of the influenza vaccine requirement for children in school-based preschool settings will be more difficult than meeting the PCV requirement due to the shorter four month window of September through December in which a preschooler six through 59 months of age will be required to obtain an annual influenza vaccination from the same private physician or regular health care practitioner providing their other immunizations and preventive pediatric health care services. The Department's intent is to ameliorate any potential access problem by permitting the child to be vaccinated with influenza vaccine anytime between September 1 and December 31 of each year. The Department has also added language in the immunization rules at N.J.A.C. 8:57-4.22(d) articulating the Commissioner's authority to suspend any vaccine requirement under N.J.A.C. 8:57-4 in the event of a specific vaccine shortage affecting the nation and New Jersey after notification to the public and to those institutions and agencies most responsible for the immunization of children and implementation of the immunization rules. The Department does not agree that special school-based immunization clinics for preschool children are necessary or should be established by the Department at this time.

9. COMMENT: The New Jersey Department of Education expressed concern over the apparent discrepancies that exist between N.J.A.C. 8:57-4.5(e), which provides a 30-day grace period only for out-of-State or out-of-country pupils to obtain past medical records and the NJDOE rules at N.J.A.C. 6A:17, particularly N.J.A.C. 6A:17-2.6(g), concerning homeless student records, which state that a homeless student shall be immediately enrolled despite the absence of normally required medical records. NJDOE asks the Department to rectify this conflict with the NJDOE regulations. (19)

RESPONSE: The Department acknowledges and appreciates the NJDOE's concern and responsibility to promptly enroll homeless students in an educational program. The Department is within its public health and statutory authority at N.J.S.A. 26:1A-9 to mandate vaccines as a condition of entrance and continued attendance in a school, preschool, or child care center. Since 1974, the Department has required all in-State pupils to document at least one dose of each required vaccine in order to be granted provisional status (see N.J.A.C. 8:57-4.5) enabling them to remain in school while completing the specific vaccine series appropriate to their age or grade. Only beginning in 1999, were out-of-State and out-of-country pupils permitted, explicitly by rule, a 30-day grace period because of the greater difficulty they often experience in retrieving a copy of their immunization records from out-of-State or out-of-country physicians, clinics, or schools compared to in-State pupils whose immunization records are more accessible, familiar and proximate to in-State physicians, clinics, or schools connected to those pupils.

The Department does not agree with the commenter's recommendation that the rules should be amended by adding language that would specify homeless pupils as a special class of enrolling pupils. The Department believes that such a prolonged grace period of 30 days or longer, for a child that has resided in New Jersey and received health services here, unduly places the school or child care center, its enrollees, and employees at higher risk for disease transmission and outbreaks in congregate settings that are vaccine preventable.

With increased utilization of the New Jersey Immunization Information System (Immunization Registry) and access to those records by school nurses, it is anticipated that over time, accessing past immunization documentation of enrolling pupils will require less effort and time for parents, physicians, and school nurses. In those special instances of homeless students seeking enrollment, the Department supports ongoing efforts of the school nurses, district liaisons, and local health departments working together to obtain past vaccination documentation of homeless children, as they have in the past for victims of floods, fires, or hurricanes in an expeditious manner for the purposes of ensuring the school health and public health as specified in N.J.A.C. 8:57-4 and also consistent with the educational goal of N.J.A.C. 6A:17.

The Department is unaware of any homeless children being refused entry into a school because they were unable to provide vaccine documentation. The Department will monitor any inquiries from parents, schools, or local health departments concerning this issue and if problems become evident, will work with the NJDOE to resolve an issue where homeless children are being refused entry from school due to lack of an immunization record.

10. COMMENT: The Office of the Child Advocate generally supports the new rules but has concerns that vaccine shortages and vaccine distribution problems can create difficulties as children cannot comply with the various vaccine requirements when the vaccine is not available at private and public sector health providers, including those that rely almost exclusively on vaccines provided by the Vaccines For Children Program (VFC) and therefore a 60-day provisional admission into a school or child care setting should be permitted upon physician documentation that a parental attempt to obtain the necessary vaccine has been made. The commenter also expressed concern that the steps taken to alleviate a vaccine shortage at N.J.A.C. 8:57-4.22(d) are inadequate, as they only would apply if there is a national vaccine supply shortage affecting New Jersey. (20)

RESPONSE: The Department acknowledges and appreciates the general support of the Office of the Child Advocate to add four vaccines to the list of required immunizations for pupils in child care centers and schools. The Department concurs with the observation of past national vaccine supply and distribution problems, most of which are beyond the control of the Department and cannot be predicted. When vaccine supply and distribution problems arise they adversely effect the supply of privately purchased and publicly purchased vaccines alike and affect all health care providers. The Department believes the language at N.J.A.C. 8:57-4.22(d) is sufficient to address any need to suspend a given vaccine requirement as it articulates the Commissioner's authority to suspend enforcement in the event of a national or State vaccine shortage. The Department has relaxed the immunization rules in previous years when other vaccine shortages prevented pupils from timely compliance with the immunization rules. The Department anticipates that this new subsection will better articulate a process to meet any imminent vaccine supply crisis. The Department does not agree it is necessary to establish a special 60-day provisional admission period in these rules as a means of dealing with a vaccine shortage. The Department believes that a formal notice of suspension of a specific vaccine requirement due to a shortage by the Commissioner is sufficient to ensure that no child will miss school or child care attendance due to a vaccine shortage, which may persist even beyond 60 days. In the past, school officials and local health officials have been reasonable in accepting communications from a physician explaining why a specific child seeking vaccinations cannot receive a required vaccine at the appointed time, due to reasons beyond the parent's control, such as a physician's lack of vaccine inventory.

11. COMMENT: The New Jersey Department of Children and Families (NJDCF) supports the proposed amendments and new rules adding four new Food and Drug Administration (FDA) licensed vaccines for children in child care centers and schools to the list of required vaccines that have

been recommended and endorsed by the Advisory Committee on Immunization Practices (ACIP), American Academy of Pediatrics (AAP), American Academy of Family Physicians (AAFP), and Centers for Disease Control and Prevention (CDC), United States Public Health Service. (21)

RESPONSE: The Department acknowledges and appreciates the support of the NJDCF in promoting the health of New Jersey's children by adding the proposed amendments and new rules to N.J.A.C. 8:57-4.

12. COMMENT: Will the Department allow a 30-day grace period prior to provisional status for out-of-State and out-of-country pupils to enter school without documentation of at least one dose of each vaccine as being administered? (22)

RESPONSE: The Department will allow a 30-day grace period prior to the onset of provisional admission for a new pupil first entering a New Jersey school from out-of-State or out-of-country. Since 1984, the Department has permitted local school districts to offer incoming pupils from out-of-State or out-of-country a 30-day grace period the first time they enter a New Jersey child care center or school in order to obtain past immunization records from out-of-State or out-of-country physicians or clinics where the pupils may have received vaccinations, due to difficulties some parents encountered in retrieving vaccination documents from distant locations. The Department's proposed amendment at N.J.A.C. 8:57-4.5(e) only changes the word "may" to "shall" to ensure Statewide uniformity and equity in applying this subsection for these children that are new residents of New Jersey.

13. COMMENT: The commenter expressed the concern that the proposed language at N.J.A.C. 8:57-4.10(e) may be unclear to school nurses and local health department immunization record audit staff and suggests that at N.J.A.C. 8:57-4.10(e) the language should read, "Children nine (9) years and older who have not completed this requirement shall receive tetanus and diphtheria toxoids (adult Td) or tetanus, diphtheria and acellular pertussis (Tdap) instead of DTP. . ." (22)

RESPONSE: The Department does not agree that the Tdap vaccine requirement proposal be changed as the commenter suggests at this time. The Department is aware that there are two Tdap vaccines licensed by the FDA that can be given respectively as early as 10 or 11 years of age and this fact has created a degree of complexity to the proper administration of this one time booster vaccination. The Department believes that the proposed language at N.J.A.C. 8:57-4.10(e) is medically correct since at this time no Tdap vaccine formulation is licensed by the FDA for nine year old children and the Tdap dose can only be used as a one time booster dose following the completion of a vaccine series comprised of DTP, DTaP, DT, or Td. The Department will monitor the implementation of the new Tdap vaccine booster rule and, if necessary, will provide additional guidance to schools and local health department staff who assess and audit immunization records for compliance with the immunization requirement.

14. COMMENT: The commenter expressed concern that insufficient supplies of influenza vaccine, as has occurred in the past, will make it difficult for physicians, parents, and child care centers to implement the proposed new influenza rule, and can create problems for local health departments as they audit child care center immunization records for the annual influenza vaccination. (22)

RESPONSE: The Department acknowledges the commenter's concern over the availability of influenza vaccine given the national supply and distribution problems experienced in recent years. The Department expects that with each successive year there will be larger quantities of influenza vaccine available for pediatric use. In the event of a national or State vaccine shortage, the Department will now be able to more expeditiously suspend a specific vaccine requirement to cope with a shortage as established in the proposed subsection at N.J.A.C. 8:57-4.22 (d). The Department will provide local health authorities additional guidance regarding the audit of influenza vaccine records upon implementation of this rule after September 2008, and as it relates to the auditing of influenza vaccination records in child care centers that may require unique auditing standards for this particular vaccine in the event of an influenza vaccine shortage.

15. COMMENT: Our State chapter of the American Academy of Pediatrics (AAP) supports the proposed amendments and new rules to add the four new vaccines that are recommended by the ACIP, AAP, AAFP, and CDC, United States Public Health Service. These vaccines have been proven to be safe and effective for children. We suggest that in the future a mechanism be put into place whereby each time a new pediatric vaccine becomes licensed, and then recommended by the ACIP that it automatically become part of the State vaccine requirements. Such a mechanism will shorten the delay between licensure and recommendation for new vaccines and the establishment of State mandates. (23)

RESPONSE: The Department acknowledges and appreciates the support of the New Jersey Chapter of the AAP for the proposed addition of four recently licensed and ACIP recommended vaccines to the State immunization requirements. As medical practitioners and pediatricians are aware, the recommended vaccine schedule is becoming increasingly crowded and more complex. This complexity makes it more difficult to implement, administer, monitor, and enforce new immunization requirements. In addition there are other issues such as age indications, disease epidemiology, multiple vaccine products, costs, disease severity, vaccine safety profile, vaccine efficacy, ease of implementation, and the public, parental, and physician acceptance of a new vaccine to consider. While there may be some minimal administrative advantage to simply adopting all the ACIP recommendations as new State immunization requirements, the Department prefers to maintain administrative flexibility by continuing the current rulemaking process of considering recent ACIP vaccine recommendations and proceeding in a more deliberative fashion evaluating whether or not, and when, a vaccine should be required for children as a condition to attend a licensed child care center or school. The Department does not believe that each newly licensed and nationally recommended vaccine should be automatically added to the required vaccines set forth at N.J.A.C. 8:57-4 for child care center and school entry.

16. COMMENT: The Sanofi Pasteur Corporation generally supports the addition of four ACIP recommended vaccines to the list of required vaccines at N.J.A.C. 8:57-4, but suggests that the Department add language to the meningococcal vaccine rule to clarify that the meningococcal conjugate vaccine, Menactra(TM) cannot be administered to children younger than 11 years of age. (24)

RESPONSE: The Department appreciates the support of the commenter for the addition of new immunization rules. The Department is aware that there are two different meningococcal vaccines with different and overlapping age indications. The meningococcal polysaccharide vaccine or Menomune(TM), is licensed by the FDA for administration to persons two years of age or older, while the meningococcal conjugate vaccine, Menactra(TM) is only licensed for use in persons 11 through 55 years of age. While the meningococcal conjugate vaccine is the preferred vaccine for 11 through 12-year-old children in Grade Six, there will be some children who as a result of living or traveling to the "meningitis belt" from Africa to the Middle East, or as a result of having a chronic condition, will have received the meningococcal polysaccharide vaccine previously in the years before their 11th birthday. In the event of conjugate vaccine shortages, the polysaccharide vaccine can also be used as an alternative vaccine. In the event of meningococcal outbreaks, either vaccine can be used. Both vaccines are considered by the FDA to be safe and effective. Further, the FDA is currently considering the expanded licensure of the meningococcal conjugate vaccine for children two through 10 years of age. The Department does not believe it is appropriate to specify in the rule that the meningococcal conjugate vaccine is the only vaccine that will be acceptable to meet the meningococcal vaccine requirement for children entering Grade Six while others may be licensed soon, or to set an age indication, which is likely to be lowered soon. Setting such strict standards now may result in many vaccines being unduly declared as invalid and would require that children unnecessarily receive additional or repeat vaccine doses. The Department expects that most physicians will be purchasing and administering the ACIP recommended and preferred meningococcal conjugate vaccine to children at 11 years of age as it coincides with the usual age at the Grade Six level. The Department also expects that outreach and

marketing efforts to physician office practices by pharmaceutical company representatives will be reinforcing its use for that age group. The Department believes that the proposed language is sufficient as it provides for a minimum of protection against meningococcal disease while maintaining flexibility in the implementation of this new rule. The Department will continue to monitor changing FDA licensure, newly licensed meningococcal vaccine products, ACIP recommendations, CDC statements, and physician practice related to the use of meningococcal vaccines and, if necessary, will consider more specific or different language in future rulemaking. The Department does not agree with the suggestion to set a minimum age for the meningococcal conjugate vaccine at this time.

17. COMMENT: The New Jersey State Nurses Association (NJSNA) supports the proposed amendments and new rules adding four new vaccines as licensed by the FDA and recommended by the ACIP, AAP, and AAFP to the list of required vaccines at N.J.A.C. 8:57-4. The NJSNA also supports the addition of a four-day grace period for the timing of vaccines, and that a pupil's health record be kept separate from his or her educational record for privacy purposes. (25)

RESPONSE: The Department acknowledges and appreciates the support of the NJSNA and their commitment to improving the health of school children in New Jersey.

18. COMMENT: The National Association of Child Care Professionals supports the proposed amendments and new rules that require children to be age-appropriately immunized before admission to a licensed child care center, particularly for the pneumococcal conjugate vaccine and further suggests that the Department also add hepatitis A vaccine to the list of required vaccines at N.J.A.C. 8:57-4 for child care center attendance. (26)

19. COMMENT: One commenter stated it is inappropriate to urge hepatitis A vaccine for children. (10)

RESPONSE TO COMMENTS 18 AND 19: The Department acknowledges and appreciates the support of the National Association of Child Care Professionals for urging that the recommended and age-appropriate immunizations shall be received by all children before entering a child care setting. Although hepatitis A vaccine is now an ACIP recommended vaccine for all children over one year of age, the Department only plans to implement influenza and pneumococcal conjugate vaccine requirements for children in preschool or child care centers through this rulemaking process. The Department chooses to maintain its flexibility in determining which vaccines and when, through public rulemaking, are to be added to the list of required vaccines for child care center or school attendance at N.J.A.C. 8:57-4. The Department will monitor issues related to the consideration and possible inclusion of hepatitis A, other recently licensed vaccines, and ACIP recommended pediatric vaccines to the list of required vaccines at N.J.A.C. 8:57-4 in future rulemaking actions.

Opposition to the Proposed Amendments and New Rules

Persons or organizations who presented at the public hearing on January 26, 2007 or others who wrote during the 60-day public comment period in opposition to the proposed amendments and new immunization rules for child care center attendance and school entry, presented similar themes or concerns that have been organized into 34 major comment issues, numbered as 20 through 93. There was one person (48) who specifically expressed opposition to a number of other provisions and suggested changes whose comments primarily comprise those numbered as 94 through 103.

The comments of those persons in opposition of the proposal and the Department's responses are listed below:

20. COMMENT: Vaccines in general, and especially influenza vaccine, should be left to parental choice and not be required by government authorities. (4, 6, 7, 8, 9, 10, 13, 15, 17, 27, 29, 31, 32, 33, 34, 36, 41, 43, 44, 49, 50, 53, 54, 57, 58, 59, 61, 62, 63, 65, 66, 73, 76, 77, 78, 80, 81 and form letters 82 through 120)

21. COMMENT: Many commenters stated that if flu or any other vaccine continues to contain thimerosal or until the quality and safety of vaccines are improved, parents should have the right to decide whether or not to have their child receive the vaccine. (form letters 82 through 120)

RESPONSE TO COMMENTS 20 AND 21: As discussed in the Summary of the N.J.A.C. 8:57-4 Notice of Proposal at 38 N.J.R. 5284(a), the Department promulgated the rules at Subchapter 4 to implement and meet its mandate established at N.J.S.A. 26:1A-7 and 26:2-137.1b. In particular N.J.S.A. 26:1A-7 authorizes the Department to establish rules that "cover any subject affecting public health and the prevention of disease including immunization against disease of all school children in the State of New Jersey." Across this country state legislatures and state agencies have mandated certain vaccinations as a condition of school or child care center entry. All but two states, West Virginia and Mississippi, permit religious exemptions to mandatory vaccinations. Approximately 19 states with religious exemptions also permit philosophical exemptions.

Through the implementation and enforcement of State immunization laws, disease transmission in school settings has dramatically decreased, as has the morbidity and mortality of these vaccine-preventable diseases among the general population. Given the high density of New Jersey's population, our past history of multiple vaccine-preventable disease outbreaks affecting children, a highly mobile population, a high number of recently arrived, documented and undocumented immigrants, and the corridor state nature of New Jersey, it is prudent to ensure that the highest number of children possible receive vaccines to protect them and others from those vaccine-preventable diseases for which no generally effective treatment exists. It would be imprudent from a public health policy and administrative perspective to allow parents to pick and choose which, if any, of the required vaccines for school entry their children will receive. There will be a small percentage of children with religious and valid medical exemptions to immunization; however, school officials, other parents, and most of the public support the protection of the greatest number of school children possible from acquiring or transmitting vaccine-preventable communicable diseases in educational settings where children congregate.

The Department continues to believe that the immunization requirements articulated in these rules provide a safety net to ensure that all children in child care centers or schools are protected through vaccinations, are equitable in that all enrolled children are expected to comply with the rules unless a religious or medical exemption is granted, contribute to a healthful learning environment, and represent sound medical, school health, and public policy. These rules over time may also help to eliminate racial health disparities as they pertain to vaccine protection levels among some segments of the population.

Most parents expect that their children will attend schools or child care facility settings that are as disease-free or risk-free as possible so that the educational process is not disrupted. The ability to transmit pertussis, meningococcal disease, pneumococcal disease, and influenza through the respiratory route before characteristic symptoms become apparent, puts other unsuspecting and susceptible persons at risk of acquiring and spreading disease.

The Department does not support a change through rulemaking that would permit the addition of a philosophical or parental choice exemption to the rules in this subchapter because such a change may lead to an increased number of children not being immunized, which can lead to

more cases of vaccine preventable diseases and subsequent complications and possible deaths that can follow thereby adversely affecting the health of children, the school community, and the larger society. It is outside the authority of the Department to create a parental choice, conscientious exemption, or philosophical exemption to these immunization rules as the addition of a philosophical exemption would require actions by the New Jersey Legislature. The Department believes that the language at N.J.A.C. 8:57-4.4(a) is sufficient for those parents requesting a religious exemption.

22. COMMENT: One commenter whose son had been damaged by a vaccine as a child and also has autism, is a parent advocate who now assists other parents in writing religious exemptions. The commenter stated that since some school system staff are improperly asking parents seeking a religious exemption what their religion is, there needs to be a philosophical exemption. (7 and 10)

RESPONSE: The Department agrees with the commenter that school system staff should not be asking parents seeking a religious exemption, what religion they practice. It has been the policy of the Department since 1974 to advise school personnel that it is not proper to ask a parent for his or her religion as a requirement or condition necessary for submission of a religious exemption. Religious exemptions are granted at the local school level on case-by-case basis as described at N.J.A.C. 8:57-4.4(a). The Department does not agree that there should be a philosophical exemption because of the issue presented.

23. COMMENT: One commenter noted that she had heard reports that some church affiliated parochial schools are improperly refusing to grant religious exemptions, therefore, there needs to be a philosophical exemption. (65)

RESPONSE: The Department disagrees with the commenter's suggestion that there should be a philosophical exemption in N.J.A.C. 8:57-4 for situations where church affiliated parochial schools refuse to grant religious exemptions. N.J.A.C. 8:57-4.4(b) grants religious affiliated schools or child care centers the authority to either withhold or grant a religious exemption from the required immunizations for pupils entering or attending their institutions without challenge from any secular health authority. The Department adopted this provision "because a school or child care center operated by a specific religion is more aware and knowledgeable of the tenets of that specific religion than is a local or State health official, and, therefore, more reasonably can grant or deny religious exemptions to its adherents or members." 32 N.J.R. 3463(a). It is within the church affiliated parochial school's authority to deny a religious exemption as it deems appropriate and such denial does not necessitate a philosophical exemption, which may lead to adverse public health implications if an increased number of children are not immunized. The Department is unaware of what the commenter means by "improperly refusing to grant religious exemptions" and therefore is unable to provide any further response.

24. COMMENT: One commenter questioned the need for compulsory vaccinations and indicated previously there were mandatory vaccinations in England from 1853 to 1898 and the laws were overturned in 1908 after the smallpox vaccine had caused a syphilis epidemic, that Japan had also overturned mandatory vaccination laws in 1998 due to the high costs of compensating vaccine injury victims, and that the United States is the only country that currently forces vaccinations by law. (7)

25. COMMENT: One commenter noted that since Japan has a lower infant mortality rate than the United States, the State of New Jersey should use the delayed flexible immunization vaccination program used by the Japanese since the United States vaccination program contributes to excess infant deaths compared to Japan. (48)

RESPONSE TO COMMENTS 24 AND 25: In the United States, individual states rather than the Federal government promulgate immunization laws. All states have chosen to promulgate compulsory vaccination laws for children in schools and child care centers. While there are countries in Western Europe and elsewhere, which do not require vaccination, there are others in Europe and elsewhere, which do require vaccination. The Department is unaware of any other state's legislature, which is considering repealing existing compulsory school vaccination requirements, as some other countries have done in past years. The Department describes the purpose behind compulsory vaccination laws for children in schools and child care centers in the response to Comments 20 and 21.

26. COMMENT: The compulsory vaccination of children in schools and child care centers are a violation of civil rights, parental rights, and constitutional rights regarding the free exercise of religion. (27, 37, 38, and 74)

RESPONSE: The decision to give the State government the authority to require uniform Statewide immunizations for children in schools was established in 1974 by the New Jersey Legislature at N.J.S.A. 26:1A-7. Compulsory immunization is well within the police power of the State to protect the public health. Local and state governments have adopted and enforced immunization laws in the United States for school children since 1827, for example, in Boston, Massachusetts and as a statewide mandate for school children since 1855 in Massachusetts. The United States Supreme Court in *Jacobson v. Massachusetts*, 197 *U.S.* 11 (1905) upheld, as constitutional, the state's use of its police power to protect the public against infectious disease, specifically smallpox, through a compulsory vaccination program. The *Jacobson* court mentioned that "the principle of vaccination as a means to prevent the spread of smallpox has been enforced in many states by statutes making the vaccination of children a condition of their right to enter or remain in public schools." *Jacobson*, at 197 *U.S.* 31 and 32. Religious exemptions from the immunization mandates in the United States are available to parents in all but two states. The public or State interest in preventing diseases does not violate the First Amendment Right to Free Exercise of Religion. The Department disagrees with the commenters that the New Jersey immunization rules at N.J.A.C. 8:57-4 are either a violation of parental rights, civil rights or the Free Exercise Clause of the First Amendment of the United States Constitution. As previously stated, N.J.A.C. 8:57-4.4(a) establishes the method by which a parent or legal guardian may apply for a religious exemption to the immunization requirements.

27. COMMENT: Some commenters have stated that the State of New Jersey should pass introduced bills A165 or "S1626 [sic]," or similar bills to establish philosophical and conscientious objection exemptions to the immunization rules rather than to mandate more vaccines. (6, 9, 33, and 65)

RESPONSE: The Department appreciates the commenters' remarks but the Department lacks the authority to pass legislation.

28. COMMENT: One commenter stated his opposition to mandatory vaccinations because he is a firm believer in chiropractic care and against the injection of foreign substances into the body of anyone, especially children. (34)

RESPONSE: The Department has already responded to the subject of parental choice and philosophical exemptions to the immunization rules in the response to Comments 20 and 21. The only two exemptions in the immunization rules in New Jersey are medical exemptions or religious exemptions as specified respectively, at N.J.A.C. 8:57-4.3(b) and 4.4(a).

29. COMMENT: Several commenters opposed to mandatory school vaccination requirements and supporting the establishment of a philosophical exemption stated that, "If vaccines are safe and effective, then unvaccinated children are the only ones at risk, and it should be of no concern to anyone else." (32, 49, and 78)

RESPONSE: Those unvaccinated children who would have philosophical exemptions would place themselves at higher risk of contracting vaccine

preventable diseases, such as recent experiences with measles, mumps, and pertussis have demonstrated and those unvaccinated children also increase the risk of disease transmission to others, who may have medical contraindications to receiving a vaccine, who may have a religious objection to vaccine, who are immunocompromised, who are too young to be immunized, who have not yet completed a given vaccine series to afford them minimum disease protection, those who do not develop a fully protective antibody response to a vaccine, or those persons affected by either vaccine-induced or natural disease acquired waning immunity. All of society shares in the great achievement of disease reduction and elimination as a result of the imposition of mandatory immunization school requirements compared to the small scientifically documented risks. To leave the decision of vaccination to be one of individual choice may be hazardous to the public health and greater good when that choice can deprive others and place our entire society, and especially our most vulnerable persons, at increased risk of vaccine preventable diseases once again. The Department disagrees with the commenters statement that children who are unvaccinated should be of no concern to others.

30. COMMENT: Influenza is a benign disease, the influenza vaccine is not efficacious, and the vaccine does not limit the spread of disease therefore it should not be required for school. (4, 6, 9, 10, 11, 12, 13, 14, 15, 17, 29, 36, 39, 48, 63, 65, and 73) One commenter (48), provided the Department with copies of two articles entitled, "Influenza Vaccination: policy versus evidence," by Tom Jefferson (Cochrane Vaccines Field), published by the British Medical Journal on October 28, 2006, discussing some influenza efficacy effectiveness and safety concerns. The second article provided was entitled, "Influenza Vaccine: Review of Effectiveness of U.S. Immunization Program and Policies Considerations," by DA Geier et al. published in the Journal of American Physicians and Surgeons, Fall, 2006, discussing concerns about influenza vaccine effectiveness and safety.

31. COMMENT: Several commenters stated that the number of influenza deaths annually reported by the CDC is exaggerated. One commenter (17) stated that the data from the National Center of Health Statistics for the years 1979 through 2000 showed the average numbers of deaths from flu in children under five years of age in a typical year was 17 nationwide, therefore, the childhood flu mortality figures often publicized by the CDC have been greatly exaggerated. (6, 9, and 17)

32. COMMENT: One commenter stated that in most cases if a child gets the flu, he or she gets better in a few days. Handwashing is an effective way to reduce the flu. (73)

33. COMMENT: Some commenters also expressed that vaccinating children against influenza will have no effect on reducing the incidence and spread of influenza in others, such as older children, adults, or the elderly. (6 and 8) One commenter (6) provided three articles entitled, "Flu Shots Ineffective for Adults; Don't Save Lives," by Carla Johnson (Associated Press), February 15, 2005; "Annual Flu Deaths: (The Big Lie)," by Neil Z. Miller, published in the British Medical Journal on December 10, 2005; and an article entitled, "Two Studies Question the Effectiveness of Flu Vaccines," by Elizabeth Rosenthal, which questioned the effectiveness of flu vaccinations and the severity of influenza disease.

RESPONSE TO COMMENTS 30, 31, 32 AND 33: Influenza is a serious disease that accounts for more illness and deaths annually than all other vaccine preventable diseases combined according to the Centers for Disease Control and Prevention (CDC). Seasonal influenza places the very young, those with chronic diseases or immunocompromised conditions, and the elderly at the highest risk of disease complications, hospitalization, and death. The CDC reports that each year approximately 200,000 persons are hospitalized and 36,000 die from related influenza infection in the United States. Young children have the highest influenza attack rate and are as likely as the elderly to be hospitalized for influenza. The CDC reported that during the 2003 to 2004 flu season, nationally 153 persons less than 18 years of age died of influenza. The CDC reported that during the 2005 to 2006 flu season 47 children died of influenza. During the 2004 to 2005 flu season, two influenza related pediatric deaths were reported in New Jersey. The CDC reported in early February 2007, there had been at least nine children nationally who died from influenza and six other deaths had tentatively been linked to influenza thus far in the 2006 to 2007 flu season. The CDC estimates that between 40 to 90 children under age five die from influenza associated disease each year. Young children also have a high hospitalization rate comparable to older adults 65 years of age or older as a result of influenza disease and its most common complication of pneumonia. The Department is unaware of any deaths in young children caused as a direct result of receiving an influenza vaccination. As these statistics bear out, influenza is a very serious disease and therefore such advisory bodies, agencies, and professional organizations as the ACIP, CDC, AAP, AAFP, and other health advocacy organizations have recommended the influenza vaccine for all preschool-aged children. Influenza is a contagious viral disease, for which there is no cure, and one that can cause severe complications among even healthy children and especially among those with compromised immune systems. Unfortunately, one cannot predict who will suffer severe disease with complications. The Department does not agree that influenza is such a benign disease that it is not necessary to recommend an immunization intervention or to initiate a vaccine requirement to reduce and prevent its incidence and transmission within the susceptible at-risk preschool-age population.

The efficacy of inactivated influenza vaccine depends primarily upon the age and immunocompetence of the vaccine recipient, the similarity between the virus within the vaccine and in circulation, and the specific outcome(s) being measured. The Department is aware that for any given year, there can be an imperfect match between the viral strains recommended by the World Health Organization (WHO), Global Influenza Surveillance Network and the CDC for inclusion in the vaccine and the circulating wild strain. However, even with an imperfect match there is some protection afforded to those individuals who receive the influenza vaccine. The influenza vaccine is generally 70 to 90 percent effective at preventing moderate and serious illness in healthy persons less than 65 years of age; 30 to 40 percent effective among frail elderly persons; 50 to 60 percent effective in preventing hospitalization among the elderly; and 80 percent effective in preventing death among the elderly. The influenza vaccine is more effective at preventing illness in young persons with their young and intact immune systems than it is among the elderly with more fragile immune systems. The CDC states that the hospitalization rate for children 24 months of age and younger are comparable to that of persons 65 years of age and older. Children 24 through 59 months of age are at less risk of hospitalization from influenza than are younger children, but are at increased risk for influenza-associated clinic and emergency department visits. Additional information and references to other studies related to the efficacy of the influenza vaccine is described in the ACIP Recommendations for the Prevention and Control of Influenza published on July 13, 2007 and can be accessed online at: http://www.cdc.gov/mmwr/PDF/rr/rr5606.pdf. The Department does not agree that because a vaccine does not have a 100 percent efficacy rate against a given disease, that it should not be considered as a required vaccination for preschool-aged children in child care center settings. No vaccine currently licensed and in use or required for school entry has a 100 percent efficacy rate.

The Department is aware of many studies, which have demonstrated the effect that vaccinating children against influenza will have a positive effect on reducing the overall burden of influenza disease on other children and older adults. A study done in Tecumseh, Michigan in 1968, by AS Monto et. al entitled, "Modification of an Outbreak of Influenza in Tecumseh, Michigan by Vaccination of Schoolchildren," and published in 1970 by the Journal of Infectious Diseases, reported that during an epidemic more cases of influenza occurred in a neighboring town where there was no influenza program to vaccinate school age children, compared to the town where there was a school-based program to vaccinate all school age children. Similarly, in Japan between 1977 to 1987 influenza vaccine was mandatory for Japanese school children and the school based program implemented there reduced excess mortality by 50,000 lives per year. Following the relaxation of the program in 1987 and the repeal of the law in 1994, the mortality rate increased to the higher rates experienced before 1977 as reported by TA Reichert et. al in an article entitled, "The Japanese Experience with Vaccinating Schoolchildren Against Influenza," and published in 2001, by the New England Journal of Medicine. Young children with their suspect hygienic practices have been recognized for many years as prime vectors for the acquisition and transmission of influenza. Handwashing is an important means to reduce the likelihood of acquiring influenza however, the influenza virus is primarily transmitted via the respiratory route. Studies in the scientific literature have documented the ability of this unvaccinated age group to spread influenza and adversely affect the elderly population, and conversely the ability of vaccinated youngsters to

reduce overall community infection rates, such as "Illness Among Schoolchildren During Influenza Season: Effect on School Absenteeism, Parental Absenteeism from Work, and Secondary Illness in Families" reported by KM Neuzil et. al published in the Archives of Pediatric and Adolescent Medicine in 2002. This fact is even more critical as an estimated 60 percent or more of preschool-aged children in New Jersey daily attend child care centers or similar facilities where children congregate. The use of the nasal spray delivered live attenuated influenza vaccine (LAIV) offers promise that due to its relative ease of administration even more children will be vaccinated against influenza. The Department does not agree with the commenters that society does not benefit from immunizing preschool children attending child care centers against influenza. The Department thanks the commenters (6 and 48) for the information and references provided related to the effectiveness and safety of influenza vaccine.

34. COMMENT: The flu vaccine is ineffective because it merely protects from last year's flu strain and does nothing to protect against this year's flu. (29)

RESPONSE: Each year there are new strains of the influenza virus selected for inclusion in the vaccine as determined by the World Health Organization and CDC. Selection is usually based on the predominant circulating strains in Asia. Since antigenic drift of the influenza virus usually occurs each year, the vaccine must be specially reformulated and manufactured each year to protect against the expected circulating strain for the upcoming flu season lasting from September through March in the United States. The Department disagrees with the commenter that the flu vaccine being prepared for use in Fall 2007, will only protect against influenza circulating in 2006 and not that expected to be circulating this Fall.

35. COMMENT: Several commenters opposed mandatory flu vaccinations for day care or preschool and suggested another focus. It was suggested that instead of vaccines, the State should promote and mandate breastfeeding, hand washing, removal of all vending machines in school, that nutritious meals are served in school, that proper health and nutrition is taught in school, that there be daily physical education in schools, and that children not attend school or day care when ill. It was suggested that the State should instead focus on the real epidemic of childhood obesity, the importance of diet and proper hygiene for good health, and health issues other than vaccination. (28, 47, 60, and 70)

RESPONSE: The Department appreciates these suggestions of the commenters, however, they are not implicated in the current rulemaking, which covers the immunization of pupils in schools.

36. COMMENT: One commenter stated that if the influenza vaccine became mandatory in New Jersey, she will consider moving from New Jersey. (73)

RESPONSE: The Department does not mandate certain vaccines as a condition of entry and continued attendance in child care centers without a reasonable scientific, medical, and epidemiologic basis that will advance the public health of New Jersey children and residents. The Department does not agree that requiring an annual influenza vaccination, or implementation of any other new vaccine requirement, would be a primary motivating reason for residents to move to other states.

37. COMMENT: One commenter stated that some parents have stated to her that if the influenza vaccine were required, they would consider not sending their children to preschool or day care. (36)

RESPONSE: Contrary to compulsory elementary education of children, attendance in a preschool or child care setting is voluntary. Parents choosing not to send their children to a child care center due to opposition to an immunization rule, and without a religious or medical exemption to these rules, will need to pursue other arrangements for securing day time child care services.

38. COMMENT: Vaccines are dangerous, harmful, and have risks. (4, 5, 6, 7, 8, 10, 13, 17, 31, 33, 42, 44, 47, 51, 52, 56, 59, 61, 62, 68, 70, 71, 72, 73, and 78, and form letters 108 through 120) One commenter (56) stated her four month old daughter had eight seizures after her "shot" and became autistic within weeks of her mandatory vaccinations and her son has severe learning disabilities and believes that all vaccines carry risks as more children are exposed to more viruses and metals, and therefore is opposed to mandating more vaccines without more vaccine safety studies. One commenter (7) provided the Department with a booklet entitled, "The Vaccination Superstition," about the dangers of smallpox vaccine that was published in 1902. Another commenter (6) provided the Department with five large loose leaf binders of scientific and informational materials comprising a compendium primarily focused on the subjects of thimerosal, vaccine dangers, vaccine compositions, and influenza. One commenter (13) expressing concern about the composition of vaccines also provided the Department with additional references on the subject of mercury, the use of foreign nations for conducting clinical trials, equine influenza, drug industry marketing efforts, and the potential for problems associated with using materials derived from cattle with Bovine Spongiform and Encephalophy (BSE) that may later get used in medical products for humans and questioned the safety of existing vaccine products. One commenter (62) opposed to vaccination mandates provided a copy of an article, entitled, "Why Do Pediatricians Deny the Obvious," by Judy Converse, which places part of the blame for the increased incidence of obesity, autism, food allergies, asthma, attention deficit disorders, and nutrient deficiencies, upon the increasingly aggressive immunization schedule and the fact that pediatricians focus more on attention on immunizing children than on their pediatric patients' nutritional needs.

RESPONSE: Vaccines are among the safest drugs administered to children and adults. Immunization has been listed as one of 10 greatest public health achievements of the 20th Century by the United States Public Health Service as announced in the Morbidity and Mortality Weekly Report (MMWR) of April 2, 1999. Vaccines have been administered to virtually all children in the United States since the 1960's and have dramatically impacted the incidence of disease cases and reduced complications from most vaccine preventable diseases by 99 percent or greater compared to vaccine prelicensure. While there is no drug or vaccine that is 100 percent safe and without any possible side effects, the side effects and adverse events following vaccinations occur rarely considering the number of children being vaccinated and the number of vaccine doses they receive. Approximately 85 percent of all reported adverse events are minor, local in nature, and resolve without a visit to a physician or hospital. Vaccine safety is monitored during prelicensure clinical trials and subsequent postlicensure surveillance systems via the Vaccine Adverse Event Surveillance System (VAERS) established in 1990, the Vaccine Safety Datalink (VSD) project with health maintenance organizations (HMO's) established in 1991, and with the establishment of a network of seven Clinical Immunization Safety Assessment Centers (CISA) in 2001.

There is a recently published summary of VAERS data over 10 years that provides an extensive overview of reported adverse events following vaccination that can be accessed at http://www.cdc.gov/mmwr/PDF/ss/ss5201.pdf. While various side effects or adverse events can occur, for most vaccines there are rarely any serious post-vaccination events. The Department recognizes that rarely some serious adverse events following immunization can occur. However, these rare events do not outweigh the benefits that vaccines have provided by preventing serious infectious diseases, disease complications, hospitalizations, and some deaths and thereby creating a more disease-free, and therefore healthier environment for all children and society. The Department thanks the commenters (6, 7, 13, and 62) for the information and references provided related to the subjects of thimerosal, vaccine dangers, vaccine compositions, and influenza.

39. COMMENT: Several commenters stated that vaccines are dangerous because they cause one or more of the diseases or conditions included among the following list: attention deficit disorder, attention deficit hyperactive disorder, human immunodeficiency virus (HIV), Alzheimer's

disease, asthma, arthritis, autism, autoimmune disorders, Bell's Palsy, brain/nerve disorders, cancer, developmental disorders, diabetes, encephalopathy, Epstein-Barr, fibromyalgia, Guillain-Barre syndrome (GBS), influenza, leukemia, lupus, mental retardation, multiple sclerosis (MS), muscular dystrophy, neuritis, neuropathy, optic neuritis, partial facial paralysis, plexus neuropathic sculitis, seizures, sudden infant death syndrome (SIDS), or vasculitis. (4, 5, 6, 7, 8, 10, 17, 28, 33, 42, 44, 47, 48, 51, 56, 57, 58, 59, 62, 64, 65, 68, 71, and 72)

RESPONSE: The commenters provided no specific scientific evidence that the vaccines currently in use and the four new vaccines to be required individually or as a group are the direct cause of the diseases or the conditions they listed. The Department disagrees with the commenters that the four new vaccines to be required are the primary causative agent of the diseases or conditions they listed.

40. COMMENT: Several commenters stated that if the new vaccine requirements were added, the State will be financially liable for vaccine injuries as a result. (10, 42, 62, 64, 68, 71, and 72) One commenter states that the parents of children who have been injured as a result of receiving mandated vaccines, should have their medical expenses paid for by the State. (62)

RESPONSE: The Department is unaware of any State, which has been ordered to pay for a vaccine injury to a child because that child had received a State required vaccine in order to attend a child care center, school, or college. The Department has provided additional information on vaccine injury compensation in the response to Comment 44. It is prudent public health policy to reduce or eliminate certain serious vaccine preventable diseases, which can cause illness and death through immunization. The reduction of these diseases is a great health benefit to every child, individual, and the entire society while the potential risk of a vaccine associated serious adverse event to an individual receiving vaccine is small. Therefore, the Department disagrees that the State should pay all medical costs related to any injuries subsequent to receipt of a vaccine required under N.J.A.C. 8:57-4.

41. COMMENT: One commenter asserted that the reason more health care workers have such a low coverage rate for receiving the annual flu shot is because they are afraid of getting the flu from the shot. (9)

42. COMMENT: One commenter stated that she got influenza two days after receiving the influenza shot. (6)

RESONSE TO COMMENTS 41 AND 42: It is medically impossible to get influenza from the inactivated influenza vaccine. The inactivated influenza vaccine cannot transmit influenza virus to the vaccine recipient. The claim or assertion among some persons that one can get influenza from the influenza shot is a myth. The Department disagrees with the opinion that people get influenza disease from the influenza shot.

43. COMMENT: Some commenters stated that although the live attenuated influenza virus (LAIV) vaccine contains no thimerosal, it remains dangerous and should not be used because it can shed influenza virus to immunocompromised and other susceptible persons and result in severe disease and that vaccinated persons should be quarantined for 21 days after LAIV vaccination. (6 and 48)

RESPONSE: During the 2005 to 2006 influenza season, there were 100,000 doses of the LAIV administered in school settings at 22 school districts in 13 states. These programs were well accepted and had high participation rates among pupils and school staff. These programs resulted in reduced absenteeism at those participating schools and a somewhat reduced incidence of influenza in the community as recorded in a February 2007 FACT SHEET entitled "The FluMist(TM) for School Programs in Carroll County, MD, San Bernandino County, CA, and Knox County, TN," published by the National Association of County and City Health Officials. The CDC reported that one unpublished day care center study found one case of LAIV vaccine transmission resulting in a case of influenza through viral shedding to one child and reports that viral shedding can occur among recently vaccinated children with a mean shedding of 7.6 days (range one to 21 days) that usually occurs from day two to day nine after vaccination. Due to this fact, the inactivated influenza vaccine, rather than LAIV, remains the medically preferred vaccination for health workers and household members who are in close contact and caring for severely immunocompromised persons. Until recently the LAIV vaccine had only been approved for healthy persons five through 49 years of age. The Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) has been considering for months whether it can be approved less than five years of age. On September 19, 2007, the LAIV vaccine or FluMist(TM) was approved by Federal health officials for children between two and five years of age. There is no medical reason to establish a 21-day quarantine period for each child receiving LAIV to be kept from a child care center or school since no such recommendation has been made by any professional vaccine advisory group or organization. The Department will be monitoring any new ACIP recommendations or other CDC guidance on the use of this vaccine in children less than five years of age.

44. COMMENT: One commenter stated that vaccines cause death and injuries and the Federal government cannot guarantee the safety of vaccines, such as influenza vaccine, as is evidenced by the enactment of the National Vaccine Injury Compensation Program (VICP) in 1986. (39)

RESPONSE: The VICP is a Federal no-fault system that was established to compensate the individuals or families who experience certain serious and rarely occurring health events following vaccination on a "no-fault" basis. Health events, which are compensable are listed within a Vaccine Injury Table. All routinely ACIP recommended vaccines are added to the injury table and the VICP as a matter of course and without regard to their potential for serious adverse events. The VICP has met its goals of providing compensation to those injured by rare adverse events and offering liability protection for vaccine manufacturers and vaccine administrators. More specific information about the VICP is available at http://www.hrsa.gov/vaccinecompensation.

45. COMMENT: Vaccines have been proven ineffective at preventing diseases, as witnessed by disease cases and outbreaks that still occur among vaccinated persons and since other alternative treatments of disease are available. (4, 6, 10, 48, and 61)

RESPONSE: The record of vaccines in preventing diseases is an established and accepted fact in the medical and scientific community. With the introduction of any new childhood vaccine in the United States there have been decreases in disease case reports of 99 percent or higher, compared to vaccine prelicensure disease case levels. For example, there was a recently published report on March 16, 2007, in the Morbidity and Mortality Weekly Report (MMWR), "Surveillance for Acute Viral Hepatitis - United States, 2005," indicating that the incidence of acute hepatitis B has dramatically decreased by 79 percent from 1990 to 2005 with the widespread use of the vaccine among children. There is no vaccine that is 100 percent effective at preventing disease for every individual. There have been documented instances when further study and epidemiologic analysis of disease surveillance reports revealed the need to add another dose of vaccine, or change the appropriate age or timing of a vaccination, due to an increase or outbreak of disease among immunized persons. In 1989, a second dose of measles, mumps, and rubella (MMR) vaccine was recommended by the ACIP and CDC because approximately five percent of those vaccinated did not mount a sufficient immune response to the first dose routinely administered after the first birthday. More recently, there have been increased cases of pertussis observed among vaccinated pupils in middle school and high school nationally and in New Jersey, which many experts attribute to waning immunity of the pertussis vaccine. As a result, the ACIP has recommended that a booster vaccine containing acellular pertussis, Tdap, be given at the 10 to 11 year old office visit to replace the Td booster that would have been given at that time in order to now provide additional protection against pertussis, as well as tetanus and diphtheria. Further, pertussis disease is often not detected in its early stages and available antibiotics do not cure the disease. If antibiotics are given early enough in the course of pertussis, it can shorten the period of communicability to others or shorten the disease duration in the ill person. It has also recently been observed that as many as 10 to 20 percent of children vaccinated against chickenpox still contract "breakthrough" chickenpox infection, which is generally less severe and serious than

contracting the wild chickenpox virus. The ACIP has recently also recommended that in order to decrease the number of these "breakthrough" cases that a second dose of a varicella (chickenpox) vaccine should be given at four through six years of age. There are no generally available, efficient, effective, easily tolerated or implemented anti-viral therapies against influenza. Pneumococcal disease is a respiratory disease that can have serious complications such as meningitis, pneumonia, and bacteremia if it goes untreated. To avoid these and other sequelae, antibiotics must be initiated promptly. With the growing resistance of pneumococcal organisms to the commonly used antibiotics it becomes even more important that vaccines become the primary means to control pneumococcal disease.

Meningococcal disease is a rare but terrifying disease due to its rapid progression from flu-like symptom onset to frequent death within several hours without prompt initiation of antibiotic therapy. Even in cases where optimal antibiotic therapy is initiated there can be serious life-changing sequelae, such as hearing loss, limb loss, or mental retardation. Due to the reasons cited above, most medical experts and practitioners believe the preferred medical intervention is to control these diseases through prevention using available vaccines, rather than reliance on therapies to treat a disease after it becomes manifested. The Department believes that although diseases still occur among vaccinated persons, many more vaccine preventable diseases would occur if there were fewer persons being vaccinated.

46. COMMENT: There are no long-term efficacy or safety studies of these four new vaccines as separate products, or when given with other existing vaccines. (6, 7, 8, 9, 10, 32, 33, 36, 39, 41, 44, 46, 49, 51, 59, 65, 67, 75, and 80) One commenter (6) provided the Department with an article entitled, "No Evidence Flu Vaccine Works for Toddlers," by Amanda Gardner, HealthDay website, February 24, 2005. One commenter (51) provided the Department website articles from the National Vaccine Information Center (NVIC) entitled, "Studies Fail to Demonstrate Safety or Effectiveness of Influenza Vaccine in Children and Adults," October 31, 2006; a NVIC e-news Commentary by Barbara Loe Fisher of December 27, 2006 questioning the impact of influenza disease and the need for influenza vaccinations; and an NVIC e-news Commentary by Barbara Loe Fisher of January 12, 2007 questioning the development and use of such vaccines as hepatitis B, human papilloma virus (HPV), and a future human immunodeficiency virus (HIV) vaccine for newborns now being tested in Africa.

RESPONSE: Commenters expressed concern that there are no long-term efficacy and safety studies performed on these vaccines before they were licensed, recommended for use, and now are to be required for school or child care attendance. Since the decision to license a new vaccine can only be based on prelicensure clinical trials conducted over several years, or other FDA criteria, it is not reasonable or ethical to study for another decade or two and delay implementation of a vaccine that has been demonstrated to be efficacious and safe and approved by the FDA and recommended for use by the major vaccine advisory bodies of medical experts. The World Health Organization has issued position papers stating that pneumococcal conjugate vaccine (PCV), meningococcal conjugate vaccine (MCV), and influenza vaccines are safe and effective vaccines. The FDA, CDC, and other medical researchers perform postlicensure vaccine monitoring and studies to ensure vaccine safety and efficacy in clinical practice over a longer period of time. The PCV had preclinical trials of 38,000 children with almost 20,000 children receiving doses of vaccine. The trials were so positive that they were terminated early so that this vaccine could be offered to children sooner. The ACIP and CDC have stated that the PCV vaccine can be safely administered simultaneously at the same office visit as are the polio, HIB, and the DTap vaccine doses. Since its licensure in early 2000, PCV has demonstrated an excellent efficacy and safety record in clinical practice to date.

Influenza vaccine has been administered to certain children considered at risk of developing influenza and serious complications for decades. In June 2002 the influenza vaccine became more widely recommended for healthy preschool-aged children six through 23 months of age and in 2006 the influenza vaccine recommendation was expanded to include all healthy children six through 59 months of age. A recently published safety study of 45,000 children six through 23 months of age by S.J. Hambridge et al., entitled, "Safety of Trivalent and Activated Influenza Vaccine in Children 6 to 23 Months of Age," published in the October 25, 2006 issue of the Journal of the American Medical Association (JAMA) found almost no serious side effects requiring medical treatment six weeks after children were vaccinated with influenza vaccine. Another study by A.W. McMahon et al., entitled, "Adverse Events After Inactivated Influenza Vaccine Among Children Less Than Two Years of Age: Analysis of Reports From the Vaccine Adverse Event Reporting System, 1990 - 2003," published in Pediatrics, February 2005 found that there was no significant increase in the number of serious adverse events related to receipt of influenza vaccine after the ACIP recommendations of July 2002, which stated that children less than two years of age be vaccinated, compared to the number of adverse events reported before July 2002. Another study comprising 13,383 children by M.J. Goodman, et al., entitled, "The Safety of Trivalent Influenza Vaccine Among Healthy Children 6 to 24 Months of Age," was published by Pediatrics in May 2006 and found no medically significant adverse events related to influenza vaccine among children six to 23 months of age. This vaccine has been considered to be a safe and efficacious vaccine for those infants and toddlers with chronic health conditions for many decades, and one would expect the same vaccine safety and efficacy profile would apply or even be enhanced among healthy children.

The Tdap vaccine was licensed for adolescent use by the FDA based on clinical trials that demonstrated immunogenicity that was not inferior to the currently licensed tetanus and dipthteria (Td) or pediatric dipthteria, tetanus, and acellular pertussis (DTaP) products and demonstrated an overall safety profile clinically comparable to licensed Td products. The Tdap vaccine contains the same exact antigenic ingredients found in the DTaP vaccine routinely given up to the seventh birthday, except that it contains a reduced amount of diphtheria and acellular pertussis antigens. Since these component antibodies are known to wane over five to 10 years, the ACIP and CDC has recommended for decades that a Td booster be given to children and adults every 10 years beginning at age 10 to 11. The experience with the Td vaccine over decades of use is that it is very safe and effective at preventing diphtheria and tetanus. There is no reason to expect that by substituting a Tdap booster for the previously recommended Td booster given at age 10 to 11, the safety and efficacy profiles will suffer; Tdap contains the same antigens that have been used in other vaccines that have been, or would be, administered to the child. In addition to the ACIP recommendation of March 24, 2006 that all adolescents receive a dose of Tdap, on December 15, 2006, the ACIP also recommended a one time Tdap booster dose for all adults.

The MCV or Menactra(TM) vaccine was licensed by the FDA in January 2005. It is manufactured using the same conjugate technology as that used to make the Haemophilus influenzae type b (Hib) and pneumocococcal conjugate vaccines that have been safely administered to millions of children. There is no available vaccine to protect against the meningococcal serogroup B, however one dose of this vaccine does provide protection against disease caused by the serogroups A, C, Y, and W-135 that accounts for about 75 percent of all cases of meningococcal disease in children 11 to 18 years of age. The incidence of meningococcal disease is highest among infants, but incidence increases at adolescence to a level that is greater than the general population. The case fatality ratio from meningococcal disease is the highest for this age group, at around 20 percent. Even one sporadic case in a school setting causes considerable disruption to the educational facility, families, and the wider community and is a life-threatening medical emergency for the individual and family directly affected. The decision by the FDA to license MCV or Menactra(TM) was made based on safety and immunogenicity data from six studies that included more than 7,500 adolescents and adults receiving the vaccine. The antibody responses and seroconversion rates of the MCV or Menactra(TM) were the same when compared to the meningococcal polysaccharide vaccine or Menomune(TM) previously licensed in 1981 and still in use. The only available single-dose formulation of MCV or Menactra(TM) contains no thimerosal. Prelicensure studies found that most vaccine reactions were local in nature, similar to those found with the Td vaccine. MCV was licensed by the FDA on the basis of non-inferiority to the previously licensed meningococcal polysaccharide vaccine for immunogenicity and safety. Studies revealed that MCV could safely be administered at the same time as Tdap. The duration of protection after MCV administration is unknown; additional monitoring and studies over the next several years will be necessary to ascertain duration and to see if a booster dose will be needed later. Since no studies included pregnant women, this vaccine is not medically indicated for them.

During prelicensure clinical trials vaccines under study are customarily tested with some, but not all, of the other existing vaccines to provide some safety and efficacy data on the candidate vaccine when used in combination with other vaccines in use. Postlicensure monitoring and studies by the FDA, CDC, and others will continue to assess the efficacy and safety of these four new vaccines when given separately or in combination. If postlicensure studies indicate problems, the FDA would take the necessary steps to revoke or modify vaccine licensure and the ACIP would amend its vaccine recommendations to make the vaccines even safer and more efficacious. The Department thanks commenters (6 and 51) for the information pertaining to the questionable influenza vaccine efficacy among toddlers.

47. COMMENT: Some commenters expressed concerns that the vaccine ingredients contained substances, such as aluminum, mercury, and formaldehyde, which are toxic chemicals and can cause serious chronic conditions or neurological disorders. (4, 5, 6, 13, 17, 30, 33, 46, 49, 52, 56, 57, 58, 59, 65, and 76 and form letters 82 through 107) One commenter (5) provided the Department with materials from a vaccination debate website with a graph from Australia entitled, "Graphical Evidence Shows Vaccine Didn't Save Us," "Hazardous Substance Fact Sheets on Formaldahyde, Glutaraldehyde, and Aluminum Phosphate," published by the Department, and an article entitled, "Unseen and Underfought-Children and Cancer." One commenter stated that only thimerosal-free vaccines be administered to children, as the substance is toxic and since research has shown that mercury poses particular risks for children and developing fetuses. The commenter stated she encourages parents to have their children vaccinated but only with thimerosal-free vaccines. The commenter also provided additional information and materials from the Deirdre Imus Environmental Center for Pediatric Oncology related to eliminating toxic and hazardous substances from institutional and home settings and also provided other materials describing ongoing educational efforts promoting the prevention of exposure to environmental factors that may cause adult, and especially pediatric cancer, as well as other health problems with children. (46)

48. COMMENT: One commenter having two daughters with autism expressed concern that there were too many toxic chemicals and heavy metals in vaccines that were injuring children. (5)

RESPONSE TO COMMENTS 47 AND 48: All ingredients of these four new vaccines to be added to the list of required vaccines, and the amounts present, have been considered by the FDA when licensing each vaccine for use and were determined not to be toxic. There are several aluminum salts used as adjuvants in the preparation of the pneumococcal conjugate vaccine and the Tdap vaccine. There are no aluminum salts in influenza or meningococcal vaccines. Adjuvants have been used since the 1930's to enhance the body's uptake of the specific vaccine antigen and only minor local reactions have been associated with their widespread use. Aluminum is present in the soil, water, air, and in the food we eat. Vaccines contain very small amounts of aluminum, however, because very large amounts of aluminum can cause serious neurologic events in people, the Agency for Toxic Substances and Disease Registry (ATSDR) has established guidelines to limit quantities. The amount of aluminum that infants are exposed to in food and vaccines is considerably less than the ASTDR guidelines and much less than that which has been found to be safe in laboratory animals.

Formaldehyde is used as an inactivation agent in the manufacturing process to kill, inactivate, or reduce the pathogenic virulence of bacterial toxins and to limit the ability of the infectious viruses to replicate and grow. Formaldehyde is used in the manufacturing process for Tdap, meningococcal conjugate vaccine, and inactivated influenza vaccine. Formaldehyde is diluted in the manufacturing process and some residual remains as a manufacturing by-product. Formaldehyde is not added to a vaccine. There is some concern that high concentrations of formaldehyde can cause cancerous changes in cells when studied in laboratory test tubes. Studies indicate that formaldehyde does not seem to be a cause of cancer in humans and those laboratory animals exposed to large quantities of formaldehyde do not go on to develop malignant cancers. The amount of residual formaldehyde in vaccines is so minute that it is considered to be safe. All humans have formaldehyde in their circulatory systems, which is necessary for the synthesis of amino acids and other proteins. The amount of formaldehyde in any vaccine is at least 10 times less than the amount of formaldehyde circulating in a two month old child. Experimental animal studies have revealed that 600 times more formaldehyde than that found in vaccines have been safely given to animals.

The preservative thimerosal, an ethylmercury substance used in vaccines for decades, has been removed from all routinely administered pediatric vaccines, except some inactivated influenza vaccine formulations, since 2001 as a precautionary measure. This effort was part of a larger FDA initiative to reduce human exposure to all forms of mercury found in drugs and food, which include both ethylmercury, as well as methylmercury. Thimerosal has been used as a preservative in multi-dose vials of vaccines to prevent bacterial contamination. There is no thimerosal in the meningococcal conjugate, pneumococcal conjugate, or the Tdap vaccines. There are currently manufactured thimerosal-free influenza vaccines available for pediatric administration and some influenza products with only trace residual amounts left after the post-production thimerosal removal, but these minute amounts have no documented biological effect and are well within the Federal limits set for thimerosal content. The vaccine manufacturers are working to increase the quantities of preservative-free vaccine. Despite considerable debate and national and international studies on the subject of thimerosal, there have been no convincing scientific data or evidence that ethylmercury causes harm to the developing nervous system. Based upon guidelines established by the FDA, the Environmental Protection Agency, and the ATSDR, no child will now receive excessive mercury from childhood vaccines regardless of whether or not their influenza shot contains thimerosal as a preservative.

The Department does not agree with the commenters assertions that the aluminum, formaldehyde, and thimerosal used in the vaccine manufacturing process, even in such minute quantities, is the cause of many neurological or behavioral disorders, chronic diseases, or other serious health problems after considering all the exposure studies of these substances in humans and studies with laboratory animals, which suggest these substances are likely harmless. These substances have been used to make vaccines more effective and safer for humans, rather than more harmful. The Department thanks commenters (5 and 46) for the information and references provided related to chemical vaccine composition.

49. COMMENT: Some commenters expressed concerns that vaccines contain substances, such as yeast, eggs, and soy, which can cause allergic reactions in infants who may have an unknown allergy to these substances and therefore can risk injury. (4, 13, and 33)

RESPONSE: Persons with past severe or anaphylactic reactions to eggs should not routinely receive influenza vaccine as stated in the Federally mandated Vaccine Information Statement (VIS) for influenza. None of the other three new vaccines being added to the list of required vaccines contain egg protein. There is also some yeast protein residual found in PCV, however there is no evidence of severe or anaphylactic reactions to yeast extract following vaccinations. The PCV contains some residual soy peptone, which is used in the culture media for the cultivation of microorganisms, however, there is no evidence that the soy ingredient causes severe allergic or anaphylactic reactions. The ACIP and CDC advise that a severe allergic (anaphylactic) reaction to any vaccine component or following a dose of any vaccine, is a contraindication to receipt of further doses and needs to be brought to the attention of the patient's physician. The Department does not agree that an extremely rare possibility of allergic reaction to a vaccine or its components outweighs the benefits that vaccines provide by preventing serious disease.

50. COMMENT: The Vaccine Adverse Event Reporting System (VAERS) is a flawed system used by the FDA and CDC, that primarily due to underreporting, underestimates the number of serious adverse events following vaccination. (6, 8, 10, 11, 51, and 67)

51. COMMENT: One commenter became skeptical about the safety of licensed vaccines due to the fact that her son had received two doses of a new vaccine that was later pulled off the market. (8)

52. COMMENT: One commenter stated that after her son had a vaccine reaction, she was unable to obtain a VAERS form to report the vaccine reaction, despite calling the 1-800-VAERS telephone number for one form to be sent to her address. (11)

53. COMMENT: One commenter stated that after her friend's baby received an MMR shot, a seizure developed and the physician never reported the reaction to VAERS and therefore there are actually more reactions occurring than being reported to VAERS. (6)

RESPONSE TO COMMENTS 50, 51, 52 AND 53: VAERS is a passive postlicensure system of the FDA established in 1990, which collects data from citizens or medical providers on reported health conditions that temporally occur subsequent to a vaccination. Submission of a VAERS report does not imply that a cause and effect relationship exists between a vaccination and a reported condition. The National Childhood Vaccine Injury Act of 1986 (Pub. L. No. 99-660, codified at 42 U.S.C. §§300aa-1 through -34) requires vaccine administrators and manufacturers to report specific adverse events that occur after the administration of routinely recommended vaccines, when they are made aware of such events. Vaccine administrators are also required to provide the parent with the appropriate copy of a national Vaccine Information Statement (VIS) for each dose of vaccine that is given to a child. The VIS contains important information for the parent pertaining to the disease, the vaccine, contraindications to receipt of the vaccine, side effects, and how to submit a VAERS report to the FDA. Limitations, such as differential reporting rates, simultaneous administration of different vaccines, temporal reporting bias (for example, a person is more likely to report an event that happens close to vaccination), and lack of background vaccination-rate data generally prevent making vaccine-related causal associations using VAERS data. For these reasons, it is incorrect and misleading to cite VAERS data to show that a given vaccine causes a specific number of adverse events or deaths. Despite its limitations, VAERS data has proven helpful by identifying some potentially serious problems that may only become evident after any given vaccine becomes widely used, but were not detected during the prelicensure clinical trials. Approximately 85 percent of all VAERS reports in the United States comprise non-serious events. Serious reported events, which include hospitalization, life-threatening conditions, disability, or death only comprise 15 percent of all VAERS reports. While physicians are only required to report certain serious adverse events, they or parents, may also report any other events they consider unusual to VAERS. While there may be underreporting of adverse events to VAERS, parents have the option of directly submitting a report through the VAERS website at http://vaers.hhs.gov/ or calling the VAERS telephone number at 1-800-822-7967 and requesting that a form be mailed out to them. VAERS report forms are also available from state immunization programs. Most VAERS report forms are received from drug companies, physicians, and public health departments; reports from parents represent about four percent of the total VAERS reports submitted. Additional information about this monitoring system can be obtained from the VAERS website provided above.

VAERS is not the only mechanism used to assess vaccine safety after licensure of a vaccine. The FDA and CDC utilize several other postlicensure surveillance systems to monitor safety after vaccine use becomes widespread. The Vaccine Safety Datalink (VSD) Project was established in 1991 and includes immunization and other health information on over eight million persons in eight health maintenance organizations in the United States, which is another useful tool to study postlicensure vaccine safety. The CDC has also recently established a national network of Clinical Immunization Safety Assessment Centers (CISA). The objectives of CISA are to enhance understanding of known serious or unusual vaccine reactions, including the pathophysiology and risk factors for such reactions, as well as to evaluate newly hypothesized syndromes or events identified from the assessment of VAERS data to clarify any potential relationship between the reported adverse events and immunization. Most licensed vaccines continue to be evaluated in large studies comprising tens of thousands of people receiving vaccines. These FDA designated Phase IV studies are intended to detect rare or delayed adverse reactions that were not evident in the smaller prelicensure clinical trials.

These CDC efforts and other non-governmental studies supplement the VAERS data to help identify possible rare events in order to ensure continued evaluation of a vaccine's postlicensure safety record. In the event vaccine safety problems arise, the FDA and the ACIP will revoke or amend the vaccine licensure or vaccine recommendations and fulfill their responsibility to act to protect the public, as they have in the past. This was done in October 1999, when the Rotashield(TM) Vaccine was withdrawn from the market due to increased cases of intussusception. Children who received Rotashield (TM) vaccine during that time without experiencing problems are now not considered to be at increased risk of developing intussusception in the future. Discovery of this problem in the early postlicensure period by the VAERS system is evidence that the monitoring system for vaccine exists and can work to protect the public from any unexpected severe vaccine associated adverse events. The Department does not agree with the commenters that VAERS is an insufficient tool to help monitor vaccine safety.

54. COMMENT: Insufficient time has elapsed from the recent 2006 ACIP recommendation that all preschool-aged children receive an annual influenza vaccination before any adverse events may become evident for the Department to now mandate a new influenza vaccine requirement for children in child care centers. (16, 32, 49, and 78)

RESPONSE: The influenza vaccine is not a new vaccine. For many years, influenza has been a licensed vaccine available for pediatric use. A review of past ACIP documents revealed that since 1964, the ACIP has recommended an annual influenza vaccination for children with asthma. The ACIP has stated in past recommendations that influenza vaccine could be given to any child over six months of age, regardless of risk factors, to reduce the impact and burden of disease. The influenza vaccines are considered safe and effective vaccines by the WHO. This vaccine has specifically been recommended for children considered to be at high risk from influenza as a result of having chronic conditions such as diabetes, heart conditions, lung conditions, HIV and asthma for decades. Children six through 35 months of age receive a dose that is half that of an adult dose. Since 2002, the ACIP has encouraged annual influenza vaccination for all healthy children age six through 23 months, when feasible. Since 2005, the ACIP has recommended that all children six through 23 months of age receive an annual influenza vaccination. Since February 2006, the ACIP has recommended that all children six through 59 months of age receive an annual influenza vaccination.

One study, which included children three years of age and older by W.C. Gruber, et al., entitled, "Live Attenuated and Inactivated Influenza Vaccine in School-age Children," was published in the American Journal of Disease in Children, in 1990; 144(5) and found that influenza vaccine was well tolerated and immunogenic in children. There have been other studies evaluating healthy children, children in day care centers, and high-risk children, which are referenced in a publication entitled, "Increasing Influenza Immunization Rates in Infants and Children: Putting Recommendations into Practice," published by the National Foundation for Infectious Diseases, April 2003. Given the clinical experience of vaccinating young children for many years, the more recent ACIP comprehensive recommendation of 2006 for all healthy preschool-aged children to receive an annual influenza vaccination does not portend increased dangers in vaccinating all children in infancy or as toddlers. There remains the commitment, however, to continue to monitor the administration of influenza vaccine through the existing postlicensure monitoring systems as previously discussed in the Department's response to Comments 50, 51, 52 and 53 and as more children are now being administered this vaccine than in past years. The Department does not agree with the commenters' assertion that insufficient time has elapsed for the Department to establish an annual influenza vaccine requirement for children in child care center settings.

55. COMMENT: Children as young as two months of age should not be vaccinated. (30 and 41)

RESPONSE: The ACIP determines the recommended ages at which vaccines are to be given after a review of prelicensure clinical trials data. Children need to be immunized in early infancy because they are susceptible to certain serious infectious diseases at a young age. The efficacy and safety data from these trials is first reviewed by the FDA for licensure and later by the ACIP and other professional medical organizations to determine dosage and timing parameters for vaccine administration. For decades vaccines, such as DTP, polio, HIB, and hepatitis B have been

recommended and given as a series of vaccinations routinely beginning at two months of age, or as soon as six weeks of age. Studies have shown that 90 percent of infants develop protective immune responses to the routinely recommended childhood vaccines between two to six months of age. The Department is unaware of any scientific data or other evidence that vaccinating children beginning at two months is too soon, or that routine initiation of childhood vaccinations should be postponed until three months of age or older. The Department has no reason to believe that also administering the new pneumococcal conjugate vaccine at the ACIP recommended age of two months would have a deleterious effect on either that vaccine's safety or its efficacy.

56. COMMENT: The Department is only mandating these four new vaccines at N.J.A.C. 8:57-4 to benefit pharmaceutical companies. (4, 5, 6, 13, 27, 30, 32, 33, 41, 44, 45, 48, 49, 51, 53, 54, 57, 58, 62, 65, 73, 76, 78, and 81)

RESPONSE: Over the past several years, physicians and legislators have urged the Department to add the meningococcal and pneumococcal conjugate vaccines to the list of required vaccines for children at N.J.A.C. 8:57-4. At least 12 other states already mandate pneumococcal conjugate vaccine for child care center attendees. The National Meningitis Foundation and the ACIP support the use of the meningococcal vaccine in preadolescents, teens, and college students and the implementation of school immunization requirements for the meningococcal vaccine. The recent epidemiology of increased pertussis incidence among preadolescents in New Jersey, and the fortuitous licensure in 2005 of two new tetanus, dipthteria, and reduced acellular pertussis (Tdap) vaccines containing acellular pertussis that can be given to persons over age six for the first time, presents a reasonable public health intervention that needs to be implemented and made a vaccine requirement for pupil attendance in a Grade Six class.

The Department's decision whether or not to implement a new vaccine requirement is not based upon the financial interests of a vaccine manufacturer or prospective profit by vaccine manufacturers. Rather the decision to require a new vaccine is based on the public health benefits of preventing cases of disease and possible disease complications through the immunization process. The Department only considers adding a new vaccine to the list of mandated vaccines if it has been licensed by the FDA, recommended for universal use by the ACIP, AAP, AAFP, CDC, and other government agencies or professional medical organizations, is on the ACIP Recommended Childhood and Adolescent Immunization Schedules, and there is a sufficient medical and epidemiologic data available to make a reasonable decision.

Since most children (85 percent in 2006) affected by these new rules will have already received the pneumococcal conjugate vaccine as part of routine pediatric preventive care, and only one dose would be required under these rules for children over one year of age, most parents will not incur an additional or excessive financial burden to meet the PCV requirement. As a result of this new rule, the drug company would at most only realize a marginal increase in profit from sales of this vaccine. Similarly, the meningococcal conjugate and Tdap vaccines are only given one time as a single dose and at the same office visit, therefore any profit realized would be limited to that dose and one office visit. By contrast, implementation of an annual influenza vaccine may produce some more sales and profits for the drug companies than in the past since the 2005 National Immunization Survey (NIS) by CDC estimated that only 37 percent of New Jersey's toddlers received an influenza vaccination in 2004. However, since the influenza vaccine is among the least expensive of all the routinely recommended vaccines for children and the required vaccines for school or child care attendance, the profit margin would be considerably less compared to the other existing required vaccines. The Department does not agree with the commenters that it is mandating vaccines for the purpose of increasing the profits for vaccine manufacturing drug companies.

57. COMMENT: Influenza vaccine should not be required since it contains thimerosal and that may contribute to, or is a cause of autism. (4, 5, 7, 8, 9, 10, 13, 15, 17, 27, 29, 31, 32, 33, 34, 36, 41, 43, 44, 49, 50, 53, 54, 55, 57, 58, 59, 61, 62, 63, 65, 66, 73, 76, 77, 78, 80, and 81 and form letters 82 through 107) One commenter (5) provided the Department with the following articles and references concerning thimerosal and autism: A pamphlet entitled, "Flu Vaccines - What You Need to Know," published by SafeMinds; a blog article from the Huffington Post about thimerosal and autism from David Kirby; excerpts from meeting on Scientific Review of Vaccine Safety Datalink Information of June 7 and 8, 2000 in Norcross, GA; an executive summary abstract from a 2004 Institute of Medicine report entitled, "Vaccines and Autism"; excerpts from organizational meeting of a closed session meeting of the Immunization Safety Review Committee of the Institute of Medicine (IOM) on January 12, 2001; and a copy of a newspaper article in the Daily Record of Morris County dated November 12, 2006, discussing autism and its possible link to thimerosal in vaccines.

58. COMMENT: If influenza vaccine is made mandatory, then at the very least, the word "mercury-free" influenza vaccine should be added to the influenza rule. (6 and 48)

59. COMMENT: One commenter stated she is opposed to influenza vaccine mandate because her child was diagnosed with autism, and as she began to research autism, it led her to the link between thimerosal-containing vaccines and autism and the realization that thimerosal in vaccines is likely related to the autism epidemic. (17)

60. COMMENT: One commenter whose nephew is autistic stated that influenza vaccine still contains thimerosal and feels that the dramatic rise in autism rates correlate with the increase of mercury in vaccine doses. (8)

61: COMMENT: Several commenters stated that mandating influenza vaccine, which contains thimerosal, will exacerbate the already high rate of autism of one in 94 children in New Jersey, and will exact greater additional costs to the long-term health of our children, strain on their families, and a growing taxpayer and State burden to provide for the special needs of these affected children in excess of any benefit realized from the influenza vaccination of all children in day care centers and preschool. (5, 59, and 65)

62. COMMENT: Since the removal of thimerosal from most vaccines since 2001 there has been a dramatic decrease in the number of autism spectrum disorders being diagnosed. (4, 5, 33, and 62)

RESPONSE TO COMMENTS 57 THROUGH 62: The Department recognizes that autism is a devastating disorder that exacts great emotional and economic burdens upon families and school systems caring for autistic children. The cause of autism remains unknown, however early identification and intervention can improve an autistic child's condition. Since 2002, there has been a Governor's Council on Autism in New Jersey established to present and deal with some of the issues parents are confronted with in the care of an autistic child. In 2007, the New Jersey Legislature passed a series of autism-related bills and on September 12, 2007, Governor Jon Corzine signed seven bills into law to establish a Statewide autism registry, augment funding for the Governor's Council on Autism, and to provide for increased autism awareness and training for teachers and physicians. The State of New Jersey is sensitive to the autism problem and is committing more resources to autism. A recent New Jersey Supreme Court decision on September 12, 2007 held that the State Health Benefits Commission for State employees should pay for the speech, occupational and behavioral therapies of an autistic child. *Micheletti v. State Health Benefits Comm'n*, 389 *N.J.Super.* 510 (App. Div.), aff'd, 192 N.J. 588 (2007). This ruling may serve to have wider impact upon other health insurance company policies in this State regarding autism related services.

The CDC and National Institutes of Health (NIH) are working at the national level to fund studies to assess health effects of thimerosal and to determine if there is any association between thimerosal and autism, learning or developmental disorders, or other chronic diseases or adverse health outcomes. The Institute of Medicine has reviewed and studied data in 2001 and in 2004 and issued three reports respectively entitled,

"Thimerosal-containing vaccines and neurodevelopmental disorders" and "Mesasles-Mumps-Rubella Vaccine and Autism," in 2001 and "Vaccines and Autism," in May 2004. In the 2004 report of the Institute of Medicine (IOM) Immunization Safety Committee, the IOM concluded that "the body of epidemiological evidence favors rejection of a causal relationship between a MMR vaccine and autism. The committee also concludes that the body of epidemiological evidence favors rejection of a causal relationship between thimerosal-containing vaccines and autism," but they have recommended continued research and studies. In 2003, the Journal of the American Medical Association (JAMA) reported the results of a population based epidemiologic study entitled "Association Between Thimerosal-Containing Vaccine and Autism" by J. Hviid et. al of 467,450 children in Denmark that compared children vaccinated with thimerosal-containing vaccines with other children vaccinated with thimerosal-free vaccine and found there was no significant difference for risk of autism and autistic spectrum disorders between the two study groups. In 2003, Pediatrics reported the results of another Denmark study by KM Madsen et. al entitled "Thimerosal and the Occurrence of Autism: Negative Ecological Evidence from Danish Population Based Data," that demonstrated that despite the removal of thimerosal from vaccines, the incidence of autism continued to increase. Similar ecological study results have been reported from Sweden, the United Kingdom, and other countries and these are described in the published 2004 IOM Report on Vaccines and Autism. In the United States, studies by Loring Dales, M.D. in 1999 and 2001, revealed that the number of autism cases in California increased even when the number of MMR vaccine doses decreased over the study period. A 1999 study by Brent Taylor, M.D., et. al in the United Kingdom found that the number of diagnosed autism cases did not increase after the MMR vaccine was introduced. Since 2001, all manufactured vaccines administered to children contain no thimerosal, except some formulations of influenza vaccine.

There are sufficient quantities of thimerosal-free influenza vaccine and influenza vaccine with only a trace of thimerosal left after the manufacturing process, that are available for distribution and administration to preschool-aged children attending child care centers in New Jersey; with each successive year, the vaccine companies are manufacturing more preservative-free influenza vaccine. The vast majority of the medical science and evidence to date does not support a causal association between thimerosal in vaccines and autism. Based on the currently available information from multiple scientific studies, the Department disagrees with the assertion of the commenters that thimerosal in vaccines is a cause of autism. The most recent studies that have been published in the medical and scientific literature on the cause of autism have suggested that autism has a strong genetic component, although environmental factors still remain under study. The Department also disagrees with the observations of some that since thimerosal has been removed from most vaccines there has been a dramatic decrease in the number of autism spectrum disorder cases being diagnosed. There is no national or international data to support such a pronouncement; unfortunately, autism cases continue to be detected. Despite these recent studies, researchers are continuing to search for the cause(s) of autism. The current evidence to date suggests that there is no association between vaccines containing thimerosal and autism. The Department thanks the commenter (5) for providing information related to thimerosal and autism.

63. COMMENT: New Jersey has the highest rate of autism in the country and that may be attributed to vaccines. (70)

RESPONSE: Virtually all states have mandated the same childhood vaccines for child care center and school entry as those required in New Jersey. Other variables, which may contribute to New Jersey's high rate other than vaccination, include superior physician diagnostic skills, more complete reporting, more awareness on the part of physicians, schools, and parents, or other less apparent factors, such as genetics or other environmental impacts. The school children in New Jersey have not been required to document receipt of vaccines in excess of those required of children in other states. The Department disagrees with the assertion that New Jersey's high rate of autism may be a result of the rules at N.J.A.C. 8:57-4.

64. COMMENT: One commenter stated that the Kiddie Kollege Day Care Center in Gloucester County was recently shut down by the State because the facility exceeded the Federal standard of mercury per meter of air, and expressed concern that because the standard flu shot contains "250" times the mercury that was sufficient to shut down Kiddie Kollege, there would potentially be great danger as a result of vaccinating children attending every child care center in the State. (9)

RESPONSE: All currently licensed influenza vaccines are within the Federal limits for thimerosal content set by the various responsible Federal governmental agencies. Thimerosal is a methylmercury substance, which is a different form of mercury from ethylmercury. Studies comparing the two suggest that they are processed differently in the human body and ethylmercury is much less likely than the elemental methylmercury that is found in the environment, to accumulate in the body and cause harm. There are thimerosal-free formulations and formulations containing only a trace of thimerosal in the influenza vaccines, which are licensed by the FDA and available for pediatric use, which contain substantially less thimerosal than the "standard flu shot." The recently expanded FDA licensure of the nasal influenza vaccine, FluMist(TM) for children two through five years of age is another available thimerosal-free vaccine. The Department disagrees that vaccinated children who may have received some thimerosal-containing vaccines pose any personal or environmental threat to other children or staff in child care centers.

65. COMMENT: The Department lacks the authority through the rulemaking process to mandate additional vaccines for children in schools since that should be the responsibility of the New Jersey Legislature. (7, 11, 13, 15, 16, 42, 64, 68, 71, and 72)

66. COMMENT: Some commenters expressed displeasure that the Commissioner or another "high level official" was not present at the public hearing held on January 26, 2007. (4, 11, 42, 64, 68, 71, and 72)

RESPONSE TO COMMENTS 65 AND 66: The Department is the State agency charged with the responsibility to protect and preserve the health of its residents as set forth at N.J.S.A. 26:1A-37. Since 1974, the Legislature has given the Department authority to use its expertise, in consultation with the Public Health Council, to promulgate changes or add new immunization requirements to the list of vaccinations required as a condition of school or child care center attendance as set forth at N.J.S.A. 26:1A-7. N.J.A.C. 8:57-4 is mandated by N.J.S.A. 26:1A-7, which grants certain powers to the New Jersey Public Health Council (PHC) with regard to the State Sanitary Code. Former Governor Codey's Reorganization Plan No. 003-2005 (June 27, 2005), 37 N.J.R. 2735(a) (August 1, 2005), recasted the role of the PHC, established at N.J.S.A. 26:1A-7, as being of a consultative and advisory nature in relation to the powers of the Commissioner of Health and Senior Services (Commissioner). The Department has the authority to determine which vaccines should be added to the list of required vaccines and draft the appropriate language to successfully implement newly licensed vaccines *Id.*; See also N.J.S.A. 26:2-137.1b and 18A:40-21.1.

The Department promulgates new immunization rules through the formal administrative rulemaking process established in the Administrative Procedure Act, N.J.S.A. 52:14B-1 et seq. and the Rules for Agency Rulemaking, N.J.A.C. 1:30 which has prescribed opportunities for public input such as issuance and publication of a public notice, a 60-day public comment period, and a public hearing as appropriate. The Department followed all necessary procedures to notify the public of the public hearing date and place, and of their opportunity to submit verbal or written comments during the comment period. The administrative process requires a hearing officer to accept testimony, review the comments, and make recommendations for adoption. The Commissioner, Deputy Commissioner, and similar Department officials review and approve the notice of adoption, which includes the summary of hearing officer recommendations and agency responses, the summary of public comments and agency responses, and the summary of agency-initiated changes, as appropriate. The use of the formal administrative rulemaking process to add or change immunization requirements is not unusual, as it is a mechanism commonly used in most states. Aside from the rulemaking process utilized by the Department, the New Jersey Legislature also has authority to add new immunization rules or amend existing rules, and in recent years has enacted by statute the hepatitis B and meningococcal vaccine requirements for school and college attendance. The Department does not agree with the commenters that the Department lacks the authority to write amendments or new immunization rules.

67. COMMENT: Children already receive too many vaccines, and the addition of these four new vaccines can be detrimental to a child's immune system. (4, 6, 7, 8, 10, 11, 14, 15, 29, 33, 36, 44, 47, 50, 52, 55, 59, 63, 70, 73 and 76) Three commenters stated that with new vaccines being developed and used, other diseases may arise to take the place of the diseases that are reduced or eliminated through vaccination. (6, 8, and 29)

RESPONSE: Since the 1970's children have been vaccinated with many new vaccines that have been licensed and recommended for the purpose of reducing the incidence and burden of diseases preventable through immunization. As a result of improved vaccines, children in the 2000's now receive more vaccines, but actually fewer antigens than children in the 1960's when only seven vaccines were routinely administered. The human immune system is bombarded daily from birth with multiple antigens, agents, and toxins around and within them unrelated to vaccines or vaccine preventable diseases and it routinely functions to protect the body from all these potentially dangerous agents. There is no scientific evidence that suggests the human immune system is jeopardized by the body manufacturing multiple antibodies from weakened vaccine antigens or that the immune system is being weakened or used up. The healthy immune system constantly replenishes the billions of circulating T and B lymphocyte cells used to fight disease, therefore these cells are never used up. According to one published estimate by Paul A. Offitt, M.D., et. al, in an article entitled "Addressing Parents Concerns: Do Multiple Vaccines Overwhelm or Weaken Infant's Immune System?" in the January 2002 issue of Pediatrics, infants could easily handle as many as 10,000 vaccines at once. There is no scientific evidence that as a result of extensive vaccine use and the resultant reduced incidence of infectious vaccine preventable diseases that there are now replacement diseases of a more serious and chronic nature emerging, however, medical experts continue to monitor for such a theoretical eventually. The Department disagrees that mandating an additional two vaccines for preschool children and two vaccines for pupils in Grade Six would unduly tax or jeopardize the function of a child's immune system placing him or her at a health risk.

68. COMMENT: The Department should not mandate these four new vaccines because the duration of vaccine induced immunity is unknown and natural disease induced immunity may be more preferable. (7, 8, 10, 12, 14, 29, 47, and 60) Two commenters also stated that since diseases, such as scarlet fever, bubonic plague, or typhoid fever have been controlled and eliminated without vaccines, and that it is not necessary to control diseases through vaccinations. (7, and 10)

69. COMMENT: Many diseases had already seen dramatic decreases in the number of cases before vaccines were developed and widely used due to such things as better sanitation, hygiene, food nutrition, and cleanliness. The role played by vaccinations in reducing the incidence of disease is actually less than what many health professionals proclaim. (5, 7, and 10)

RESPONSE TO COMMENTS 68 AND 69: The duration of vaccine induced immunity for any new vaccine is uncertain and cannot be precisely determined without the passage of time. Factors, such as waning immunity, competence of one's immune system, and vaccine handling and storage procedures can also affect vaccine efficacy. Contrary to the belief of some, acquiring natural disease does not necessarily confer lifelong immunity to a given disease. It is possible for a person to still contract such diseases as dipthteria, pertussis, pneumococcal disease, meningococcal disease, chickenpox, tetanus, influenza, and polio again even if the person previously had the natural disease. It is the consensus of the majority of the medical profession and the public that vaccines do an effective job, if not perfect, at dramatically reducing the number of disease cases, outbreaks, complications, hospitalizations, and deaths due to certain diseases that are now vaccine preventable. There are few persons who would argue that because vaccines are not perfect they should be abandoned so the progression of natural disease and its effects can resume once more as in the pre-vaccine era. Studies to determine duration of vaccine-induced immunity are ongoing. Plague is generally not a disease that is transmissible from person to person. Plague is contracted when one is bitten by an infected flea. Scarlet fever is a communicable febrile rash disease caused by a streptococcal infection that is usually in the throat (strep throat). The availability of antibiotic therapies has lowered the visibility, incidence, and prevalence of these two diseases, and if promptly initiated will prevent most of the serious complications. Despite the availability of antibiotics, these diseases have not been eradicated and plague still remains endemic in some areas of the United States and other parts of the world. The Department does not agree with several commenters that medical science does not need vaccines to prevent or control disease, because diseases, such as plague and scarlet fever have been virtually eliminated or controlled without any vaccines. Better sanitation, hygiene, food and nutrition, and cleanliness has undoubtedly contributed to a healthier society, however, vaccines have played a dominant role in dramatically reducing certain infectious diseases. Those vaccines, which have been developed have dramatically reduced disease incidence by 90 to 99 percent or greater following licensure and widespread use. A review of historical New Jersey morbidity statistics confirms that following widespread implementation of vaccines the incidence of dipthteria, measles, mumps, rubella, polio, and pertussis in New Jersey was dramatically reduced. The Department disagrees with the commenters that vaccines have little or no impact on the reduction of disease incidence, which can be prevented through immunization.

70. COMMENT: One commenter stated opposition to more vaccine mandates since a Bergen Record newspaper article stated all water supplies in Northern New Jersey are contaminated and harmful to human health, since contaminants often come from sewage run offs, which contain human degradation products, such as residual cardiac medications, hormones, antibiotics, and multiple vaccine residuals. (43)

RESPONSE: The Department is unable to respond to this comment since the safety of the water supply, or the possibility that some vaccine by-products are contained within it, and its possible effect on the nervous and immune system is not implicated in this rulemaking. Further, the regulation of water plant distribution and sewage disposal is outside the authority of the Department.

71. COMMENT: Three commenters opposed the meningococcal conjugate vaccine (MCV) requirement and two commenters stated opposition because the vaccine "could cause Guillain-Barre syndrome (GBS)." (48, 51, and 73)

RESPONSE: GBS is a serious, rare neurological disorder that can occur, often in healthy persons, either spontaneously or after certain infections. There has been a meningococcal polysaccharide vaccine licensed by the FDA for use in the United States since 1981. Since 2004, new college students living in a New Jersey college dormitory have been required to receive a meningococcal vaccination. The FDA licensed a new meningococcal conjugate vaccine in January, 2005, and was recommended for use by the ACIP in persons 11 through 55 years of age. In October 2005, the CDC alerted the public that there was a possible but unproven rare risk that GBS could be temporally associated with receipt of MCV. As of September 2006, 17 cases of GBS had been reported within six weeks of receiving MCV. During the period of time from licensure to September 2006, 2.5 million doses of MCV were distributed by the sole manufacturer, Sanofi Pasteur. Since those 17 case reports, cases have been followed-up and there is ongoing surveillance on the part of the manufacturer, CDC, and the FDA around these circumstances and reports. By mid-February 2007, there had been over 7.5 million doses of MCV distributed from date of licensure in 2005. To date, there is no scientific evidence that MCV either causes or increases the risk of developing GBS. The various vaccine advisory bodies or authorities, such as the AAP, AAFP, ACIP, FDA, or CDC have made no changes to the vaccine's current licensure status or clinical administration recommendations. The WHO's, Global Advisory Committee on Vaccine Safety has also found MCV to be safe and effective. The Department disagrees with the commenters that MCV causes GBS.

72. COMMENT: One commenter opposed the Menactra(TM) requirement for Grade Six because it is not cost-effective in terms of the number in cases prevented, is ineffective because it does not protect against the "B" serotype strain, and the meningococcal polysaccharide vaccine or Menomune(TM) still contains thimerosal. The commenter provided a copy of his verbal testimony on the subject of MCV to the Vaccines and Related Biological Products Advisory Committee (VRBPAC), of the FDA on September 22, 2004. The commenter also provided a copy of an

article by D.K. Paran et. al, entitled, "Effects of Thimerosal on NGF Signal Transduction and Cell Death in Neuroplastoma Cells," published in Toxicological Studies, in April 2005 which discussed an in vitro thimerosal study. (48)

RESPONSE: The incidence of meningococcal disease increases at adolescence to a rate that is greater than in the general population. The case fatality rate from meningococcal disease for the age group 11 through 18 years of age is about 20 percent. Even one case can be a life threatening condition for a person and disrupts the school and affects the entire community. Although the meningococcal conjugate vaccine does not prevent against the "B" serogroup strain, it does help prevent up to about 75 percent of all cases of meningococcal disease in children 11 to 18 years of age. The distribution of meningococcal cases by strain varies over time and by age group. The CDC reports that during the 1996 through 2001 time period overall 31 percent of the strains were due to the "B" strain, which is not included in either meningococcal vaccine, while 63 percent of the cases were of the "C" and "Y" strain that are included in the vaccines. In persons 18 through 34 years of age, 41 percent of cases were due to the "B" strain, which is not included in either meningococcal vaccine. The Department believes that there is value in a vaccine that can prevent in excess of 50 percent of a disease, if not 100 percent, for one as devastating as invasive meningococcal disease. The meningococcal polysaccharide vaccine or Menomune(TM) is marketed in two presentations. The 10-dose vial presentation contains thimerosal, however the single-dose vial presentation is thimerosal-free and is available for use. The Departments thanks the commenter (48) for providing information related to the use of thimerosal and the effectiveness of Menactra(TM).

73. COMMENT: Why is it necessary to vaccinate thousands of children when meningitis only strikes one out of 100,000? (51)

RESPONSE: Meningitis is a relatively rare but life-threatening disease than can kill within hours of an onset of flu-like symptoms. Meningococcal meningitis has a high case fatality rate. Despite early initiation of antibiotic therapies, limb loss or mental retardation can occur. Even a sporadic case of meningococcal severely disrupts the affected family, school, and community as is widely reported by the news media. It is important to use the meningococcal vaccine as a tool to prevent such tragic outcomes to susceptible children and adolescents who are higher risk. Other diseases, such as measles, also have extremely low incidence rates now in large part due to vaccination, and the school vaccination requirements have not been eliminated for that vaccine or other vaccines. The Department does not believe it is appropriate to eliminate such existing school vaccination requirements based on current disease incidence because to do so jeopardizes the progress made in vaccine preventable disease control and would risk a disease resurgence.

74. COMMENT: The pneumococal conjugate vaccine (PCV) should not be a required vaccine for children in child care settings. (9, 10, 47, 48, 51, and 80)

75. COMMENT: One commenter stated that the PCV should not be required because it is not cost-effective, as it only produces marginal benefit in preventing ear infections (it's purported reason for use), and the vaccine is associated with a high incidence of serious adverse events. (48 and 51)

76. COMMENT: One commenter stated the Prevnar(TM) or (PCV) vaccine should not be required because his child is vaccine-damaged and felt that Prevnar vaccine probably did the most damage, because the vaccine is not cost effective as determined by a Harvard University study, the vaccine has a high incidence of serious adverse events, and because the vaccine does not prevent ear infections. (9)

RESPONSE TO COMMENTS 74, 75 and 76: Since 2000, the FDA has licensed PCV and it has been routinely administered. This vaccine was first licensed in the United Kingdom and has been recommended and administered there successfully since 1999. PCV is not a newly licensed vaccine. It became such an accepted vaccine by physicians and parents that a vaccine shortage resulted in 2001. In 2005, there were 59 cases of pneumococcal disease reported among children 0 through 59 months of age in New Jersey. There are at least 12 other states with a PCV requirement for children in child care settings. While the primary series of PCV in infancy consists of two to three doses, only one dose is generally recommended after one year of age. There is no thimerosal in PCV. The vaccine has exhibited an excellent efficacy and safety profile since its widespread use with over 20 million doses being administered in the United States. The National Immunization Survey (NIS) of 2006 published by CDC on August 31, 2007 in the MMWR reported that about 86 percent of children 19 through 35 months of age in New Jersey have received PCV. This vaccine is recommended by the WHO for worldwide use based on its efficacy and safety profile. The commenters did not provide any scientific or medical rationale for why PCV should not be a required vaccine. Since the vaccine's implementation there has been a direct dramatic decrease nationally in the rates of meningitis and pneumococcal disease among children. In addition, the vaccine has had an indirect benefit by reducing bacterial carriage and therefore transmission, with a consequent substantial decrease in pneumococcal disease cases among the elderly. The Department also believes that use of this vaccine helps to reduce the problem of increased antibiotic resistance in pneumoccoccal organisms. Although some commenters have stated the vaccine is not effective because it does not contain all the pneuomococcal serotypes, the PCV vaccine contains the seven serotypes that cause approximately 90 percent of the severe pneumococcal disease in the United States in children less than six years old prior to the vaccine's use. The Department is unaware of a Harvard University study addressing the cost effectiveness of PCV and is unable to respond remarks pertaining to that study. Contrary to the assertion of several commenters, the FDA originally licensed Prevnar(TM) for invasive pneumococcal disease, not to prevent ear infections. The FDA later approved its use for ear infections because studies later found that it was effective in preventing some ear infections. A recent study of 150,000 children published in the April 4, 2007 issue of Pediatrics found that pneumococcal conjugate vaccine has actually had a positive effect on reducing the number of children likely to develop frequent ear infections, although that was not the primary impetus for the recommendation and implementation of this vaccine in 2000. When one considers the direct and also the indirect benefits being experienced with this vaccine accruing to the entire population, the vaccine may actually be more cost-effective than what was initially calculated before the positive indirect benefits were considered by the ACIP and CDC. The Department is unaware of any studies or reports in the medical literature indicating an excessive number of serious adverse events and deaths being reported or associated with PCV. The Department disagrees with the commenters that PCV should not be added to list of required vaccinations for children in child care center settings.

77. COMMENT: One commenter stated the Prevnar(TM) vaccine may cause insulin dependent diabetes based on the findings in a published article by Dr. J.B. Classen about HIB vaccine. (10)

RESPONSE: The Department is unaware of any credible or accepted scientific study in the medical literature that links HIB or Prevnar(TM) vaccine to insulin dependent diabetes to support the article written by J.B. Classen as was referenced by the commenter. HIB conjugate vaccine has been licensed by the FDA for use since 1987 and has been routinely used since then for all children up to 59 months of age. The Department is unaware of any study or credible article in the scientific literature that links HIB vaccine or PCV to the onset of diabetes and does not agree that PCV causes diabetes.

78. COMMENT: The Tdap vaccine should not be a required vaccine. (73)

RESPONSE: The FDA licensed two Tdap vaccines in the Spring of 2005. Before licensure of this vaccine, a pertussis-containing vaccine could not be given to persons seven years of age or older. It is an accepted fact in the medical community that the protective qualities of the DTaP vaccine given to children up to the seventh birthday wanes in five to 10 years. In the past several years there has been increased pertussis (whooping cough) incidence nationwide and in New Jersey among children 10 through 17 years of age. With the availability of this new vaccine and implementation of a sixth grade requirement for vaccination it is anticipated that there will be a decrease in the number of pertussis cases

among middle school children, fewer school-based outbreaks, and additional protection afforded older persons with whom they are in contact from acquiring pertussis. Economic studies have demonstrated that a single dose of Tdap vaccine during adolescence is the most cost-effective immunization strategy to reduce pertussis. There is an urgent public health need based on national and New Jersey surveillance and epidemiologic data that this vaccine be added as a required vaccine at the Grade Six level. The commenter provided no scientific or medical rationale explaining why Tdap should not be a required vaccine. The Department disagrees with the commenter that Tdap should not be added to the list of required vaccines at N.J.A.C. 8:57-4, because there exists a clear epidemiologic and ethical imperative that this vaccine be mandated as soon as possible to prevent pertussis in adolescents and those with whom they have contact.

79. COMMENT: The Department should delay adding new vaccines to the list of required vaccines at N.J.A.C. 8:57-4 until planned national studies as the "Amish Study" and the national Omnibus Autism lawsuit over thimerosal in vaccines are completed, thereby limiting the Department's exposure to lawsuits or reducing the State's potential for increased financial liability. (7, 10, 14, 16 and 69) One commenter provided the Department a copy of a CDC document outlining and describing the ongoing five-year CDC-funded Centers for Autism and Developmental Disabilities Research and Epidemiology (CADDRE) Study. (69) One commenter (14) provided the Department informational materials related to the Autism Master File dated January 19, 2007, which provided an update of the Omnibus Autism Proceeding.

RESPONSE: The Department is not aware that the Comprehensive Comparative Study of Vaccinated and Unvaccinated Populations Act of 2006 (Amish Act) introduced on July 27, 2006, has actually been passed by the United States Congress. The Department is aware that since 2002, there has been an Omnibus Autism Proceeding in Federal court and that a court hearing related to thimerosal and autism causation just recently began in June 2007. The Department notes that three of the four vaccines to be added to the list of required vaccines do not contain thimerosal and another suspect vaccine, MMR, never contained thimerosal. While some influenza vaccine for young children still does contain some or a trace amount of thimerosal, there are other thimerosal-free formulations available for use. Due to the above facts, the studies and litigation referred to by the commenters have little relevance to the current rulemaking process to mandate Tdap, MCV, PCV, and influenza at this time. The Department will postpone the official implementation of the four new vaccine rules until September 2008, as it became apparent that there was insufficient time to effectively implement the new rules before the beginning of the 2007-2008 school year.

If any future study findings or litigation dictate findings that are relevant to the recommended immunization schedule, the Department will consider making any necessary amendments to the rules at that time. The Department does not agree with some commenters that to adopt new immunization rules before national studies or lawsuits are concluded makes the State liable in the event of vaccine injuries following receipt of a required vaccine. The Department adopts rules that conform to FDA licensure, are part of the routine childhood immunization schedule, are recommended or endorsed by such credible expert bodies and organizations as the ACIP, AAP, AAFP, CDC, and others, and are considered by the medical profession to be a standard of pediatric care. As such, the Department has a reasonable medical and scientific basis for the new rules. The Department does not agree with the commenters that the implementation of the new vaccine rules at N.J.A.C. 8:57-4 should be postponed indefinitely while the State awaits the outcomes of a national five-year study or national lawsuit. Such a delay would unnecessarily place children at risk of diseases over several years when there are newly licensed and recommended vaccines now available to offer protection. The Department thanks commenters (14 and 69) for the information related to ongoing CDC studies on Autism and the ongoing Omnibus Autism Proceedings.

80. COMMENT: One commenter requests that the Department set up an office to establish a mandatory reporting system to keep complete records of all people injured and dying as a result of vaccine mandates. (13)

RESPONSE: The Department does not agree that there should be a mandatory reporting system established for persons injured as a result of a required vaccine or that there be a new office created within the Department to gather, complete, and analyze the records of all vaccine injured children who received a required vaccine. Establishment of such an office within the Department would duplicate the Federally mandated Vaccine Adverse Event Reporting System (VAERS), which serves the same function.

81. COMMENT: One commenter requests that the State review the safety of all mandated vaccines and that such a review be done independently of drug companies and governmental agencies, and that vaccine be guaranteed as effective for each child. (5)

RESPONSE: The Department performs an internal review of the available scientific literature, studies, recommendations, and other expert references when considering new vaccines to be added to the immunization rules at N.J.A.C. 8:57-4. The Department believes it is inefficient for the State to duplicate the procedures and studies, which have been reviewed by the Federal regulatory agencies or national vaccine advisory bodies, which are charged with that task to determine the safety and efficacy of each vaccine. The Department does not agree that the State should initiate a safety study of all the required vaccines for child care or school attendance that is independent of Federal government agencies or drug companies, or that before each vaccine becomes required it must be guaranteed effective for every single child.

82. COMMENT: One commenter requests that the State investigate each individual vaccine for safety and efficacy, and also assess cumulative effects of all vaccines being given before adding any new vaccines to the list of required vaccines and that the investigations to research each vaccine be done with public participation but exclude investigative with financial, institutional, or a professional interest in the investigation outcome. (8)

RESPONSE: The Department does review from a variety of sources the available safety and efficacy for each vaccine under consideration for addition to the immunization rules at N.J.A.C. 8:57-4. The FDA is charged with determining whether a vaccine is safe and effective before granting licensure. The FDA determines the risk-benefit ratio of a given vaccine as part of its licensure deliberation. The Department believes it is inefficient to duplicate the existing Federal procedures and structures and to establish a distinct State structure to fulfill the same purpose. The Department does not agree that the State should research and investigate each recommended vaccine for safety and efficacy, and also assess the cumulative effects of all vaccines being given, before adding any new vaccine to the list of required vaccines at N.J.A.C. 8:57-4 and that such an investigation use external investigators and public participation while excluding investigators with financial, institutional, or a professional interest in the investigation outcome. Such studies are very complex and by excluding persons with expertise in clinical practice, vaccine research, clinical trials, State or Federal agencies, or ties to health institutions the outcomes from such research would be suspect or non-credible to most in the medical science discipline.

83. COMMENT: One commenter requests that there should be tracking so one knows the ingredients of every shot given and the reaction from each and every shot. (6)

RESPONSE: The Department does not agree that the State should establish a system that describes the ingredients of each vaccine and all possible reactions from each vaccine. Such an initiative would duplicate the use of the Federally mandated Vaccine Information Statement (VIS) and its Federally mandated contents pertaining to vaccine use, some vaccine contents, and medical contraindications or precautions for the use of these vaccines.

84. COMMENT: One commenter requests that the State devise its own methodology to perform a safety and efficacy analysis because the FDA, CDC, and pharmaceutical companies cannot properly evaluate vaccines. (9)

RESPONSE: The Department does not agree it should devise its own vaccine approval and recommendations for vaccines because the FDA, CDC, and the drug companies cannot properly evaluate vaccines; this would duplicate the existing national mechanism for granting vaccine approvals and establishing recommendations for vaccine use. Any subsequent State developed system would likely be less rigorous and comprehensive than the existing national systems. To establish a similar structure in New Jersey or within the Department to perform the roles of those three institutions is impractical and duplicative. The attendant costs of acquiring expert personnel and the financial resources to support and operate such an organization would be cost prohibitive.

85. COMMENT: The process used by the FDA to license vaccines and the process used by the ACIP to nationally recommend vaccines is flawed and can also be subject to conflicts-of interest among the deliberating participants. (5, 9, 10, 13, 56, and 58) One commenter (5) provided the Department with two articles entitled, "A Conflict of Interest in Vaccine Policy Making," Majority Staff Report of the Committee on Government Reform, U.S. House of Representatives, August 21, 2000, and minutes of the June 29 and 30, 2006 ACIP meeting discussing the ACIP conflict of interest policy.

RESPONSE: The scientific process used by the FDA to license vaccines is outlined in a booklet published by the National Institutes of Health (NIH) and can be accessed online at: http://www.niaid.nih.gov/publications/vaccine/pdf/undvacc.pdf. The process used by the ACIP reviews existing scientific evidence, clinical trials data, and epidemiologic data to determine how best to use the licensed product and makes vaccine recommendations for the nation. It is the understanding of the Department that conflict of interest questionnaires are supplied to persons serving in both reviewing bodies, and that when a participant has a possible conflict of interest on a specific product under consideration for licensure or recommendation that person must recuse himself or herself from voting. The June 29 and 30, 2006 ACIP meeting minutes addressing this issue are accessible online at http://www.cdc.gov/vaccines/recs/acip/downloads/min-jun06.pdf on page one of the document. The Department is not the appropriate jurisdiction, nor is it in any position to question or change the existing clinical trial structure, scientific data considered, or current licensure methodology of the FDA to license new vaccines. The Department is not the appropriate jurisdiction nor is it in the position to question the integrity of the ACIP members as they work to review the existing data to make national vaccine recommendations and would refer the commenters to the ACIP or its members who may be contacted at (404) 639-8836. The Department has no knowledge that either the FDA vaccine licensure process or the ACIP vaccine recommendation process is flawed, improper, or not based on scientific evidence. The Department disagrees with the commenters that the national systems established to license and recommend vaccines are severely flawed. The Department thanks the commenter (5) for the information related to conflicts of interest effecting vaccine licensure and ACIP recommendations.

86. COMMENT: The Department should not require the four new vaccines because there are concerns that the vaccine supplies may be insufficient given that vaccine shortages have occurred in the recent past. (9, 29, 36, 67, 69, and 79)

RESPONSE: The Department recognizes that there have been national vaccine shortages in recent years, particularly affecting the PCV, MCV, and influenza vaccines. One cannot accurately predict any national vaccine shortage. Most vaccine shortages occur shortly after a new vaccine is licensed and it becomes recommended for use by the ACIP and the AAP. The vaccine manufacturers have worked through the several problems of meeting a high demand for the PCV and MCV following its licensure and recommendation for routine use. The PCV shortage ended in September 2004, and the MCV shortage ended in November 2006 after private corporations achieved increased manufacturing capacity. There has been no shortage of the two Tdap vaccines since their licensure in the Spring of 2005. The influenza vaccine remains a more variable commodity from year to year because it can only be manufactured following a complex and lengthy process for one influenza season and then has to be reformulated all over again for the next year's influenza season. While there have been supply and distribution problems associated with the influenza vaccine for the past several years, there has always been pediatric influenza vaccine that goes to waste in medical providers' refrigerators because it goes unused at the end of each flu season. The vaccine manufacturers are producing more influenza vaccine each year for the pediatric and adult population, while increasing the amounts of thimerosal-free influenza vaccine for pediatric use. In the event of a State or national vaccine shortage affecting any vaccine required for school or child care attendance, the Department will be able to suspend that specific vaccine requirement as described at N.J.A.C. 8:57-4.22(d). The Department does not anticipate any threat of possible future vaccine shortages among the four new vaccines being required, with the possible exception of influenza vaccine. The Department believes there is an effective mechanism in place to waive a specific vaccine requirement if that is necessary, and therefore does not agree with the commenters that implementing these four new vaccine requirements should be postponed until vaccine supplies are assured.

87. COMMENT: The Department should not mandate these four new vaccines because they may increase health care costs for parents, and perhaps increase health insurance premiums for employees or employers. (9, 14, 48, and 65)

RESPONSE: The Department recognizes that the more recently licensed vaccines are more expensive than those developed in past decades. Pharmaceutical companies must expend considerable sums of money over a period of about 10 years before a vaccine becomes licensed for use by the FDA. The Department agrees that requiring an annual influenza vaccination for children attending a child care center or preschool may require parents to make an additional pediatric office visit, however the influenza vaccine is among the least expensive of the recommended vaccines children receive. Receipt of PCV would not likely require an additional office visit since it is generally administered at the same office visits as the DtaP, hepatitis B, HIB, and polio vaccinations. Although early calculations indicated that PCV had a high cost-to-prevention ratio, subsequent dramatic decreases noted in the incidence of pneumococcal disease among young children and an indirect effect of the vaccine playing a role in reducing disease incidence among the elderly, suggest that when both direct and indirect benefits of this vaccine are considered, the cost-effectiveness of this vaccine is improved. As new vaccines are licensed, recommended, and become universally administered by medical professionals they become the standard of medical care. Disease prevention costs are less than the costs associated with illness, treatments, complications, hospitalizations, and institutional disruptions. Realizing this economic fact, most insurance companies will cover the cost of the recommended vaccines for children as part of their policy benefits. In addition, many states including New Jersey at N.J.S.A. 26:2-137.1 and N.J.A.C. 8:57-8, mandate that those vaccines recommended by the ACIP be a covered service by most health insurance companies. In this case, the insurer is required to cover a vaccine because it is recommended by the ACIP, not because it is a required vaccine for school entry and attendance. It is difficult to ascertain what impact the implementation and use of these new vaccines will have on the decisions of health insurers to change or raise the premiums they charge individual policyholders, employees, or employers. Despite more costly vaccines available now to prevent more diseases than ever, vaccines still remain among the most cost-effective medical interventions to reduce the incidence of certain serious diseases among children. The positive effects of vaccines over decades of use by families, physicians, schools, and society-at-large support the fact that the immunization of children is a prudent and beneficial investment for all. The Department does not agree with the commenters that these vaccines should not be mandated because they may increase overall health costs. The Department believes instead, that use of these vaccines reduces direct personal and societal health costs, other indirect attendant social costs, and will reduce economic costs as a result of preventing diseases through immunization.

88. COMMENT: Several commenters stated that the Human Papilloma Virus (HPV) should not be added to the list of required vaccines. (33, 44, 48, 61, and 80) One commenter reported the successful reversal of HPV that was accomplished by changing one's diet and improving one's immune system, without the need of vaccination. (61)

RESPONSE: The HPV vaccine is not considered to be a treatment for HPV, but rather is intended to prevent the disease from establishing itself in a susceptible person. Although the New Jersey Legislature had previously introduced a bill on October 23, 2006, to mandate the recently licensed HPV vaccine for girls in grades seven through 12, it was later withdrawn. The Department did not propose to add the HPV to the list of required vaccines in its published notice of proposal of December 18, 2006. At this time, there is no plan for the Department to require HPV, however, legislative actions can occur independent of Department rulemaking initiative.

89. COMMENT: Hepatitis B vaccine should be removed from the list of required vaccines and the vaccination mandates repealed because hepatitis B is not an easily communicable disease in the United States, the hepatitis B vaccine has caused significant health problems, and based on the decade plus of experience, vaccination is ineffective as it has not significantly decreased the disease incidence in the United States. (48 and 51)

RESPONSE: The routine administration of the hepatitis B vaccine to all infants and adolescents since 1991 has had a dramatic effect on the incidence of acute hepatitis B infection in the population, by reducing the national disease incidence about 80 percent. The current hepatitis B rules under N.J.A.C. 8:57-4 for children in grades nine through 12 are required by N.J.S.A. 18A:40-21. The current hepatitis B rules for children in Kindergarten through Grade Six became effective under the Department's authority at N.J.S.A. 26:1A-7. The Department finds no medical, epidemiologic, or public health reason to rescind the hepatitis B requirement for children in the elementary grades. The Department has no authority to repeal the Grade Nine through 12 hepatitis B requirement that was statutorily mandated. Any citizen initiative or request to repeal the law passed by the Legislature for children in grades nine through 12 should be directed to the Legislature, not the Department. In addition, the Department disagrees with the commenter that there is a need to repeal the hepatitis B vaccine requirement because the Department is aware that 46 other states have also established hepatitis B vaccine mandates and the vaccine has proven its effectiveness over time as noted in a published article on March 16, 2007 in the Morbidity and Mortality Weekly Report (MMWR), "Surveillance for Acute Viral Hepatitis - United States, 2005," which reported that the incidence of acute hepatitis B has dramatically decreased by 79 percent from 1990 to 2005 with the widespread use of the vaccine among children.

90. COMMENT: Three commenters associated with the Netherlands Reformed Church and the Netherlands Reformed Christian School requested that the members and families of their Congregation be exempted from all laws and rules pertaining to mandated immunization. (37, 38, and 74)

RESPONSE: New Jersey does not require parents to demonstrate membership in a recognized church or a religious denomination, such as Christian Science or others, which are opposed to vaccination in order to obtain a religious exemption. The Department does not agree that a blanket religious exemption to all parents who are adherents of a specific church congregation or children attending a specific religious affiliated school should be established. Such a blanket exemption may be considered discriminatory, preferential, and Constitutionally problematic. All parents seeking a religious exemption from the immunization rule may submit a written request to the respective school or child care center as specifically provided at N.J.A.C. 8:57-4.4(a).

91. COMMENT: Some commenters stated that some vaccines contain aborted fetal tissue, which conflicts with their religious beliefs. (42, 64, 68, 71, and 72)

RESPONSE: Fetal tissue is not used to produce vaccines. Some cell cultures originally derived from fetal tissue were obtained from legal therapeutic abortions in the 1960s to create human cell-lines that are used to grow vaccine viruses. There is no fetal tissue culture used in the manufacture of the four new vaccines being added to the list of required vaccinations for children in schools at N.J.A.C. 8:57-4. No new fetal tissue is needed to produce cell lines to make vaccines, now or in the future. If parents are opposed to vaccinations for religious reasons, they may submit a request for a religious exemption as specified at N.J.A.C. 8:57-4.4(a).

92. COMMENT: Five related families with a child on the autism spectrum and one other person requested that the Department should establish an exemption from the immunization rules for parents who have medically challenged children and for their siblings, or for those with diagnosed developmental disorders. (42, 64, 68, 71, 72, and 59)

RESPONSE: The Department does not believe that it is necessary to establish a special exemption, other than the existing religious and medical exemptions from the immunization rules, for certain medically challenged children or those with diagnosed developmental disorders, or for their siblings. The existing rule at N.J.A.C. 8:57-4.3 provides for physicians to write medical exemptions from certain vaccines if vaccines are contraindicated for valid medical reasons as enumerated in the recommendations of the Advisory Committee of Immunization Practices or the American Academy of Pediatrics (AAP). Each child is a separate person, and medical contraindication in one child does not necessarily imply that the same medical contraindication extends to siblings or family members.

93. COMMENT: The State of New Jersey should pass legislation to eliminate vaccines containing thimerosal. (9)

RESPONSE: The Department is aware that the New Jersey Legislature has introduced bills to ban thimerosal-containing vaccines in New Jersey. The Department appreciates the commenter's remark, but the Department lacks the authority to pass legislation.

94. COMMENT: The language at N.J.A.C. 8:57-4.23(b) should state four days "after," instead of four days "before," either the specified minimum age or dose spacing interval. (48)

RESPONSE: In 2001, the ACIP recommended that the four-day grace period option be worded as "four or fewer days before." Prior to the 2001 ACIP recommendation, a vaccine given too early, or even one day early, was considered medically invalid and revaccination was medically indicated, which created some friction and issues among parents and physicians. There has never been a problem with a vaccine dose being considered invalid and requiring revaccination because it was administered after its minimum age or dose spacing interval. Most states have incorporated the ACIP recommended language of 2001, into their immunization rules. The Department does not agree with the commenter's suggestion that the language should be changed to "four days after."

95. COMMENT: Each existing vaccine and the proposed new rules and subsections should be prefaced with the language "Unless exempted from immunizations," or "For children not exempted from further vaccination," within Sections 8:57-4.5, 4.10, 4.11, 4.12, 4.15, 4.16, 4.19, 4.20 and 4.23. (48)

RESPONSE: The Department has implemented rules since 1974 that are to apply to all pupils. The only exceptions granted a pupil from receiving the required vaccines are for religious or medical exemptions. Those exemptions are established at N.J.A.C. 8:57-4.3 and 4.4. There are less than one percent of children enrolling in Kindergarten in New Jersey with a religious exemption from vaccination. There is no reason to preface each rule with a negative exclusionary statement limited to only a few children. Administrative rules are customarily written for general compliance, with the exceptions to the rules subsequently noted elsewhere. The Department disagrees with the commenter that each vaccine requirement should be prefaced with a statement announcing that the immunization rules only apply to those children without exemptions.

96. COMMENT: The Department should provide a 30-day grace period at N.J.A.C. 8:57-4.5(a) for parents to submit either a medical or religious

exception after they have notified a school or child care center of their intention to do so. (48)

RESPONSE: The immunization rules require submission of immunization records for most children before admission to a child care center or school. Provisional admission is permitted so that a child who has started the immunization series of vaccines can remain in school while he or she continues to receive the remaining required vaccine doses in a timely manner. There is no reason why a parent should be provided a grace period of up to 30 days to submit a written request for a religious exemption. Parents with a religious objection to the immunization of their child have previously made that decision well before they seek to administratively enroll their child into a child care center or school. These parents do not require 30 days to write a religious exemption statement for submission to the child care center or school. A parent cannot directly write a medical exemption; such an exemption request must come from the child's physician. For children who have received routine pediatric health care in New Jersey, provision of this documentation by physicians can be done very quickly rather than taking weeks. Since the 1970s, all states have required vaccination of children for admission into a licensed child care center or school, virtually all parents and physicians have been made aware that such required health documentation is necessary for attendance through media communications, family experiences, school and child care centers pre-enrollment procedures, and at the time of sick and well-baby medical visits. The Department disagrees with the suggestion that the rules should provide a 30-day period for a parent to submit a medical or religious exemption while his or her child remains in attendance.

97. COMMENT: The Department should amend the language at N.J.A.C. 8:57-4.7(a), Records required, to read: "Provided the child's parent or guardian consents, every school, preschool, or child care center shall maintain an official State of New Jersey School Immunization Record for every pupil. This record shall include the date of each immunization and shall be separated from the child's educational record and other medical records for the purpose of immunization record audit. For those parents who do not consent, the school, preschool, or child care center shall recognize the right of privacy for the child's parent or guardian and maintain the records of refusal in the child's other medical records and no [sic] disclose said records without obtaining prior consent from the child's parent or guardian prior to each disclosure." (48) (The commenter underlined his proposed changes.)

RESPONSE: Pursuant to the authority of N.J.S.A. 26:1A-7 and 26:1A-9 the immunization rules require that parents or guardians submit documentation of vaccinations of children enrolling in a school or child care center prior to admission as specified at N.J.A.C. 8:57-4.2. Schools or child care centers are to document these vaccines on a standard and official State of New Jersey Immunization Record form as specified at N.J.A.C. 8:57-4.7. Parents who refuse to provide such immunization records, or who have not submitted a written request for a medical or religious exemption from the immunization rules are prohibited from having their child attend an educational facility in New Jersey and will have to homeschool their child. The immunization records must be accessible to State or local health officials as stated at N.J.A.C. 8:57-4.9 to audit pupil records to assess school compliance with the immunization rules. The Department disagrees with the suggestion that parents be given a choice to submit required vaccination information or that additional restrictions or unnecessary obstacles be placed upon local or State health authorities as they access those records, as it is their responsibility to ensure school or child care center compliance with the immunization rules. The Department believes there are sufficient procedures and practices in place to maintain the privacy of pupil health records and disagrees with the commenter that there needs to be additional language added to the rules to protect a child's school health record(s).

98. COMMENT: The Department should change the language at N.J.A.C. 8:57-4.10(e) to specify that a child age seven through nine only receive a thimerosal-free Td vaccine, or if that is not available, a thimerosal-free Tdap vaccine. (48)

RESPONSE: There are currently available thimerosal-free formulations of Td vaccine. There is no scientific evidence that administering a Td vaccine containing thimerosal is harmful to a child seven years of age or older. It is counter to FDA licensure and ACIP medical recommendation to administer a Tdap vaccine to a person less than 10 years of age since the FDA has not licensed either of the two Tdap vaccines for children less than 10 years of age. The Department disagrees with the suggestion to change the language because the Department chooses to conform to the FDA licensure and current ACIP recommendations on the use of Tdap.

99. COMMENT: The Department should change its language in all existing vaccine requirements and the new proposed vaccines to permit antibody titers or history of disease to be acceptable documentation in lieu of receiving vaccinations. (48)

RESPONSE: A history of previous disease from a parent or physician is currently only acceptable as documentation in lieu of receiving vaccinations for one disease, varicella (chickenpox). A parental or physician history of previous disease is often very difficult to ascertain and document, and with most of the required vaccines, contracting a vaccine preventable disease does not necessarily confer immunity from a subsequent infection. Serological tests to determine immunity are also often difficult to interpret and are not appropriate for most of the required vaccine preventable diseases in these rules. The existing New Jersey immunization rules at N.J.A.C. 8:57-4 permit serological proof of immunity for only hepatitis B, measles, mumps, rubella, and varicella, as do most other states. The reason for proposing a Tdap vaccine at Grade Six is to reduce the incidence of pertussis affecting that age group and those in middle school. There is no licensed serological test for pertussis that is recognized as being a valid correlate to pertussis disease protection, and there is no licensed vaccine that contains only pertussis antigen. There are no blood tests that would be acceptable evidence of immunity for the meningoccal, influenza, or pneumococcal diseases due to their various strains and subgroups. The Department disagrees that additional alternatives to vaccination, such as serologic testing and disease histories should be added to these rules at this time.

100. COMMENT: The Department should add language at the beginning of N.J.A.C. 8:57-4.20(a) and (b) stating, "Unless exempt from vaccination or they have a history of an adverse reaction to other vaccines" and also at N.J.A.C. 8:57-4.20(b) to specify that the meningococcal containing vaccine shall be Thimerosal-free. (48) (The commenter underlined his proposed changes.)

RESPONSE: The Department has already responded to the proposed exemption language in the response to Comment 95 above. Generally, a mild or moderate adverse reaction to one vaccine does not medically contraindicate the receipt of other vaccines. It is the child's physician who is responsible for determining if a past adverse event may temporarily or permanently justify deferral of other vaccines based on the guidelines of the AAP, ACIP, and CDC, as specified at N.J.A.C. 8:57-4.3(b). The physician would write a medical exemption for the parent to submit to the school for a medical exemption from the specific immunization requirement for the pupil. The Department disagrees that any adverse reaction to another vaccine should be grounds for a medical exemption from the meningococcal vaccination and believes that the existing language relating to medical exemptions at N.J.A.C. 8:57-4.3 is sufficient to address these matters. The Department believes it is not necessary to specify that the meningococcal vaccine in the rule shall only be a thimerosal-free vaccine formulation. The overwhelming majority of children in Grade Six will receive the preferred, and more readily available, meningococcal conjugate vaccine (Menactra(TM)) that is thimerosal-free from their physicians. The less available (Menomune(TM)) vaccine containing thimerosal in some multi-dose vial presentations however remains licensed for use by the FDA as a safe and effective vaccine.

101. COMMENT: When a pupil is determined to be out of compliance because he or she received a vaccination outside of the four-day grace period, as stated at the amended N.J.A.C. 8:57-4.23(b), the school must first advise the parent that there are options, such as serological testing, furnishing a disease history, or determining if there is a medical exemption before they are to be revaccinated. (48)

RESPONSE: It is not the responsibility of the school administrator or school nurse to determine the proper medical course of action regarding a

vaccination deficiency that is in best interest of the child. When a vaccination is improperly given the parents are notified to take their child to their doctor for an evaluation and medical care, as the rules require. Since disease histories (except for varicella) are not acceptable as proof of immunity, the physician will either revaccinate, perform a serological test if one is acceptable under these rules, or request a medical exemption from vaccination based on a valid reason as set forth in the ACIP or the AAP publications, as specified at N.J.A.C. 8:57-4.3(b). The Department disagrees that schools should be required to first determine that all these alternatives have been considered or completed before a child should be referred to a physician to be revaccinated, as they fulfill their institutional responsibilities of monitoring and assessing immunization records, as is required under the immunization rules.

102. COMMENT: The Department should add a new section to the immunization rules as follows, "N.J.A.C. 8:57-4.24 Informed consent (a). The parent or guardian shall be advised in writing by school officials of the availability of an exemption for religious or medical reasons prior to each vaccination, required to sign that each has been informed of his or her exemption rights and understands those rights, given a copy of the document they have signed, and a copy of that signed notification of exemption form placed in the child's admission records whenever a child is enrolled in a school; (b). For children currently enrolled, the school shall obtain a signed copy of a notification of exemption and place it in all of the enrollment records for each student enrolled within 120 days of the effective date of this regulation; (c). The penalty for a school to [not] obtain a signed notification of exemption document shall be the loss of State funds for that student for each day that student is enrolled after the date that document is required to be part of each child's school admission records." (48) (The commenter underlined his proposed changes.)

RESPONSE: Physicians and other licensed health providers who provide pediatric health supervision for children administer vaccinations, rather than schools. Most of the required vaccines under these rules are routinely administered to all children and all vaccine series are generally completed by age five, and before school entry. The National Childhood Vaccine Injury Act of 1986 requires that before a specific vaccine is administered, a parent or guardian must be provided with the appropriate Vaccine Information Statement (VIS). These statements outline medical reasons for the deferral of a recommended vaccine, and if such a contraindication to a vaccine exists it would be grounds for a physician to request a medical exemption from a specific vaccine or vaccines on the patient's behalf. In the course of providing routine pediatric preventive care and medical supervision to a child, if parents have a religious reason for objecting to the vaccination of their child, one would expect that would be communicated to the physician. The parents would already be made aware that when they enroll their child in school they will need to submit a written request for a religious exemption to exempt them from the immunization rules. There is no need for schools to advise all parents or guardians of these two exemptions in writing, which would just add additional and unnecessary burdensome administrative duties to school and child care center personnel. The mandatory retention of approved medical exemption and religious exemption requests by schools is already specified at N.J.A.C. 8:57-4.3(c) and 4.4(c), respectively. The suggestion that schools obtain signed copies of the availability of specified exemptions for each vaccine and for each pupil currently enrolled, within 120 days after this new proposed rule becomes effective, is unnecessary, unrealistic, administratively burdensome, duplicates medical exemption and religious exemption actions previously completed, and unfeasible since about 1.8 million children are currently enrolled in licensed child care centers and schools in New Jersey. The suggestion that the failure of a school to obtain and have on file with the child's school admission records a copy of a signed notification of exemption of the availability of specified exemptions, will mean loss of State funds for the school is an area the Department has no authority or jurisdiction over. The Department disagrees that a new section at N.J.A.C. 8:57-4.24, Informed consent, as suggested should be added to the immunization rules.

103. COMMENT: The Department should amend a new N.J.A.C. 8:57-4.25, Penalties, to read, "Except as provided in 8:57-4.24, each violation of this subchapter shall be subject to the penalty set forth at N.J.S.A. 26:1A-10." (48)

RESPONSE: The Department of Health and Senior Services does not have the authority to substitute or remove a statutorily defined penalty and to initiate actions to reduce the amount of State funds that support school or child care center educational activities. As previously stated in the response to Comment 102, the Department disagrees with the commenter's proposal to add a new rule at N.J.A.C. 8:57-4.24 to assess financial penalties.

Summary of Agency-Initiated Changes:

1. The Department has changed the date of birth set forth at N.J.A.C. 8:57-4.10(h) and (j) from January 1, 1996 to January 1, 1997 in order to capture the same cohort of 11 year old children who would be either entering or transferring into Grade Six from out-of-State or out-of-country on or after September 1, 2008, as discussed in the Department's response to Comment 7.

2. The Department has changed the specified enrollment or attendance date from September 1, 2007 to September 1, 2008 at N.J.A.C. 8:57-4.10(h), (i) and (j) in recognition of extending the operative date of these rules by one year to September 1, 2008, as discussed in the Department's response to Comment 7.

3. The Department has changed the specified enrollment or attendance date set forth at N.J.A.C. 8:57-4.18(a) and (b) from September 1, 2007 to September 1, 2008 in recognition of extending the operative date of these rules by the year to September 1, 2008, as discussed in the Department's response to Comment 7.

4. The Department has changed the specified enrollment or attendance date set forth at N.J.A.C. 8:57-4.19 from September 1, 2007 to September 1, 2008 in recognition of extending the operative date of these rules by one year to September 1, 2008, as discussed in the Department's response to Comment 7.

5. The Department has changed the date of birth set forth at N.J.A.C. 8:57-4.20(a) and (b) from January 1, 1996 to January 1, 1997 in order to caption the same cohort of 11 year old children who would be entering or those transferring from out-of-State or out-of-country into Grade Six on or after September 1, 2008.

6. The Department has changed the specified enrollment or attendance date from September 1, 2007 to September 2008 at N.J.A.C. 8:57-4.20 (a) and (b) in recognition of extending the operative date of these rules by one year to September 1, 2008, as discussed in the Department's response to Comment 7.

Federal Standards Statement

The adopted amendments, new rules, and recodifications are authorized by N.J.S.A. 26:1A-7, and are not subject to any Federal standards or requirements. Therefore, a Federal standards analysis is not required. To the extent that this subchapter requires schools, preschools, and child-care centers to maintain records as to pupils' immunization records, the Department has elected to follow the Family Educational Rights and Privacy Acts (FERPA), 34 CFR Part 99 requirements concerning the privacy of pupil educational records by requiring the separation of immunization and educational records. The Department has followed, and continues to generally follow, the periodically-revised recommendations of Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention of the U.S. Department of Health and Human Services for the routine administration of each communicable disease vaccine to the pediatric population, as applicable to

New Jersey. The Department has generally followed, and continues to follow, the annual "Recommended Childhood and Adolescent Immunization Schedule" and the annual "Recommended Immunization Schedule For Children and Adolescents Who Start Late or Who Are More Than 1 Month Behind" as approved by the ACIP, the American Academy of Pediatrics and the American Academy of Family Physicians, regarding the appropriate periodicity, dosage, and contraindications applicable to the vaccines. The recommendations for each communicable disease and the recommended immunization schedules are available for download through the ACIP website at http://www.cdc.gov/nip/ACIP/default.htm. Paper copies of the various ACIP recommendations and immunization schedules as published in the Morbidity and Mortality Monthly Report by the Centers for Disease Control and Prevention are available by subscription through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; telephone (202) 512-1800. The Department has not exceeded the recommendations described above.

Full text of the adoption follows (additions to proposal indicated in boldface with asterisks ***thus***; deletions from proposal indicated in brackets with asterisk *[thus]*):

8:57-4.5 Provisional admission

(a) A child shall be admitted to a school, preschool, or child-care center on a provisional basis if a physician, an advanced practice nurse (certified registered nurse practitioner or clinical nurse specialist) or health department can document that at least one dose of each required age-appropriate vaccine(s) or antigen(s) has been administered and that the pupil is in the process of receiving the remaining immunization(s).

(b) Provisional admission for children under age five shall be granted in compliance with the specific requirements set forth in N.J.A.C. 8:57-4.10 through 4.15 and 4.18 for a period of time consistent with the current Advisory Committee on Immunization Practices (ACIP) of the United States Public Health Service or the American Academy of Pediatrics (AAP) immunization schedule, but shall not exceed 17 months for completion of all immunization requirements.

(c)-(d) (No change.)

(e) Those children transferring into a New Jersey school, preschool, or child-care center from out-of-State or out-of-country shall be allowed a 30-day grace period in order to obtain past immunization documentation before provisional status shall begin.

(f)-(g) (No change.)

8:57-4.7 Records required

(a) Every school, preschool, or child-care center shall maintain an official State of New Jersey School Immunization Record for every pupil. This record shall include the date of each immunization and shall be separated from the child's educational record and other medical records for purpose of immunization record audit.

(b)-(e) (No change.)

8:57-4.8 Reports to be sent to Department of Health and Senior Services

(a) A report of the immunization status of the pupils in every school, preschool, or child-care center shall be made using the "Annual Immunization Status Report (IMM-7)," set forth in the chapter Appendix, incorporated herein by reference and shall be sent through the mail or submitted electronically, through the addresses set forth in (b) each year to the Department of Health and Senior Services by the principal, director, or other person in charge of the school, preschool, or child-care center.

(b) The Department of Health and Senior Services shall provide:

1. The annual immunization status report for electronic submission at http://www.nj.gov/health/cd/imm7/annualstatusrpt.shtml;

2. The instructions for completion at http://nj.gov/health/cd/documents/imm-7_instructions.pdf; and

3. A paper copy of the annual immunization status report along with the instructions for completion upon:

i. Verbal request to the Department at (609) 588-7512; or

ii. Written request mailed to the New Jersey Vaccine Preventable Disease Program, Department of Health and Senior Services, PO Box 369, Trenton, NJ 08625-0369.

(c) This report shall be submitted by January 1 of the respective academic year after a review of all appropriate immunization records.

(d) (No change.)

(e) Those schools, preschools, and child-care centers not submitting the annual report by January 1 shall be considered delinquent. A delinquency involving schools, preschools, and child-care centers may be referred to the New Jersey Department of Education or the New Jersey Department of Children and Families, as appropriate based on the length of time delinquent, number of times delinquent, and efforts made toward compliance. The local health department will also be notified of the delinquency.

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

(a)-(d) (No change.)

(e) Children seven through nine years of age who have not completed this requirement shall receive tetanus and diphtheria toxoids (adult Td) instead of DTP. Any combination of three doses of DTP, DTaP, DT, or Td in a child seven through nine years of age shall be acceptable as adequate immunization for this vaccine series.

(f)-(g) (No change.)

(h) Every child born on or after January 1, *[1996]* ***1997***, and entering or attending Grade Six, or a comparable age level special education program with an unassigned grade on or after September 1, *[2007]* ***2008***, shall have received one dose of Tdap (Tetanus, diphtheria, acellullar pertusis) given no earlier than the 10th birthday.

(i) Children entering or attending Grade Six on or after September 1, *[2007]* ***2008,*** who received a Td booster dose less than five years prior to entry or attendance shall not be required to receive a Tdap dose until five years have elapsed from the last DTP/DTaP or Td dose.

(j) Children born on or after January 1, *[1996]* ***1997***, and transferring into a New Jersey school from another state or country after September 1, *[2007]* ***2008***, shall have received one dose of Tdap, provided at least five years have elapsed from the last documented Td dose.

8:57-4.11 Poliovirus vaccine

(a) Every child less than seven years of age shall have received at least three doses of live, trivalent, oral poliovirus vaccine (OPV), or inactivated poliovirus vaccine (IPV) either separately, in combination, or as a combination vaccine containing inactivated poliovirus, one dose of which shall have been given on or after the child's fourth birthday or, alternatively, any combination of four doses.

(b)-(c) (No change.)

(d) For children seven years of age and older, any combination of three doses of OPV or IPV shall satisfy the poliovirus vaccine requirement.

(e) (No change.)

8:57-4.12 Measles virus vaccine

(a) Every child born on or after January 1, 1990 shall have received two doses of a live measles-containing vaccine, or any vaccine combination containing live measles vaccine, such as the preferred measles, mumps, and rubella (MMR) vaccine, prior to school entrance. The first dose shall have been administered on or after the child's first birthday, and the second dose shall have been administered no less than one month after the first dose.

Recodify existing (c) and (d) as (b) and (c) (No change in text.)

(d) Children born on or after January 1, 1990, and enrolling in school (Kindergarten, Grade One, or a higher grade) with no documented doses of measles vaccine, shall receive the second dose of measles or another measles-containing combination vaccine, no sooner than one month and no later than two months after receiving the first dose.

(e) Children who present documented laboratory evidence of measles immunity shall not be required to receive the first or second dose of measles vaccine.

(f) (No change in text.)

8:57-4.15 Haemophilus influenzae type b (Hib) conjugate vaccine

(a) Every child from two months to 11 months of age enrolling in or attending any child-care center shall have received a minimum of two age-appropriate doses of a separate or a combination Hib conjugate vaccine, or fewer as appropriate for the child's age.

(b) (No change in text.)

8:57-4.16 Hepatitis B virus vaccine

(a) Every child born on or after January 1, 1990 shall have received three doses of hepatitis B vaccine, or any vaccine combination containing hepatitis B virus, prior to school entry into a Kindergarten through Grade 12, or a comparable age level special education program with an unassigned grade.

(b) Children born on or after January 1, 1990 attending or transferring into a New Jersey school with no documented doses of hepatitis B vaccine, shall receive the first dose before entering school and shall receive a second dose of a hepatitis B containing vaccine, no later than three months after receiving the first dose and shall receive the third dose no later than 12 months following the first dose.

1. A child entering school with one documented dose shall have no longer than six months to complete the three dose hepatitis B series.

2. A child entering school with two documented doses shall have no longer than four months to complete the three dose hepatitis B series.

(c) Unvaccinated children 11 through 15 years of age who have not begun or completed the hepatitis B vaccine series, can be given two doses of any hepatitis B vaccine licensed and approved for a two dose regimen to satisfy the hepatitis B requirement. If the child is age-eligible to receive the two dose regimen, the second and final dose shall be received no later than six months following the first dose.

(d) (No change in text.)

8:57-4.18 Pneumococcal conjugate vaccine

(a) Every child from two months through 11 months of age enrolling in or attending any child-care center or preschool facility on or after September 1, *[2007]* ***2008***, shall have received a minimum of two age-appropriate doses of pneumococcal conjugate vaccine (PCV), or fewer as medically-appropriate for the child's age according to the ACIP recommendations, incorporated herein by reference, as amended and supplemented.

1. The 2000 ACIP Recommendations for Preventing Pneumococcal Disease Among Infants and Young Children, is published in the October 6, 2000 issue of the Morbidity and Mortality Weekly Report (MMWR), which is available at www.cdc.gov/mmwr/PDF/rr/rr4909.pdf.

(b) Every child 12 months through 59 months of age enrolling in or attending a child-care center on or after September 1, *[2007]* ***2008***, shall have received at least one dose of PCV on or after their first birthday.

8:57-4.19 Influenza vaccine

Children six months through 59 months of age attending any child-care center or preschool facility on or after September 1, *[2007]* ***2008***, shall annually receive at least one dose of influenza vaccine between September 1 and December 31 of each year.

8:57-4.20 Meningococcal vaccine

(a) Every child born on or after January 1, *[1996]* ***1997,*** and entering or attending Grade Six or a comparable age level special education program with an unassigned grade on or after September 1, *[2007]* ***2008***, shall have received one dose of a meningococcal-containing vaccine, such as the medically-preferred meningococcal conjugate vaccine.

(b) Every child born on or after January 1, *[1996]* ***1997,*** and transferring into a New Jersey school from another state or country on or after September 1, *[2007]* ***2008***, shall have received one dose of meningococcal vaccine.

8:57-4.21 Providing immunization

(a) A board of education and/or a local board of health may provide, at public expense, the necessary equipment, materials and services for immunizing children with the following immunizing agents, either singly or in combination:

1.-10. (No change.)

11. Pneumococcal conjugate vaccine;

12. Influenza vaccine;

13. Meningococcal vaccine; or

14. (No change in text.)

8:57-4.22 Emergency powers of the Commissioner, Department of Health and Senior Services

(a)-(c) (No change)

(d) In the event of a national or State vaccine supply shortage, as determined by the Centers for Disease Control and Prevention and Commissioner, respectively, the Commissioner or his or her designee may temporarily suspend the immunization requirement for the particular immunization affected by the supply shortage, after provision of notice to the public, such as through any of the methods below:

1. Electronic posting on the Department's website;

2. Print and electronic news media;

3. The Department's Local Information Network and Communications System (LINCS);

4. The Department's Vaccine Preventable Disease Program; or

5. Any other method reasonably calculated to inform those persons most likely to be affected by or interested in the temporary immunization suspension.

8:57-4.23 Optimal immunization recommendations

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

(b) All vaccine doses included within, and mandated by, this subchapter that are administered less than or equal to four days before either the specified minimum age or dose spacing interval shall be counted as valid and shall not require revaccination in order to enter or remain in a school, preschool, or child-care facility.

8:57-4.24 Penalties

Each violation of this subchapter shall be subject to the penalty set forth at N.J.S.A. 26:1A-10.

APPENDIX

INSTRUCTIONS FOR COMPLETING THE ANNUAL IMMUNIZATION STATUS REPORT ON-LINE

The instructions below have been developed to assist New Jersey Schools in completing the Annual Immunization Status Report (IMM-7) on-line. N.J.A.C. 8:57-4.8(c) requires schools to submit this report by January 1 of the respective academic year after a review of all appropriate students immunization records.

The IMM-7 is available on the New Jersey Department of Health and Senior Services (NJDHSS), Vaccine Preventable Disease Program website at http://nj.gov/health/cd/imm7/annualstatusrpt.shtml. Once you complete this report and click on "submit" it will automatically be sent to NJDHSS. A printed copy must be sent to your Local Health Department and one copy must be retained in your files. Please read the following instructions carefully.

STEP-BY-STEP INSTRUCTIONS:

Before you start to fill out the report, please make sure that you have all the correct and final information available. The top half of the report is required demographic information for your school. The bottom portion is a table in which you are required to input the immunization status of all pupils in the designated grades, to report compliance with N.J.A.C. 8:57-4, Immunization of Pupils in School.

1) Fill out the report by typing text into the appropriate areas and checking boxes where needed.
2) To move from field to field, use the Tab key or click in the box with your mouse where you want to fill in text.
3) Please be sure to fill out all required fields marked with red asterisks. The report will not respond to the "submit" command until the

required fields are completed.

4) If you would like to clear the report and remove all data that you have entered on that page, click on the reset button on the bottom of the page.

5) Once the report is completed in its entirety, print and send one copy to your local health department and print one copy to be retained for you files.

6) To print the report, click on File/Print on the toolbar or right-click on the mouse and click on print.

7) Once you have printed a copy of the report, click the submit button on the bottom of the page.

NOTE: Below is a breakdown of each field on the Annual Immunization Status Report. Please refer to this section if you have a question on a specific field when filling out the report.

DEMOGRAPHIC INREPORTATION:

-- Enter school ID (The school ID is located at the top right hand corner of the Immunization Status Report cover letter). The cursor will automatically tab over to the next box.
-- Enter the county in which your school is located.
-- Enter the municipality code. The municipality code table is enclosed with these instructions.
-- Enter the school district.
-- Enter the name of school or child care facility.
-- Enter the previous name of the school if the facility has recently changed names.
-- Enter the mailing address; include street address, city, and zip code.
-- Enter the school address if different from the mailing address.
-- Enter the name of person completing the report.
-- Enter the telephone number of the school.
-- Enter the school email address if available.
-- Enter the name of principal/person in charge.
-- Enter the title of the principal/person in charge.
-- Enter the total school/child care enrollment.
-- Enter the type of elementary/secondary school/child care facility (public/private).

IMMUNIZATION STATUS TABLE:

COLUMNS:

-- Check Not Applicable for any field that does not apply to your school.
-- Pupils Meeting All Immunization Requirements - Enter the number of pupils that are up-to-date with required immunizations per N.J.A.C. 8:57-4.
-- Pupils with Provisional Admittance - Enter the number of pupils who have begun, or are in the process of completing, the required immunizations.
-- Pupils with Medical Exemptions - Enter the number of pupils who have a valid medical exemption.
-- Pupils with Religious Exemptions - Enter the number of pupils who have a valid religious exemption that explains how the administration of immunizations conflicts with the pupil's exercise of bona fide religious tenets or practices.
-- Pupils with Status Unknown - Those pupils coming from out of state/out of country who have been granted a 30-day grace period to obtain immunizations before they start their provisional period.

ROWS:

-- If your school has pre-kindergarten classes, enter those children on the pre-k line.
-- If your school has a kindergarten grade, enter those children on the kindergarten line.
-- Do not include data in the grade 1 boxes unless the student is beginning school for the very first time in grade 1.
-- If your school has grade 6 enter those children on the grade 6 line.
-- Un-graded special education pupils should be included with the appropriate age cohort class.
-- Transfer Students - all students newly transferring into grades K-12 from out-of-State/out-of-country since submission of last status report.

CHILD CARE FACILITIES: Please note that child care facilities must enter the immunization status of all enrolled children who are over 2 months of age on the pre-k line.

Annual Immunization Status Report

* Required Fields

***School ID:** ___ - ___ - ___

NOTE: Please add a leading zero to your id, if your label shows 8 digits.

*County: _____ *Muncipality Code: _____

School District: _____

*Name of School/ Child Care Facility: _____

If Facility Recently Changed Name, List Previous Name: _____

Mailing Address:

*Street: _____

*City: _____ *Zip Code: _____

School Address (if different from above)

Street: _____

Street:

City: Zip Code:

*Name of Person Completing the Form: *Telephone:

School Email Address:

Name of Principal/ Person in Charge: Title:

*Total School/Child Care Center Enrollment:

*Elementary/ Secondary School/Child Care Facility: ☐ Public ☐ Non-Public ☐ Head Start ☐ Preschool/ Nursery/ Day Care

The school is responsible for assuring that all pupils are in compliance with the New Jersey Immunization requirements. In the boxes below, enter the status of all pupils in your entry level grade, grade 6, and transfer students (any grade).

- Child care facilities must enter the immunization status of all enrolled children who are over 2 months of age on the pre-k line
- If your school has pre-kindergarten classes, enter those children on the pre-k line.
- If your school has a kindergarten grade, enter those children on the kindergarten line.
- Do not include data in the grade 1 boxes unless the student is beginning school for the very first time in grade 1.
- All pupils entering grade 6 record on the grade 6 line.

- Ungraded special education pupils should be included with the appropriate age cohort class.

Grade Level	Not Applicable	Pupils Meeting All Immunization Requirements	+Pupils with Provisional Admittance	Pupils with Medical Exemptions	Pupils with Religious Exemptions	Pupils with Status Unknown
Pre-k:	☐					
Kindergarten:	☐					
Grade 1:	☐					
Grade 6:	☐					
**Transfer Students (Out of State/Country only):	☐					

+ Provisional Admittance - those pupils who have begun or are in the process of completing all the required immunizations.
** Transfer Students - all students newly transferred into grades K-12 from any out-of-state/ out-of country school since submission of last year's status report.

Submit Reset

Source: Legal > / . . . / > NJ - New Jersey Register
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