Pursuant to the authority vested in the Commissioner of Health by Public Health Law Sections 2164 and 2168, Subpart 66-1 of Title 10 (Health) of the Official Compilation of Codes, Rules and Regulations of the State of New York is amended, to be effective upon Notice of Adoption in the New York State Register, to read as follows:

Paragraph (1) of Subdivision (f) of Section 66-1.1 is amended to read as follows:

(f) Fully immunized means that an adequate dosage and number of doses of an immunizing agent licensed by the United States Food and Drug Administration has been received commensurate with the child's age, or the child has been demonstrated to have immunity as defined in [subdivision (g) of] this section.

(1) For those immunizations required by section 2164 of the Public Health Law only, the number of doses that a child [should] shall have at any given age, and the minimum intervals between these doses, [is determined by] shall be in accordance with the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years, issued by the Advisory Committee on Immunization Practices (ACIP) as set forth in Morbidity and Mortality Weekly Reports (MMWR) [February 7, 2014 Volume 63 (No. 5)] February 5, 2016 Volume 65 (No. 4) and posted on the Centers for Disease Control and Prevention website at [http://www.cdc.gov/vaccines/schedules/index.html] http://www.cdc.gov/vaccines/schedules. The department will amend this section as necessary to reflect revised ACIP Recommended Immunization Schedules. Any child

who completed an immunization series following minimum intervals prescribed in an ACIP Recommended Immunization Schedule pre-dating February [2014] 2016 shall continue to be deemed in compliance as long as the number of vaccine doses the child received conforms to the current ACIP Recommended Immunization Schedule.

The Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years issued by the ACIP as set forth in the MMWR [February 7, 2014 Volume 63 (No. 5)] February 5, 2016 Volume 65 (No. 4) is hereby incorporated by reference, with the same force and effect as if fully set forth at length herein. It is available for public inspection and copying at the Regulatory Affairs Unit, New York State Department of Health, Corning Tower, Empire State Plaza, Albany, New York 12237. Copies are also available from the United States Department of Health and Human Services, Centers for Disease Control and Prevention (CDC), Atlanta, Georgia 30333, and from the CDC website at [http://www.cdc.gov/mmwr] http://www.cdc.gov/vaccines/schedules/.

(i) For all vaccinations except as provided in subparagraphs (ii) through [(vi) of this paragraph] vii below, children shall be assessed upon school entry or attendance, and annually thereafter, and [be found to] be fully immunized commensurate with their age.

(ii) [If they had] Any child who has satisfied the immunization requirements in effect in regulation on June 30, 2014, [children] entering [eighth] ninth through twelfth

grade (or comparable age level grade equivalents) in the [2015-2016] 2016-2017 school year only, shall be deemed in compliance with the immunization requirements set forth in this section, including those set forth in subparagraphs (iii) through (vi) below, until [they graduate] such child graduates from school; provided, however, that such child shall comply with the meningococcal vaccination requirement set forth in subparagraph (vii) below.

(iii) Any child entering or attending kindergarten through twelfth grade must have received the following vaccine doses, with the minimum intervals between these doses as established by the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years incorporated by reference herein:

(a) Two adequate doses of measles containing vaccine, two adequate doses of mumps containing vaccine, and at least one adequate dose of rubella containing vaccine; and

(b) Five adequate doses of diphtheria and tetanus toxoids and acellular pertussis vaccine. If, however, the fourth dose of diphtheria and tetanus toxoids and acellular pertussis vaccine was given at forty-eight months of age or older, only four adequate doses of vaccine are required. The final dose of vaccine must be received no sooner than forty-eight months of age. Doses given after age seven should start with one dose of Tdap.

(iv) For poliomyelitis vaccination, beginning on or after July 1, 2014, children shall be assessed upon entry or attendance to kindergarten and sixth grade, and/or their equivalent grades, and must have received four adequate doses of poliomyelitis vaccine. If, however, the third adequate dose of poliomyelitis vaccine was given at forty-eight months of age or older, only three adequate doses of vaccine are required. The final dose of vaccine must be received no sooner than forty-eight months of age. As the students enrolling in kindergarten and sixth grade move up a grade level each year, the students enrolling in those higher grades, or grade equivalent, must be appropriately immunized against poliomyelitis. Beginning on or after September 1, 2016, children shall be assessed upon entry or attendance to child-caring centers, day-care agencies, nursery schools and pre-kindergarten programs and must be fully immunized against poliomyelitis commensurate with their age.

(v) For varicella vaccination, beginning on and after July 1, 2014, children shall be assessed upon entry or attendance to kindergarten and sixth grade, and/or their equivalent grades, and must have received two adequate doses of vaccine. As the students enrolling in kindergarten and sixth grade move up a grade level each year, the students enrolling in those higher grades, or grade equivalent, must be appropriately immunized against varicella.

(vi) By entry to sixth grade or a comparable age level grade equivalent, any child eleven years of age or older must have received one dose of a booster immunization containing tetanus and diphtheria toxoids and acellular pertussis vaccine.

(vii) For meningococcal vaccination, beginning on and after September 1, 2016, children shall be assessed upon entry or attendance to seventh grade, or a comparable age level grade equivalent, and must have received one adequate dose of vaccine upon such entry or attendance. Children shall be assessed upon entry or attendance to twelfth grade, or a comparable age level grade, and must have received two adequate doses of meningococcal vaccine upon such entry or attendance. If, however, the first dose of meningococcal vaccine was given at sixteen years of age or older, then only one adequate dose of meningococcal vaccine is required for twelfth grade.

Paragraph (6) of subdivision (a) of section 66-1.2 is amended to read as follows:

(6) Registrants shall mean all individuals for whom an immunization or exemption to immunization or blood lead analysis is recorded in the system, at any time following January 1, 2008 for NYSIIS and January 1, 1994 for the CIR. Registrants also include individuals born in New York State (outside of New York City) on or after January 1, 2004 for NYSIIS or born in New York City on or after January 1, 1996 for the CIR.

Paragraph (8) of subdivision (a) of section 66-1.2 is amended to read as follows:

(8) Authorized users of NYSIIS and the CIR shall mean the following categories of users, who are permitted access only to records of registrants falling within their administrative or clinical responsibilities. An authorized user in a category below may designate the ability to access the system to others where indicated.

(i) health care providers who order an immunization, and their designees, including Regional Health Information Organizations or other Health Information Technology entities as defined in 18 NYCRR section 504.9(h)(2);

(ii) local health districts;

(iii) commissioners of local social services districts and their designees;

(iv) the Commissioner of the Office of Children and Family Services and his/her designees;

(v) schools;

(vi) third party payers;

(vii) WIC programs;

(viii) colleges;

(ix) professional and technical schools; [and]

(x) children's overnight camps and summer day camps[.];

(xi) registered professional nurses; and

(xii) pharmacists authorized to administer immunizations pursuant to subdivision two of section sixty-eight hundred one of the Education Law.

Paragraph (1) of subdivision (b) of section 66-1.2 is amended to read as follows:

(b) Mandated Reporting

(1) Mandated reporters to NYSIIS and the CIR include any health care provider, as defined in [paragraph (a) (3) of this] section 66-1.2 who administers an immunization or conducts a blood lead analysis of a sample.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for school entry immunization requirements resides in Title 6 of Article 21of the Public Health law (PHL): *Poliomyelitis and Other Diseases.* PHL § 2164 mandates the vaccination of children between the ages of two months and eighteen years as a condition of entry or attendance to school. PHL § 2164(10) authorizes the commissioner to promulgate regulations to effectuate the provisions and purposes of PHL § 2164.

The authority for the statewide immunization information system is PHL § 2168, which establishes the New York State Immunization Information System (NYSIIS). PHL § 2168(13) authorizes the commissioner to promulgate regulations to effectuate the provisions of PHL § 2168.

Legislative Objectives:

The legislative objective of PHL § 2164 includes the protection of the health of residents of the state by assuring that children are immunized according to current recommendations before attending child-caring centers, day care agencies, nursery schools, pre-kindergarten, or school, to prevent the transmission of vaccine preventable disease and accompanying morbidity and mortality. The legislative objective of PHL § 2168 is to establish a comprehensive database of complete, accurate and secure immunization records.

Needs and Benefits:

The purpose of the proposed regulatory changes is to update the existing school immunization requirements to ensure that children entering grades seven and twelve (or comparable age level equivalents) receive an adequate number of meningococcal vaccines consistent with recent statutory amendments; to ensure that children entering or attending child-caring centers, day-care agencies, nursery schools, or pre-kindergarten programs receive an adequate number of poliomyelitis vaccines; and to conform the regulations for the New York State Immunization Information System (NYSIIS) to statutory amendments.

In October 2015, Governor Andrew M. Cuomo signed into law Chapter 401 of the Laws of 2015, which amended PHL § 2164 to require vaccination against meningococcal disease for children entering or attending seventh and twelfth grades on or after September 1, 2016. Meningococcal meningitis is a serious disease, which can lead to death within hours. Survivors may be left with severe disabilities, including the loss of limbs, cognitive deficits, paralysis, deafness, or seizures. ACIP provides immunization advice and guidance to the Director of the Centers for Disease Control and Prevention (CDC), and recommends that a single dose of vaccine against meningococcal serogroups A, C, W, and Y (MenACWY vaccine) be administered to all adolescents at 11 or 12 years of age, followed by a booster at 16 years of age (recommendation Category A, for all persons in an age-or risk-factor based group). ACIP recommends that adolescents who received their first dose of MenACWY vaccine at age 13 through 15 years receive a booster dose at age 16 through 18 years, with a minimum interval of 8 weeks between doses, and that healthy adolescents who receive the first dose of MenACWY on or after their sixteenth birthday do not need a booster dose.[1]

In order to conform to the statutory amendment and be consistent with ACIP recommendations, the proposed regulatory change would require one dose of MenACWY vaccine for seventh grade and a second dose for twelfth grade, unless the first dose was received at sixteen years of age or older in which case only one dose will be required. Of note, the exemption set forth in Section 66-1.1(f)(1)(ii), which would deem children entering the ninth through twelfth grades (or comparable age equivalents) in the 2016-2017 school year in compliance with the immunization requirements provided they were in compliance with the immunization regulations in effect on June 30, 2014, would not apply to this new meningococcal vaccine requirement. This exemption was only intended to address new vaccine interval requirements, which began in the 2014-2015 school year, and was not intended to exempt this cohort of students from future vaccination requirements.

ACIP recommends that persons identified as being at increased risk because of an outbreak of serogroup B meningococcal disease should receive serogroup B meningococcal vaccine (MenB vaccine, recommendation Category A).[2] ACIP further recommends that a MenB vaccine series may be administered to adolescents and young adults 16 through 23 years of age (recommendation Category B, for individual clinical decision making).[3] Because MenB vaccine is not universally recommended for all adolescents at this time, the proposed regulatory change would not require MenB vaccine for school entry or attendance. However, the New York State Commissioner of Health, or his or her designee, or in the City of New York, the Commissioner of Health of the New York City Department of Health and Mental Hygiene, would have the authority pursuant to Section 66-1.10 to order the appropriate school officials to exclude from

attendance students who have not been immunized with MenB vaccine in the event of an outbreak of serogroup B meningococcal disease. In the event of such outbreak, the state and local health departments would work closely with schools to identify students who have not been immunized with MenB vaccine.

Paragraph (1) of Subdivision (f) of Section 66-1.1 was amended in 2014 to update poliomyelitis vaccination requirements, reflecting the ACIP recommended doses and intervals between doses. Prior to 2014, students were required to have three doses of poliomyelitis vaccine, at any interval. The 2014 regulatory amendments applied to children entering or attending kindergarten and sixth grade in the 2014-2015 school year, and as the students in those grades moved up a grade level each year, the students enrolling in those higher grades must also be appropriately immunized against poliomyelitis in accordance with the ACIP recommended numbers of doses and intervals between doses. However, the multi-year phase-in of the poliomyelitis interval requirements adopted in 2014 did not cover children entering or attending child-caring centers, day-care agencies, nursery schools or prekindergarten programs, who were still required to have three doses of poliomyelitis vaccine, but were not required to have intervals between doses in accordance with the ACIP schedule.

In order to ameliorate this situation, the proposed regulatory change would require that children entering or attending child-caring centers, day-care agencies, nursery schools and pre-kindergarten programs are vaccinated against poliomyelitis commensurate with their age in accordance with the ACIP-recommended doses and intervals. The age-appropriate number of doses for children in child-caring centers, day-care agencies, nursery schools and pre-

kindergarten programs is three doses by 18 months of age, unchanged from the previous requirements; however, the intervals between doses of poliomyelitis vaccine for these children must now be in accordance with the ACIP schedule.

Finally, the proposed amendments would add registered professional nurses and pharmacists authorized to administer immunizations pursuant to Education Law Section 6801(2) as authorized users of NYSIIS consistent with recent amendments to PHL § 2168 (Ch. 420 of the Laws of 2014), and to reflect the blood lead reporting mandate in Public Health Law § 2168 (Ch. 58 of the Laws of 2009).

Costs to State Government including the Department of Health:

The CDC has estimated that routine childhood immunizations resulted in a twenty-year cost savings of approximately $295 billion in direct costs and $1.38 trillion in societal costs from 1994 through 2013 and that every dollar spent on immunization saves at least ten dollars in aggregate societal costs.[4] Potential savings to Medicaid and other payers are also expected as a result of the prevention of cases of disease.

ACIP has recommended routine MenACWY vaccination of adolescents aged 11 to 12 years for over ten years, and has recommended a booster dose at 16 years of age for nearly 5 years. Current immunization coverage data suggests that most students entering grade seven in September 2016 will already meet the new MenACWY vaccine requirement, however, many adolescents entering grade twelve will need a booster dose in order to meet the new requirements. According to the 2014 National Immunization Survey-Teen (NIS-Teen), 78% (±

2.5%) of 13 year olds in the United States had received one dose of MenACWY in 2014, but only 28.5% (± 2.8%) of 17 year olds had received a booster dose on or after 16 years of age.[5] The latter estimate does not include adolescents who received a first dose on or after 16 years of age and who will not require a booster in order to meet NYS requirements.

The Vaccines for Children Program (VFC), a federal entitlement program, provides MenACWY vaccine for eligible adolescents. In addition, Section 317 of the Public Health Service Act supports purchase of vaccine for administration at no cost to certain eligible children, and also supports immunization delivery, surveillance, communication and education. Commercial health insurance, the VFC Program, and the "317 grant" will cover the cost of most of the doses of MenACWY vaccine required for grades seven and twelve. The State, however, may be required to use additional funds for the purchase and administration of vaccine to meet the new MenACWY vaccine requirements for those individuals who are underinsured or who participate in the State Children's Health Insurance Program (SCHIP).

The Department will need to provide education on and promote awareness of the regulatory changes. The Department has contact information for all schools and healthcare providers in New York State, and currently communicates with schools and healthcare providers across the state on a regular basis. The new school immunization requirements and the resultant need for education of schools and healthcare providers will not be a burden to the State as this communication takes place on a frequent basis already.

Costs to Local Governments:

School staff already collect immunization records and ensure that students comply with school entry requirements. Under the proposed regulations, schools will have to add MenACWY vaccine to their information collection protocols. School staff will be responsible for assuring that students entering or attending grades seven and twelve are in compliance with the new MenACWY vaccine requirements. Administrative procedures already in place could be utilized to notify students of the MenACWY vaccine requirement and to notify deficient students of the need to comply. Given that schools are already checking, recording, and notifying students of the vaccine requirements and their need to comply, the costs of implementing these proposed regulations will likely be minimal.

Additional costs of the administration of MenACWY vaccine by local health departments to meet the new requirements will likely be incurred. A substantial portion of the costs of operating county health departments' clinic services will be eligible for reimbursement through State public health local assistance or from third party payers. MenACWY vaccine will be available through the VFC Program for eligible adolescents, and will be reimbursed through health insurance plans for children enrolled in commercial health insurance.

Costs to Private Regulated Parties:

It is possible that the proposed regulations will prompt an initial increase in patient flow to catch up adolescents in accordance with the new MenACWY vaccine requirements. This could require some additional staffing time and office hours to accommodate these patients, but any additional visits would be eligible for reimbursement from payers. It is likely, however, that after this initial phase, no further cost will be incurred by private parties.

Local Government Mandates:

The revised school entry regulations will not impose any additional mandates on local governments or school districts. NYS school districts are already required by PHL § 2164 to verify all students' immunization histories.

Paperwork:

Since schools are already required to maintain student immunization records, there will be no increase in their paperwork.

Duplication:

No relevant rules or other legal requirements of the State and/or federal government exist that duplicate, overlap or conflict with this rule.

Alternatives:

No alternatives were considered given that other alternatives would only result in inconsistencies with national immunization policy and good medical practice.

Federal Standards:

In the United States, all school entry immunization laws are created by individual states. There is no federal standard with regard to school entry immunization regulations.

Compliance Schedule:

The regulations will be effective upon publication of a Notice of Adoption in the New York State Register, and all children must satisfy the immunization requirements of the proposed school entry regulations on and after September 1, 2016.

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1) Centers for Disease Control and Prevention. Prevention and Control of Meningococcal Disease. Morbidity and Mortality Weekly Report (MMWR). 2013; 62(RR02): 1-28.
2) Centers for Disease Control and Prevention. Use of Serogroup B Meningococcal Vaccines in Persons Aged ≥ 10 Years at Increased Risk for Serogroup B Meningococcal Disease: Recommendations of the Advisory Committee on Immunization Practices. MMWR. 2015; 64(22): 608-612.
3) Centers for Disease Control and Prevention. Use of Serogroup B Meningococcal Vaccines in Adolescents and Young Adults: Recommendations of the Advisory Committee on Immunization Practices, 2015. MMWR. 2015; 64(41): 1171-1176.
4) Centers for Disease Control and Prevention. Benefits from Immunization During the Vaccines for Children Program Era – United States, 1994-2013. MMWR. 2014; 63(16): 352-355.
5) Centers for Disease Control and Prevention. National, Regional, State, and Selected Local Area Vaccination Coverage Among Adolescents Aged 13-17 Years – United States, 2014. MMWR. 2015; 64(29): 784-792.

REGULATORY FLEXIBILITY ANALYSIS

FOR SMALL BUSINESS AND LOCAL GOVERNMENTS

Effect of Rule:

Any facility defined as a school pursuant to PHL § 2164 will be required to comply. Schools that are affected by this rule will include approximately: 1,719 public, private, or parochial child care centers; 11,169 day cares and Head Starts; 551 nursery schools; 2,166 schools with students in grade 7; and 1,416 schools with students in grade twelve.

Compliance Requirements:

All schools must document the immunization status of all students who are entering or attending their facility, including immunizations received, history of disease, serology performed, and medical or religious exemptions to said immunizations.

The approximate number of students are as follows: 118,372 in public, private, or parochial child-caring centers; 231,340 in day cares and Head Starts; 32,358 in nursery schools; 232,206 in grade seven; and 162,152 in grade twelve. However, because schools were already required to collect immunization information, the burden of compliance with this new rule is substantially minimized.

Professional Services:

Schools are already required to comply with immunization requirements for entering and attending students and, therefore, immunization record retrieval already occurs with necessary

follow-up, if applicable. It is not anticipated that schools will need to hire additional staff to meet this requirement.

Compliance Costs:

The cost to schools to meet the requirements of the proposed regulation is estimated to be minimal, because schools are already required to inspect vaccination records of all students and appropriate vaccination of the student body may result in cost savings. Specifically, it is anticipated that any costs incurred to check vaccination records will be offset by savings in direct medical costs by reducing vaccine preventable disease transmission among students, as well as savings in indirect costs associated with student and school staff absenteeism.

LHDs may incur costs for the administration of MenACWY vaccine. However, MenACWY vaccine will be available free of cost through the VFC Program for eligible adolescents, and vaccine costs and administration fees will be reimbursed through health insurance plans for children enrolled in commercial health insurance.

Economic and Technological Feasibility:

This proposal is economically and technologically feasible. Many schools currently have read-only access to retrieve immunization information from the New York State Immunization Information System (NYSIIS) for students outside of NYC, and the Citywide Immunization Registry (CIR) for students within NYC. Because schools have direct read-only access to the consolidated immunization record through NYSIIS or the CIR, they are able to efficiently identify children at risk for vaccine preventable diseases secondary to their under-immunization,

which is critical during outbreak situations. In addition, access to this information simplifies assessment of immunization coverage as required for school entry or attendance.

No software needs to be purchased and no other fees are required to access the web-based systems. Using electronic tools for student record immunization queries also results in a significant cost savings when compared to the effort required to collect and analyze the volume of paper immunization histories provided by parents to the school.

Minimizing Adverse Impact:

Many, if not all schools, already have mechanisms in place to verify immunization requirements.

Small Business and Local Government Participation:

The New York City Department of Health and Mental Hygiene (DOHMH) and New York State Education Department (NYSED) were solicited for comments on the regulations. DOHMH is a large local government jurisdiction representing nearly half of children in New York State, and NYSED oversees prekindergarten through grade 12 programs in New York State. Both DOHMH and NYSED expressed support for the proposed regulatory changes.

RURAL AREA FLEXIBILITY ANALYSIS

Pursuant to Section 202-bb of the State Administrative Procedure Act (SAPA), a rural area flexibility analysis is not required. These provisions apply uniformly throughout New York State, including all rural areas.

The proposed rule will not impose an adverse economic impact on rural facilities defined within PHL Articles 28, 36, or 40.

JOB IMPACT STATEMENT

A Job Impact Statement is not included in accordance with Section 201-a(2) of the State Administrative Procedure Act (SAPA), because it will not have a substantial adverse effect on jobs and employment opportunities.