School Immunization Requirements

Effective date: 9/1/15

SUMMARY OF EXPRESS TERMS

This proposal will amend Subpart 66-1 (School Immunization Requirements) to update regulations to ensure that children entering kindergarten through twelfth grade (or comparable age level grade equivalents) receive an adequate number of required immunizations, to incorporate the current Advisory Committee on Immunization Practices (ACIP) Recommended Schedules, to conform the regulations for the New York State Immunization Information System (NYSIIS) to statutory amendments, and to clarify acceptable certificates of immunization. The regulations would be effective September 1, 2015.

Proposed amendments to Section 66-1.1 provide that children entering eighth through twelfth grade in the 2015-2016 school year shall be deemed in compliance with all immunization requirements until graduation, if they had satisfied the immunization requirements in effect in regulation on June 30, 2014.

Proposed amendments to Section 66-1.1 provide that, children entering kindergarten through twelfth grade (excepting those children entering eighth through twelfth grade in the 2015-2016 school year) must have received, in accordance with ACIP minimum intervals and dosage recommendations:

- two doses of measles-containing vaccine, two doses of mumps-containing vaccine, and at least one dose of rubella-containing vaccine.

- five doses of diphtheria and tetanus toxoids and acellular pertussis vaccine (DTaP). If, however, the fourth dose of DTaP was given at forty-eight months of age or older, only four doses are required.

- four doses of poliomyelitis vaccine. If, however, the third dose was given at forty-eight months of age or older, only three doses are required.

Proposed amendments to Section 66-1.1 further provide that upon entry to sixth grade or a comparable age level grade equivalent, a child eleven years of age or older must receive a booster immunization containing tetanus and diphtheria toxoids and acellular pertussis vaccine.

The proposed amendments to Section 66-1.1 also update the regulation to incorporate the 2014 ACIP schedule -- the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 Through 18 Years.

The amendments to Section 66-1.1 also provide that, students who are "in process" or following the ACIP "catch-up" schedule must follow the minimum intervals prescribed by the ACIP schedule. These proposed amendments do not address additional immunizations that may be required for school admission by the New York City Health Code.

Proposed amendments to Section 66-1.2 update the regulations to conform to changes in the NYSIIS statute (Public Health Law § 2168). The proposed amendments add colleges, professional and technical schools, and children's overnight and summer day camps as authorized users of NYSIIS and grant access to de-identified registry information for research purposes. Proposed amendments to Section 66-1.2 also permit the exchange of registry information with the Indian Health Service and tribal nations. Proposed amendments to Section

66-1.2 also remove two electronic reporting exemptions and remove the ability to request an extension on the required 14 day reporting period.

Proposed amendments to Section 66-1.6 clarify acceptable certificates of immunization. The proposed amendments provide that a certificate of immunization generally must be signed by a health practitioner licensed in New York State and that a record issued by NYSIIS, the Citywide Immunization Registry (CIR), an official immunization registry from another state, an electronic health record and/or an official record from a foreign nation may be accepted without a health practitioner's signature.

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 as of September 1, 2015, to read as follows:

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 section 66-1.1(g) of this subpart.

(1) For those immunizations required by section 2164 of the Public Health Law only, the number of doses that a child should have at any given age, and the minimum intervals between these doses, is determined by the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years [Recommended Immunization Schedule 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) [January 28, 2013 Volume 62 (Suppl 1)] February 7, 2014 Volume 63 (No. 5) 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/recs/schedules/default.htm]. 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 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 [Recommended Immunization Schedule for Persons Aged 0 Through 18 Years] issued by the ACIP as set forth in the MMWR [January 28, 2013 Volume 62 (Suppl 1)] February 7, 2014 Volume 63 (No. 5) 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.

(i) For all vaccinations, except [poliomyelitis and varicella] as provided in subparagraphs (ii) through (vi) 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 satisfied the immunization requirements in effect in regulation on June 30, 2014, children entering eighth through twelfth grade (or comparable age level grade equivalents) in the 2015-2016 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 from school.

(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.

[ii] (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 [be fully immunized commensurate with their 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.

[(iii)] (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.

(2) If a child is not fully immunized, catch-up immunization must then take place according to the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years incorporated by reference at Section 66-1.1 (f) of this subpart. [Catch-up Schedule of the Advisory Committee on Immunization Practices (ACIP) as set forth in Morbidity and Mortality Weekly Reports (MMWR), February 1, 2013 Volume 62 (No. 1). The Catch-up Schedule of the ACIP as set forth in MMWR, February 1, 2013 Volume 62 (No. 1) 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.]

Subdivision (j) of Section 66-1.1 is amended to read as follows:

(j) In process means that (i) a child has received at least the first dose in each immunization series required by section 2164 of the Public Health Law (except in the case of live vaccines in which [it is acceptable for] a child [to] should wait 28 days after one live vaccine administration before receiving another live vaccine, if the vaccines were not given on the same day) and has age appropriate appointments to complete the immunization series according to the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years incorporated by reference at Section 66-1.1 (f) of this subpart or (ii) a child is obtaining serologic tests within 30 days of notification of the parent/guardian that such testing is requested or (iii) a child's serologic test(s) are negative, and therefore the child in question has appointments to be immunized within 30 days of notification of the parent/guardian to complete, or begin completion, of the immunization series based on the Advisory Committee on Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years [ACIP catch up schedule] incorporated by reference[d above] at Section 66-1.1 (f) of this subpart.

Children who are not fully immunized can only continue to attend school if they are in the process of completing the immunization series based on the Advisory Committee on

Immunization Practices Recommended Immunization Schedules for Persons Aged 0 through 18 Years incorporated by reference at Section 66-1.1 (f) of this subpart [ACIP catch up schedule]. If a child does not receive subsequent doses of vaccine in an immunization series according to the age appropriate ACIP catch-up schedule, including at appropriate intervals, the child is no longer in process and must be excluded from school within 14 days, if not otherwise exempt in accordance with Section 66-1.3.

Section 66-1.2 is amended to read as follows:

(a) *Definitions*

(1) *Statewide immunization information system* shall mean the statewide (except New York City) computerized database of immunizations developed and maintained by the New York State Department of Health, known as the New York State Immunization Information System ("NYSIIS" or "system").

(2) *Citywide Immunization Registry (CIR)* shall mean the immunization information system maintained by the New York City Department of Health and Mental Hygiene, capable of collecting, storing and disclosing the electronic and paper records of vaccinations administered to persons less than 19 years of age and those persons 19 and older with consent in accordance with the New York City Health Code. For the purposes of this definition the term New York City Department of Health and Mental Hygiene shall mean such agency or any successor agency responsible for the CIR.

(3) *Health care provider* for the purposes of this section shall mean any person authorized by law to order an immunization or any health care facility licensed under Article 28 of the Public Health Law or any certified home health agency established under Section 3606 of the Public Health Law.

(4) *Designees* shall mean individuals, acting under the authority of a health care provider or another category of authorized user, who have been specifically delegated responsibility to access NYSIIS or the CIR and perform the functions permitted the primary authorized user.

(5) *Emancipated minors* shall mean those children less than 18 years of age who by virtue of a court decision declaring them emancipated, or who because they are otherwise emancipated under the law, are able to make their own decisions regarding health care services.

(6) *Registrants* shall mean all individuals for whom an immunization or exemption to immunization 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.

(7) *School*, for the purposes of this section, shall mean any agency or entity required by law or regulation to verify immunization status for participants prior to or at selected times during enrollment, including licensed day care facilities [and permitted camps]. Such

verification is an authorized delegation of public health authority for the purposes of fulfilling this public health mandate related to verification of immunization status.

(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 subparagraph 2 of subdivision h of Section 504.9 of Title 18 of the New York Codes Rules and Regulations;

(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; [and]

(vii) WIC programs[.];

(viii) Colleges;

(ix) Professional and technical schools; and

(x) Children's overnight camps and summer day camps.

(b) Mandated Reporting

(1) Mandated reporters to NYSIIS and the CIR include any health care provider, as defined in 66-1.2 (a) (3), who administers an immunization.

(2) Mandated reporters must report any immunization to a child less than 19 years of age to either NYSIIS or the CIR, depending on the location of administration of the vaccine.

(3) Article 28 facilities or certified home health agencies established under section 3606 of the Public Health Law in which providers are responsible for administration of vaccines may, when agreed to by the facility and the provider ordering the vaccination, assume reporting responsibility for the authorized individuals administering vaccines within their facilities.

(4) A person who administers but does not order immunizations is not responsible for reporting the immunizations to the system, unless acting as a designee of the health care provider

who ordered the immunization and under whose supervision the vaccine was administered. The ordering health care provider remains responsible for supervising his/her designee and ensuring that appropriate and timely reporting occurs.

(5) When vaccines are administered based on non-patient specific orders, the health care provider ordering the immunizations shall ensure that required data elements for each vaccination are submitted to NYSIIS or the CIR, depending on the location of administration of the vaccine.

(c) Information required to be reported, methods of reporting, exceptions and timeliness of reporting

(1) Information required to be reported to NYSIIS or the CIR, to the extent available to the provider shall include: the patient's name (first, middle and last); date of birth; gender; race; ethnicity; address, including zip code; telephone numbers; birth order (if multiple birth); birth state/country; mother's maiden name; mother's or other responsible party's name (first, middle and last); Vaccines for Children program eligibility; Medicaid number; and vaccine administration date, type, lot number and manufacturer, except as noted in subdivision (3) below. A provider should report elements for any additional data fields in NYSIIS or the CIR when available.

(2) Methods of reporting. All data elements reported to the NYSIIS or the CIR must be submitted electronically except as provided in subdivision (3) below.

(i) Direct online entry of immunization information into [the statewide system] NYSIIS. Authorized users with read/write access and their designees may submit information directly to the statewide system using their individual access accounts.

(ii) Health care providers with existing electronic information systems compatible with NYSIIS. Such providers may request, on an individual or group basis, permission to download information from current systems into a Department-prescribed file format for transfer directly to NYSIIS. The provider is responsible for the costs/programming needed to effect these data transfers, ensuring that transfers are completed on a timely basis and updating provider-specific data systems when changes are made to these systems.

(iii) Historical immunization information previously submitted to a regional registry. Health care providers who have submitted immunization records to one of the regional immunization registries (Healthy Shot or Immunization Registry and Information Source ("IRIS") may authorize submission of this regionally-archived immunization history information to the statewide system.

(iv) Submission of immunization information to NYSIIS or the CIR. Providers must submit immunization information to NYSIIS or the CIR, dependent upon the IIS operating in the area in which they practice, not the IIS appropriate to the patient's area of

residence. Exchange of information between IIS's will be the responsibility of NYSIIS and the CIR.

(3) Exceptions to reporting requirements to NYSIIS.

(i) Hospitals participating in the Statewide Perinatal Data System are exempted from entering immunization information directly into NYSIIS for newborns during their initial hospital stay. Information submitted through the Statewide Perinatal Data System will populate NYSIIS required information fields. Hospitals located in New York State, outside of New York City, are required to report to NYSIIS all other immunizations administered to children less than 19 years of age while under their care.

(ii) A provider may submit incomplete immunization electronic files or may manually enter incomplete immunization information into the statewide system in fulfillment of requirements for submission of historical immunization information. Required information for immunizations administered after January 1, 2008, which is missing shall be entered when it becomes available to the provider.

[(iii) If electronic submission of information is a hardship because of lack of a computer, providers who administer less than 50 immunizations per year may request permission to submit immunization data to NYSIIS using the NYSDOH approved paper form or make other arrangements for submission of their data.]

[(iv) Providers who practice in areas where there is no internet access available or who administer less than 50 immunizations per year may request permission to submit immunization data to NYSIIS using the NYSDOH approved paper form or make other arrangements for submission of their data.]

(4) Timeliness of Reporting. Providers ordering immunizations must submit immunization information to NYSIIS or the CIR within 14 days of administration of the immunization. Providers must also submit information regarding immunizations not previously reported for each registrant [except as noted below].

For NYSIIS only:

[(i) Providers wishing to submit historical immunization information to NYSIIS via data file for their patients may request permission from the Department to submit such data.]

[(ii)] (i) Providers must submit any missing information requested by NYSIIS within 14 days of the issuance of the request.

[(iii)] (ii) For individuals exempt from administration of vaccines, providers must submit patient information, including the reason for the exemption, to the statewide system within 14 days following the in-person clinical interaction that occurs at or after what would normally have been the due date for administration of an age-appropriate immunization to that child, according to current national immunization recommendations.

[(iv) NYSIIS providers may request an extension to the 14 day reporting requirement if they are making ongoing and meaningful progress in developing alternative electronic means of data submission, including submission of immunization histories. Extensions will be reviewed by the Department and granted as appropriate.]

(d) Allowable access levels and permitted uses of NYSIIS and/or CIR data by authorized users specific to the organization they are representing.

(1) Allowable access levels.

(i) Read/write access. Only health care providers providing services to the registrant and State and local Department of Health staff may compile reports, read immunization information, enter immunization information and change immunization information, with limitations as specified below. Health care providers who have been granted a time-limited deferral on electronic data submission to NYSIIS may access the information by phone or via written request.

(ii) Read-only access. Authorized users not listed in subparagraph (i) of this paragraph such as schools are permitted read-only access to NYSIIS and/or the CIR. Read-only access allows the user to view records of only those children under their administrative responsibility and to compile reports based on data aggregated from those records.

(2) Permitted uses of NYSIIS or CIR data. All requests for use of NYSIIS information by an authorized user which are not included in the allowable uses for that person as noted in subparagraphs (i) – [(viii)] (x) of this paragraph are prohibited without the approval of the Commissioner of the State Department of Health; or, for requests for CIR information, without the approval of the Commissioner of the New York City Department of Health and Mental Hygiene or his or her designee. Approval is contingent on ongoing adherence to the terms and conditions of the user agreements. Allowable uses of the data for particular categories of users include:

(i) Health care providers or their designees may access NYSIIS or CIR data for the provision of care and treatment, either temporary or longer term, to a particular registrant. The information can be used either on a patient-specific basis or to generate reports specific to their practice to determine immunizations received by a specific groups of registrants, review of practice coverage, generation of reminder and recall notices, quality improvement, vaccine inventory and accountability inclusive of Vaccines for Children [(VCF)] (VFC) Program inventory and accountability, vaccine ordering, VFC re-enrollment, and printing a copy of the immunization record for the registrant or the registrant's parent or guardian, as appropriate.

(*a*) If other child health status or test results information becomes available through NYSIIS or the CIR that may be useful in determining the course of treatment for the child, such information will be made available on an as-needed and authorized basis to health care providers.

(ii) Schools may access NYSIIS or CIR data for verifying immunization history for students entering or registered in that school or school system or may run school-specific reports that aggregate available data. Access will be limited to data for [children] registrants enrolling or already enrolled in a particular school or school system.

(iii) Commissioners of local social services districts and their designees may access NYSIIS or CIR data with regard to children in their legal custody. Such information may be used for quality assurance and accountability by local social services districts.

(iv) The Commissioner of the Office of Children and Family Services and his/her designees may access NYSIIS or CIR data with regard to children in his/her legal custody. Such information may be used for ensuring appropriate care and treatment of children for whom the Office of Children and Family Services maintains custody and responsibility.

(v) Local health departments may access immunization data in NYSIIS and the CIR for purposes of outreach, quality improvement and vaccine accountability, epidemiological studies and disease control within their own county. Local health department staff may be granted access to immunization information in NYSIIS and the CIR for registrants whose immunizations were administered within their own county and

for registrants residing in the county whose immunizations were administered outside of the county.

(vi) Third party payers may access NYSIIS or CIR data for the purpose of performing quality assurance, accountability and outreach relating to enrollees covered by their plan. Third party payers must request information from the appropriate registries.

(vii) The Commissioner of Health and the Commissioner of the New York City Department of Health and Mental Hygiene and their designated staffs will have full read/write access to their respective systems/registries in order to fulfill file maintenance and improvement functions and may use the data in both NYSIIS and the CIR for purposes of outreach, quality improvement and vaccine accountability, research, epidemiological studies and disease control.

(*a*) The Commissioner of Health or the Commissioner of the New York City Department of Health and Mental Hygiene or his or her designee may provide, on request, registrant-specific information to other state or city immunization systems and systems maintained by the Indian Health Service and tribal nations recognized by the state or the United States [out of state immunization information systems] on a routine basis pursuant to a written agreement with each [out-of-state] system requiring such system to conform to national standards for maintaining the integrity of the data, protecting the

confidentiality of personal information and using the data only for purposes permitted in this section.

(*b*) The Commissioner of Health or the Commissioner of the New York City Department of Health and Mental Hygiene may provide registrant-specific information to federal health officials, state or city immunization systems and systems maintained by the Indian Health Service and tribal nations recognized by the state or the United States [out-of-state immunization information systems] and others identified by the Commissioner of each respective immunization information system, for activities necessary to protect public health, in accordance with any written agreement required by such Commissioner.

(c) The Commissioner of Health or the Commissioner of the New York City Department of Health and Mental Hygiene may provide institutes of higher education, medical research centers or other institutions engaged in epidemiological research or other public health research access to de-identified registrant information in NYSIIS or the CIR for research purposes if approved by the Commissioner of Health or the Commissioner of the New York City Department of Health and Mental Hygiene, as appropriate

(viii) WIC programs for the purposes of verifying immunization and lead testing status for those seeking or receiving services, as well as referral for immunizations or lead tests as needed.

(ix) Colleges may access NYSIIS or CIR data for verifying immunization history for students entering or registered in that college or college system or may run college-specific reports that aggregate available data. Access shall be limited to data for registrants enrolling or already enrolled in a particular college or college system.

(x) Professional and technical schools may access NYSIIS or CIR data for verifying immunization history for students entering or registered in that professional or technical school or may run college-specific reports that aggregate available data. Access shall be limited to data for registrants enrolling or already enrolled in a particular professional or technical school.

(xi) Children's overnight camps and summer day camps may access NYSIIS or CIR data for verifying immunization history for children attending that overnight camp or summer day camp or may run camp-specific reports that aggregate available data. Access shall be limited to data for registrants attending a particular overnight or summer day camp.

(xii) [(ix)] Any parent or guardian of a registrant less than 18 years of age or the registrant himself/herself if 18 years or older or an emancipated minor, may receive a copy of an immunization record at no cost from their local health department, the CIR or NYSIIS.

(e) Methods of Accessing Immunization Data.

Each person seeking access to NYSIIS and/or the CIR must submit a completed application for access.

(f) Maintenance of Security and Confidentiality.

(1) Each person accessing the statewide system must have a distinct password and system ID that conform to industry standards, and with level and type of access tied to the type of user, as defined in subsection (d).

(2) Each person must understand and agree to adhere to the confidentiality protocol developed by the Department or the NYCDOHMH prior to either submitting or obtaining data from NYSIIS or the CIR.

(g) Provision of NYSIIS information to registrant's family/guardian.

(1) Mandated reporters to NYSIIS must provide the parent or legal guardian of each registrant with a copy of an informational brochure or letter from the Department at the time of each registrant's initial entry into the statewide system by that provider.

(2) If the parent/guardian speaks a primary language other than English, mandated reporters to NYSIIS must make every attempt to provide statewide system-related information comparable to the Department's brochure in the primary language of the parent or guardian.

Section 66-1.6 is amended to read as follows:

The certificate of immunization required in section 66-1.3(a) of this Subpart [provided for in subdivision 5 of section 2164 of the Public Health Law] shall be prepared and signed by [the] a health practitioner licensed in New York State [who administers the immunizing agents,] and shall specify the products administered and the dates of administration. It may also show physician, nurse practitioner, or physician assistant-verified history of varicella disease and/or laboratory evidence of immunity to measles, mumps, rubella, varicella, Hepatitis B and all 3 serotypes of poliomyelitis contained in the polio vaccines. A record issued by NYSIIS, [and/or] the CIR, an official immunization registry from another state, an electronic health record, and/or an official record from a foreign nation may be accepted as a certificate of immunization without a health practitioner's signature.

REGULATORY IMPACT STATEMENT

Statutory Authority:

The authority for school entry immunization requirements stems from Article 21, Title VI, Section 2164 of the Public Health law (PHL): *Poliomyelitis and Other Diseases.* PHL § 2164 mandates the vaccination of children as a condition of entry/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 stems from Article 21, Title VI, Section 2168 of the Public Health Law (PHL): *Poliomyelitis and Other Diseases.* PHL § 2168 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 day care, pre-k, 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 receive complete series of measles, mumps and rubella (MMR), diphtheria, tetanus and acellular pertussis (DTaP), and poliomyelitis vaccines by kindergarten or school entry. The school immunization regulations were last updated for the 2014-2015 school year to require that children receive an age-appropriate number of doses of immunizations, as determined by the 2013 Advisory Committee on Immunization Practices (ACIP) Immunization Schedule.

During implementation of the regulatory changes for the 2014-2015 school year, several limitations to the existing regulations were identified, necessitating further amendments to the regulations for the 2015-2016 school year. Chief among these was the timing of the final doses of the MMR, DTaP, and poliomyelitis vaccine series. Prior to the regulatory changes for the 2014-2015 school year, students entering kindergarten through twelfth grade were required to receive two doses of measles-containing vaccine, or other acceptable evidence of immunity, regardless of age. Although ACIP statements on each of these vaccine series recommend completion of these series prior to kindergarten or school entry, the 2013 ACIP Immunization Schedule, which was incorporated by reference into the recently revised regulations, recommended administration of the final doses of each of these series at four to six years of age.[1-4] As a result, students were not required to receive the final dose until the end of the recommended age range – i.e., the child's seventh birthday. As nearly all students in kindergarten are less than seven years of age, the kindergarten requirement for measles-

containing vaccine has effectively been reduced from two doses to one dose. Likewise, students cannot be required under the existing regulation to receive the final doses of DTaP and poliomyelitis vaccines until they reach seven years of age. This was an unanticipated byproduct of the incorporation by reference of the ACIP schedule which was not identified during the regulatory change process.

It is of the utmost public health importance that students entering kindergarten be maximally protected with complete MMR, DTaP and poliomyelitis vaccine series. The United States (U.S.) is currently experiencing a record number of measles cases. Nearly 600 measles cases were reported in the U.S. from January 1 through August 15, 2014 – the highest number of cases reported since measles elimination was documented in the U.S. in 2000.[5] This number includes a large measles outbreak in New York City (NYC) and additional measles cases in New York State (NYS) outside of NYC in 2014. An ongoing large measles outbreak in the Philippines has contributed to measles cases to the U.S., including four NYS and NYC cases with confirmed or suspected epidemiologic links to the Philippines this year. A recent edition of the Morbidity and Mortality Weekly Report (MMWR) provides details on measles cases and outbreaks in the U.S. in 2014 to date.[6]

Reported cases of pertussis are also increasing nationwide. California has declared a pertussis epidemic, with over 7500 cases, including elementary, middle, and high school outbreaks, reported from January 1, 2014 to August 18, 2014.[7] NYS experienced a record peak year of pertussis incidence in 2012, with 2,713 cases of pertussis reported outside of NYC, exceeding the last large NYS pertussis outbreak of 1,969 cases in 2004. As pertussis outbreaks occur

cyclically and typically peak every three to five years, NYS could experience its next pertussis peak year as soon as 2015.

On May 5, 2014, the director-general of the World Health Organization (WHO) declared the international spread of poliomyelitis to be a public health emergency of international concern under the authority of the International Health Regulations. The WHO has designated four countries (Cameroon, Equatorial Guinea, Pakistan, and Syria) as "exporting wild poliovirus" and an additional six countries (Afghanistan, Ethiopia, Iraq, Israel, Nigeria, and Somalia) are designated as "infected with wild poliovirus."[8] Although poliomyelitis was declared eliminated from the U.S. in 1979, it remains crucial to maintain high rates of vaccination because poliomyelitis could be brought in to the U.S. from countries where poliovirus is circulating.

In contrast to the MMR, DTaP and poliomyelitis age-based immunization requirements, the regulatory amendments made for the 2014-2015 school year explicitly stated that children entering kindergarten must have received two doses of varicella vaccine or other acceptable evidence of varicella immunity. The proposed regulatory changes mirror the varicella language in the existing regulation to require completion of the poliomyelitis, MMR and DTaP vaccine series, or other acceptable evidence of immunity, for kindergarten and school entry. The move from age-based to kindergarten entry requirements will improve community immunity in schools against these vaccine preventable diseases and enhance the ability of schools to enforce immunization requirements.

In addition, the requirement for vaccine intervals to be consistent with the 2013 ACIP schedule has created significant problems for adolescent students, who received vaccine doses eight or more years ago, under standards of care that may have been appropriate at the time of vaccine administration, but may no longer be consistent with the 2013 ACIP schedule.

To ameliorate this situation, the proposed regulatory change allows those students entering eighth through twelfth grades (or comparable age level grade equivalents) only during the 2015-2016 school year to be in compliance with school immunization requirements until graduation if they had previously satisfied the school immunization requirements in effect in regulation on June 30, 2014. This change would exempt this cohort of students from the revised vaccine interval requirements established by the current ACIP schedule, but still require that such students be age-appropriately vaccinated under the prior school immunization requirements.

To improve the completeness and accuracy of NYSIIS data and to further assist educational institutions with locating up-to-date immunization histories for their students, two exemptions for electronic reporting to NYSIIS have been removed from the regulation. These exemptions were important when NYSIIS was first launched to assist with the initial training of providers. They are no longer needed as NYSIIS has been an active system for over six years. All NYS providers must report complete and timely immunization data to NYSIIS. In addition, to conform to changes in PHL § 2168, the regulations have been updated to add colleges, professional and technical schools, and children's overnight and summer day camps as authorized users of NYSIIS and to grant access to de-identified registry information for research

purposes. The regulations have also been updated to permit the exchange of registry information with the Indian Health Service and tribal nations as also allowed by amendments to PHL § 2168.

Finally, the revised regulations clarify the requirements for acceptable certificates of immunization to allow records issued by NYSIIS, the Citywide Immunization Registry (CIR), or another state immunization registry, an electronic health record, and/or an official record from a foreign nation to be accepted without a health practitioner's signature. This change reflects the increasing usage of electronic health records and immunization registries.

Costs to State Government including the Department of Health:

The proposed regulatory changes are not expected to result in substantial costs to state government, but instead will likely result in cost savings to the state. Routine childhood immunizations have been estimated to result in a cost savings of approximately $13.5 billion in direct costs and $68.8 billion in societal costs. The CDC estimates that every dollar spent on immunization saves at least ten dollars in aggregate societal costs.[9] Potential savings to Medicaid and other payers are also expected secondary to the prevention of cases of disease.

Costs to Local Governments:

The cost to local governments and school districts is difficult to estimate. School staff already collect immunization records and ensure that students comply with school entry requirements. The move from age-based to kindergarten entry requirements for MMR, DTaP and polio

vaccines will only directly impact students four to six years of age as students seven years of age and older are already required to have these doses under existing regulation. While there will be initial work associated with ensuring that students in this age range meet the new kindergarten entry requirements, this change should reduce long-term administrative costs for school districts by markedly reducing the number of "in process" students that the school must monitor. In addition, exempting the cohort of students entering eighth through twelfth grades during the 2015 – 2016 school year from the vaccine interval requirements will significantly reduce immunization assessment work for school districts. The clarification of acceptable certificates of immunization should further reduce administrative costs to school districts associated with verifying that certificates of immunization meet regulatory requirements.

Costs to Private Regulated Parties:

It is difficult to determine what if any additional expenses may be incurred by these measures, however, costs are predicted to be minimal. Given that the revised school entry requirements are consistent with ACIP immunization recommendations, many medical practices already administer these vaccines to their patients prior to kindergarten entry.

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:

The revised school entry regulations will not increase the normal amount of the State's paperwork. Because 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:

All affected children will be required to adhere to the proposed school entry regulations on and after September 1, 2015.

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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: 5,498 public, private, or parochial child care centers, 9,338 day care agencies, 642 nursery schools, and 6,387 kindergartens, elementary, intermediate, or secondary class or school buildings.

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/or medical or religious exemptions to said immunization(s).

The approximate number of students are as follows: 128,383 in public, private, or parochial child-caring centers, 187,752 in day care agencies, 39,312 in nursery schools, and 3,081,724 in kindergarten, elementary, intermediate, or secondary class or school buildings. 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/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.

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; this is critical during outbreak situations. In addition, access to this information simplifies assessment of immunization coverage as required for school entry/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 proposed regulatory changes were drafted in response to feedback from multiple stakeholders, including public and private schools, local health departments, and health care providers. In addition, New York City Department of Health and Mental Hygiene (NYC DOHMH) and New York State Education Department (NYSED) were solicited for comments on the regulations. The NYC 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 NYC 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.

ASSESSMENT OF PUBLIC COMMENT

The New York State Department of Health (NYSDOH) received 19 comments from school nurses and physicians during the comment period. Commenters strongly supported the proposed requirement that students complete the measles, mumps, rubella (MMR), diphtheria, tetanus, and pertussis (DTaP) and polio vaccine series upon kindergarten entry. Additional comments were as follows:

Comment: Amendments to the regulations should not take effect until the Fall of 2016. Schools need more time to update systems and materials and to communicate the new immunization requirements to parents. Many schools have already completed kindergarten registration, and some of those children entering kindergarten have already completed their kindergarten entry physical examinations for the 2015-16 school year. The new immunization requirements should be phased in over a series of years to ease implementation.

Response: The implementation of the proposed revisions to the immunization requirements in the 2015-16 school year is of utmost public health importance. From December 2014 through April 2015, the United States experienced a large, multi-state measles outbreak linked to an amusement park in California. In total, 147 people from seven states were reported to have measles linked to the outbreak; the majority were unvaccinated against measles. Three additional cases of measles have occurred in New York State (NYS), including New York City, since January 2015. Measles continues to circulate in many countries, including Canada, and international travelers continue to bring measles into the United States. Individuals who are not

fully vaccinated against measles are at increased risk of contracting measles if they are exposed to it, and measles can spread rapidly among undervaccinated populations. Therefore, it is critically important that the NYSDOH ensure that children attending school in NYS are fully vaccinated with two doses of MMR vaccine prior to kindergarten entry.

Comment: All students who were enrolled during the 2013-14 school year should be deemed in compliance with immunization requirements if they had satisfied the immunization requirements in effect on June 30, 2014. Only new entrants and students in select grades should be required to meet the immunization requirements that took effect in the 2014-15 school year, with a phase-in of requirements for additional grades over a seven-year period.

Response: The 2014-15 varicella and polio requirements already included a seven-year phase-in period. The amendments for the 2015-16 school year would keep the seven-year phase-in of varicella and polio requirements intact.

As a result of changes already adopted in February 2014, existing school immunization regulations require students in all grades to receive age-appropriate doses of DTaP vaccine as established by the Advisory Committee on Immunization Practices (ACIP). Prior to July 1, 2014, students younger than grade six were only required to have three doses of DTaP vaccine. The revisions to regulations adopted in February 2014 required four or five doses, depending on age and vaccine history. Based on these most recent proposed revisions, students in grades six through twelve would still meet the 2014-15 DTaP vaccine requirements with three doses of

DTaP vaccine plus a dose of Tdap vaccine – effectively the same requirement in effect on or before June 30, 2014.

Allowing students in grades five or below to be in compliance if they had met immunization requirements in effect on June 30, 2014 would not be in the best interests of public health. Four or five doses of DTaP vaccine, depending on age and vaccine history, are necessary for optimal protection against pertussis infection which continues to circulate widely in the United States. Therefore, it is of critical public health importance to ensure that students in all grades in NYS are fully vaccinated against pertussis.

Comment: School nurses have difficulty implementing a requirement that Tdap be received in grade six at 11 to 12 years of age because many children enter grade six at 10 years of age. Many school nurse hours are spent tracking 10 year old students who had not yet received Tdap upon entering grade six. The minimum age for Tdap vaccine should be decreased to 10 years of age or move the Tdap requirement to grade seven.

Response: Public Health Law § 2164 requires the administration of Tdap in grade six. A statutory change would be necessary to instead require Tdap for grade seven.

Comment: The NYSDOH should notify health care providers of the new school immunization requirements being adopted as a result of this rulemaking as soon as possible.

Response: The NYSDOH recognizes the importance of rapid, timely and complete education of providers on the new school immunization requirements. Health care provider professional associations have already been notified of the proposed amendments to regulations, and the NYSDOH will work through multiple channels to educate health care providers on the new requirements that are being adopted as a result of this rulemaking.

Comment: Health care providers, not schools, should be responsible for monitoring immunization intervals.

Response: PHL § 2164 requires schools to ensure that students comply with applicable immunization requirements. However, health care providers should follow best practices to ensure that vaccines are administered at appropriate ages and intervals. The NYSDOH will continue to work with health care providers to ensure that they are aware of minimum ages and intervals for vaccine doses, to implement systems to prevent administration of vaccine doses prior to minimum ages and intervals, and to encourage use of the New York State Immunization Information System and Citywide Immunization Registry to track vaccine intervals, appropriate schedules, and the validity of doses administered.

Comment: With respect to the amendment allowing a foreign immunization record to be accepted without a health care provider's signature, some foreign records list a student's name and date of birth on a separate page from the immunization history. If a parent submits only the

immunization history, the school may be unable to verify that the documented immunization history belongs to the student.

Response: A complete official record from a foreign nation would be necessary to be considered an official record. If the parent submits only a portion of a foreign record, it would be deemed incomplete and the rest of the document would need to be produced in order for the record to be considered an official record. The assessment of records must be handled on a case-by-case basis, but if the immunization record given does not include a name and date of birth, the record would be incomplete and not accepted as an official record.

Comment: The requirement for five doses of DTaP vaccine, or four doses if the fourth dose was given at four years of age or older, enables vaccine-hesitant parents to defer the fourth dose of DTaP vaccine until four years of age. Similarly, the requirement for four doses of polio vaccine, or three doses if the third dose was given at four years of age or older, could enable vaccine hesitant parents seeking to defer vaccination. All students should be required to have five doses of DTaP vaccine and four doses of polio vaccine.

Response: The NYSDOH agrees that all children should receive all doses of vaccine at the earliest recommended ages. The regulations, however, are aligned with the current ACIP recommendations for DTaP and polio. The ACIP does not recommend that a fifth dose of DTaP vaccine nor a fourth dose of polio vaccine be administered if the fourth and third doses of DTaP and polio vaccines, respectively, were administered on or after the fourth birthday. The final

doses of DTaP and polio vaccine given on or after the fourth birthday boosts the immune system prior to kindergarten entry.