

School Immunization Requirements

Effective date: 7/1/14

SUMMARY OF EXPRESS TERMS

This proposal will amend Subpart 66-1 (School Immunization Requirements) to update regulations so that they comply with current immunization recommendations and medical knowledge. The regulations would be effective July 1, 2014.

Proposed amendments to Section 66-1.1 provide that a child will be considered fully-immunized when (i) the child has received an adequate dosage and number of doses of an immunizing agent commensurate with his or her age or (ii) the child has otherwise demonstrated immunity to measles, mumps, rubella, hepatitis B, poliomyelitis (all three serotypes) and varicella through a positive serologic test or, for varicella only, disease as verified by a physician, nurse practitioner or physician's assistant. For those immunizations required by Public Health Law (PHL) § 2164 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 Recommended Immunization Schedule for Persons Aged 0 Through 18 Years issued by the Advisory Committee on Immunization Practices (ACIP). If a child is not fully immunized, immunization must take place according to the Catch-Up Schedule of the ACIP.

For all vaccinations except poliomyelitis and varicella, children shall be assessed upon school entry or attendance, and annually thereafter, and be found to be fully

immunized commensurate with their age. 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 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. 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.

The proposed amendments also provide that a child will be considered “in process” of receiving necessary immunizations if he or she has received at least the first dose in each required immunization series and has age appropriate appointments to complete the immunization series or is obtaining serologic tests and has appointments to complete the immunization series within 30 days of notification that serologic tests are negative. Children who are not fully immunized can only continue to attend school if they are in the process of completing the 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, the child is no longer in process and must be excluded from school, if not otherwise exempt from immunization requirements.

Proposed amendments to Section 66-1.2 update the definitions in the regulation to conform to changes in the New York State Immunization Information System (NYSIIS) statute (PHL § 2168), to account for the implementation of NYSIIS that has occurred since 2008, and to include references to the New York City Immunization Registry (CIR). The proposed amendments also expand upon the definition of authorized users as well as the types of information to be reported to NYSIIS or the CIR to include race, ethnicity, telephone numbers, birth order (if multiple birth), birth state/country, Vaccines for Children Program eligibility and Medicaid number.

Proposed amendments to Section 66-1.3 provide that a school shall not admit a child without receipt of a certificate of immunization from a health care practitioner, or from NYSIIS or the CIR, documenting that the child has been fully immunized, documentation that the child is “in process,” a signed medical exemption, or a completed religious exemption. The proposed changes state that a principal or person in charge of a school shall not refuse to admit a child to school, based on immunization requirements, if that child is in process. The proposed changes also require that a medical exemption must be reissued annually and must contain sufficient information to identify a medical contraindication to a specific immunization and specify the length of time the immunization is medically contraindicated. For both medical and religious exemptions, the principal or person in charge of the school may require additional information supporting the exemption.

Proposed amendments to Section 66-1.4 clarify that the 14 calendar day period for continued school attendance may be extended to not more than 30 calendar days for an individual student who is transferring from out-of-state or from another country and can show a good faith effort to obtain the necessary evidence of immunization.

Proposed amendments to Section 66-1.6 provide that the certificate of immunization shall be prepared by the health practitioner 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.

Proposed amendments to Section 66-1.7 provide that every school shall annually provide the Commissioner of Health, or in the city of New York, the New York City Commissioner of Health, a summary regarding compliance with immunization requirements. For all schools, excluding public schools within New York City, the summary will be provided in the form of the yearly school survey conducted by the Department of Health.

Proposed amendments to Sections 66-1.8 and 66-1.9 clarify the obligation of the school to notify the local health authority, when a child has been excluded because of

lack of acceptable evidence of immunization or exemption, and the obligation of the local health authority to arrange for a suitable health practitioner to administer immunizations.

Proposed amendments to Section 66-1.10 provide that, for those diseases listed in PHL § 2164, in the event of an outbreak of disease in a school, the Commissioner, or his or her designee, or in the City of New York, the New York City Commissioner of Health may order the exclusion of children who have been exempted from immunization or are “in process” of receiving required immunizations. Any exclusion shall continue until the Commissioner, or his or her designee, or the New York City Commissioner of Health (as appropriate), determines that the danger of disease transmission has passed. The proposed changes also require schools to maintain a current list of susceptible students who should be excluded from attendance in the event of an outbreak of vaccine-preventable disease.

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 July 1, 2014, to read as follows:

Title: Subpart 66-1 - School Immunization Requirements [against Poliomyelitis, Diphtheria, Measles, Mumps and Rubella]

SUBPART 66-1

School Immunization Requirements

[IMMUNIZATION AGAINST POLIOMYELITIS, DIPHTHERIA, MEASLES, MUMPS

AND RUBELLA]

(Statutory authority: Public Health Law Sections 2164 and 2168)

Sec.

66-1.1 Definitions

66-1.2 Statewide Immunization Information System [Registry]

66-1.3 Requirements for school admission

66-1.4 Requirements for continued school attendance

66-1.5 Immunization records from previous schools

66-1.6 Certificate of Immunization [Existing school immunization records]

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66-1.8 Immunization for children excluded from school

66-1.9 Obligation of local health authority

66-1.10 Exclusion [of susceptibles] in event of disease outbreak

Section 66-1.1 is repealed and a new Section 66-1.1 is proposed to read as follows:

Section 66-1.1 Definitions.

As used in this Subpart unless the context otherwise requires:

(a) School means and includes a public, private or parochial child-caring center, day-care agency providing day care of children as defined in this section, nursery school as defined in this section, kindergarten, and any elementary, intermediate or secondary class or school building.

(b) Child means and includes any person between the ages of two months and 18 years.

(c) Day care of children means:

(1) outside the City of New York, care provided to children away from the child's residence, for less than 24 hours per day in a licensed child day care center or a group family day care, for compensation or otherwise, for at least three hours a day.

(2) in the City of New York, any service which, during all or part of the day, regularly gives care to six or more children, not of common parentage, who are under six years of age, whether or not the care is given for compensation and whether or not it has a stated educational purpose. The total number of children receiving care shall be counted, including children or foster children of the owner or person in charge, in determining the applicability of this definition. The term shall not, however, include a service which gives care to children for five or less hours a week or a service which operates for one month a year or less.

(d) Nursery school means a place, other than one providing day care of children as defined in this section, in which organized instruction is provided for children prior to entering any public or non-public school.

(e) Health practitioner means any person authorized by law to administer an immunization. This includes a physician, nurse practitioner, nurse-midwife caring for a pregnant student, registered nurse, licensed practical nurse under the direction of a registered nurse, or physician's assistant.

(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 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) and posted on the Centers for Disease Control and Prevention website at <http://www.cdc.gov/vaccines/recs/schedules/default.htm>. The department will amend this section as necessary to reflect revised ACIP Recommended Immunization Schedules.

The 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) 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, children shall be assessed upon school entry or attendance, and annually thereafter, and be found to be fully immunized commensurate with their age.

(ii) 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 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) 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.

(2) If a child is not fully immunized, immunization must then take place according to the 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>.

(g) Immunity means that (i) for measles, mumps, rubella, hepatitis B, and all 3 serotypes of poliomyelitis found in the polio vaccines, a child has had a positive serologic test, as defined in section 66-1.1 (h), for those diseases or (ii) for varicella, a child has either had a positive serologic test, as defined in section 66-1.1 (h), or had the disease as verified by a physician, nurse practitioner, or physician's assistant statement.

(h) Serologic test means a blood test for Immunoglobulin G (IgG), or for hepatitis B, a blood test for hepatitis B surface antibody, as determined by the testing lab's criteria. Serology results reported as equivocal are not acceptable proof of immunity. A positive serologic test can be accepted in place of vaccination only for the following diseases: measles, mumps, rubella, varicella, hepatitis B and all 3 serotypes of poliomyelitis found in the polio vaccines.

(i) Grace period means that vaccine doses administered within 4 calendar days of the recommended minimum age or interval will be considered valid.

(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 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 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 ACIP catch up schedule referenced 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 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, if not otherwise exempt in accordance with Section 66-1.3.

Subdivisions (a) (1), (2), (4), (6), (7), and (8) of Section 66-1.2 are amended to read as follows:

(a) *Definitions.*

(1) *Statewide immunization information system [registry]* 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 [computerized database] 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 [written] 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 [Citywide Immunization Registry].

* * *

(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 [the statewide system] or the CIR [citywide registry] and perform the functions permitted the primary authorized user.

* * *

(6) *Registrants* shall mean all individuals [children less than 19 years of age receiving any immunizations] 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 may also include persons 19 years of age and older receiving immunizations who provide written consent to have their immunizations recorded in the system. Registrants include children who do not receive vaccines in accordance with an approved exemption pursuant to Public Health Law section 2164.] 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) Healthcare 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) health maintenance organizations.]

(vi) Third party payers; and

(vii) WIC programs.

Subdivision (b) (1), (2), (5) and subdivision (c) (1), (2)(iv), (3)(i) of Section 66-1.2 are amended and a new subdivision (c) (3)(iii) and (iv) of Section 66-1.2 is added to read as follows:

(b) Mandated Reporting

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

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

* * *

(5) When vaccines are administered based on non-patient specific [standing] 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 [the statewide system], 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 statewide system] NYSIIS or the CIR must be submitted electronically except as provided in paragraph (3) of this subdivision.

* * *

(iv) Submission of immunization information to [the correct registry] NYSIIS or the CIR. Providers must submit immunization information to NYSIIS or the CIR, dependent upon the [registry] IIS operating in the area in which they practice, not the IIS [registry] appropriate to the patient's area of residence. Exchange of information between IIS's will be the responsibility of NYSIIS and the CIR [registries will be the responsibility of the registries].

(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 [the statewide system]'s 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.

* * *

(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.

Subdivisions (c)(4)(i), (iv) of Section 66-1.2 are amended and subdivision (c)(4)(v) of Section 66-1.2 is deleted to read as follows:

(4) Timeliness of Reporting. Providers ordering immunizations [after January 1, 2008] must submit immunization information to NYSIIS or the CIR within 14 days of administration of the immunization[, except as noted below]. Providers must also submit information regarding immunizations not previously reported for each registrant [within this time period,] except as noted below.

For NYSIIS only:

(i) Providers wishing to submit historical immunization information to NYSIIS via data file for their patients [prior to the administration of the first immunization after January 1, 2008,] may request permission from the department to submit such data [before administration of immunizations].

* * *

(iv) [In select instances, providers may be granted an extension on the deadline for submission of immunization information. Extensions will be reviewed by the department and granted as appropriate based on the following reasons:] 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.

[(a) Automatic training-based deferral. Any provider who is unable to begin online submission of immunization data as of January 1, 2008 may defer implementation until the first of the month following the last interactive registry training offered by the Department, either face-to-face or via webinar, in the provider's region, without prior request to the Department for a deferral.]

[(b) Additional deferral circumstances, which require permission from the Department following a written request from the provider:]

[(1) Providers may request an extension they are making ongoing and meaningful progress in developing alternative electronic means of data submission, including submission of immunization histories.]

[(2) If immediate electronic submission of information is a hardship due to lack of a computer, providers may request an extension period during which paper submission of immunization data may be permitted on an individual basis, for a period not to exceed three months.]

[(3) Providers who practice in areas where there is no internet access available must request an extension of the deadline to submit electronically or make other arrangements for submission of their data and provide justification for the proposed length of the extension requested.]

[(v) In no instance will a deferral, either Department-approved or region-specific based on regional availability of interactive training, permanently exempt providers from reporting all immunizations given to children less than 19 years of age after January 1, 2008 and their immunization histories.]

Subdivision (d) of Section 66-1.2 is amended to read as follows:

(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 [the statewide system] 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) of this paragraph are prohibited without the approval of the commissioner of the State Department of Health; or, for requests for CIR [Citywide Immunization Registry] information, without the approval of the commissioner of the New York City Department of Health and Mental Hygiene. 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 [statewide] or CIR [citywide registry] 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 (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 [the] 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 [citywide immunization registry] data for verifying immunization history for [selected] students entering or registered in that school [for whom parents] or school system [guardians are unable to provide current immunization records] or may run school-specific reports that aggregate available data. Access will be limited to data for children 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 [citywide immunization registry] 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 [citywide immunization registry] 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 [Health maintenance organizations] may access NYSIIS or CIR [citywide immunization registry] data for the purpose of performing quality assurance, accountability and outreach relating to enrollees covered by their plan. Third party payers [Health maintenance organizations] 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 [registry] in order to fulfill file maintenance and improvement functions and may use the data in both [systems/registries] NYSIIS and the CIR for purposes of outreach, quality

improvement and vaccine accountability, research, epidemiological studies and disease control.

[(a) Information may be exchanged between the statewide immunization system and the Citywide Immunization Registry at least quarterly.]

(a) [(b)] The Commissioner of Health may provide, on request, registrant-specific information to out of [other] state immunization information systems [registries] on a routine basis pursuant to a written agreement with each out-of-state system [registry] requiring such system [registry] 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) [(c)] 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, out-of-[other] state immunization information systems [registries,] and others identified by the Commissioner of each respective immunization information system, [registry, in specific instances] for activities necessary to protect public health, in accordance with any written agreement required by such Commissioner.

(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) [viii] 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.

Subdivisions (e), (f), and (g) of Section 66-1.2 are amended to read as follows:

(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 [statewide system].

(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 [registry]-related information comparable to the department's brochure in the primary language of the parent or guardian.

Section 66-1.3 is repealed and replaced with the following:

66-1.3 Requirements for school admission.

A principal or person in charge of a school shall not admit a child to school unless a person in parental relation to the child has furnished the school with one of the following:

(a) A certificate of immunization, as described in section 66-1.6 of this Subpart, from a health care practitioner or from NYSIIS or the CIR, documenting that the child has been fully immunized according to the requirements of section 66-1.1 (f) of this Subpart.

(b) Documentation that the child is in process of receiving immunizations as defined in section 66-1.1(j) of this Subpart. A principal or person in charge of a school

shall not refuse to admit a child to school, based on immunization requirements, if that child is in process.

(c) A signed, completed sample medical exemption form issued by the NYSDOH or NYCDOHMH or a signed statement from a physician licensed to practice medicine in New York State certifying that immunization may be detrimental to the child's health, containing sufficient information to identify a medical contraindication to a specific immunization and specifying the length of time the immunization is medically contraindicated. The medical exemption must be reissued annually. The principal or person in charge of the school may require additional information supporting the exemption.

(d) A completed sample form titled: Request for Religious Exemption to Immunization, created by the New York State Education Department or a written and signed statement from the parent, parents or guardian of such child, stating that the parent, parents or guardian objects to their child's immunization because of sincere and genuine religious beliefs which prohibit the immunization of their child, in which case the principal or person in charge of the school may require supporting documents.

Section 66-1.4 is amended to read as follows:

66-1.4 Requirements for continued school attendance.

[After the 30th day of June, 1980, a] A principal or person in charge of a school shall not permit a child to continue to attend such a school for more than 14 days unless a person in parental relation to the child has furnished the school with one of the documents specified in section 66-1.3 of this Subpart, [, with the exception that the requirements for mumps immunization specified in subdivision (a) of Section 66-1.3 will be waived until July 1, 1981.] Such 14 calendar day period may be extended to not more than 30 calendar days for an individual student who is transferring from out-of-state or from another country and can show a good faith effort to get the necessary evidence of immunization.

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Section 66-1.6 is repealed and replaced with the following:

Section 66-1.6 – Certificate of Immunization

66-1.6 The certificate of immunization provided for in subdivision 5 of section 2164 of the Public Health Law shall be prepared and signed by the health practitioner 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 may be accepted as a certificate of immunization.

Section 66-1.7 is repealed and replaced with the following:

Section 66-1.7 School Survey

66-1.7 Every school, shall annually provide the Commissioner of Health, or in the city of New York the New York City Commissioner of Health, by a date determined by the applicable Commissioner, a summary regarding compliance with the provisions of this section. For all schools, excluding public schools within New York City, the summary will be provided in the form of the yearly school survey conducted by the Department of Health.

Section 66-1.8 is amended to read as follows:

66-1.8 Immunization for children excluded from school.

Whenever a child has been refused admission to or continued attendance at a school for lack of acceptable evidence of immunization, immunity or exemption as specified in [subdivisions (a) and (b) of] section 66-1.4 of this Subpart, the principal, teacher, owner, or person in charge of the school shall:

(a) notify the person in parental relation to the child of his/her responsibility to have the child immunized and of the public resources available for doing so;

[(b) provide the person in parental relation to the child with the appropriate vaccine information forms supplied by the New York State Department of Health;]

(b) [(c)] notify the local health authority of the name and address of the excluded child and of the immunization or immunizations which the child lacks; and

(c) [(d)] provide, with the cooperation of the local health authority, for a time and place at which the required immunization or immunizations may be administered.

Section 66-1.9 is amended to read as follows:

66-1.9 Obligation of local health authority.

Upon being notified by a principal or person in charge of a school of the exclusion from school of one or more children for lack of acceptable evidence of immunization, it shall be the responsibility of the local health authority to either:

(a) cooperate with the school authorities to provide a time and place, within two weeks of the exclusion, at which the appropriate immunization or immunizations may be administered, by a health [officer in the public employ or by a school physician or nurse;], practitioner as defined in section 66-1.1(e); or

(b) notify the commissioner that the required immunizations will not be administered either by local health authority or school, and that the cost of doing so by the agents of the commissioner may be recovered from the amount of State aid to which the local health authority would otherwise be entitled.

Section 66-1.10 is amended to read as follows:

66-1.10 Exclusion [of susceptibles] in event of disease outbreak.

(a) For those diseases listed in PHL § 2164 only, in the event of an outbreak, as defined in section 2.2(d) of this Title, of [diphtheria, polio, measles, rubella, mumps] a vaccine-preventable disease in a school, the commissioner, 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, may order the appropriate school officials to exclude from attendance all students [without documentation of immunity, as specified in section 66-1.3(a) or (b) of this subpart, including those who have been excused from immunization under section 66-1.3 (c) or (d) of this Subpart.] who either have been exempted from immunization under section 66-1.3 (c) or (d) of this Subpart, or are in the process of receiving required immunizations pursuant to section 66-1.3(b) of this Subpart.

(b) The exclusion shall continue until the commissioner 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, determines that the danger of transmission has passed [or until the documentation specified in section 66-1.3(a) or (b) of this Subpart has been submitted].

(c) Schools must maintain a list of susceptible students who should be excluded from attendance in the event of an outbreak of vaccine preventable disease. This list must include all students who have been excused from immunization under section 66-1.3 (c) or (d) of this Subpart and students who are in the process of completing immunization series or awaiting the results of serologic testing for any vaccine preventable disease specified under section 66-1.3 (b). The list shall be updated each time a new student enrolls in the school or a student's immunization status changes.

REGULATORY IMPACT STATEMENT SUMMARY

Background:

The authority for school entry immunization requirements and the statewide immunization information system stems from Article 21, Title VI, Sections 2164 and 2168 of the Public Health Law (PHL): *Poliomyelitis and Other Diseases*. 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 disease and accompanying morbidity and mortality. PHL § 2168 establishes the New York State Immunization Information System. Current regulations are out-of-date and need to be amended to comply with currently accepted medical practice and recommendations, to address statutory changes to PHL § 2168 and to account for the implementation of NYSIIS that has occurred since 2008.

The introduction and widespread use of vaccines have profoundly reduced the occurrence of many serious infectious diseases. Prior to vaccines, thousands of children each year, living in the United States (US), could expect to die or be left with life-long disabilities as a result of contracting diseases that are now preventable by vaccination, such as smallpox, poliomyelitis, rubella, measles, diphtheria and pertussis. Similarly, once commonly encountered and often deadly diseases such as diphtheria and rubella are becoming a rarity in the US as a result of the routine use of vaccination against these and

other infectious diseases. Many of these now vaccine-preventable diseases, due to their person-to-person mode of transmission, have historically occurred at very high rates in pre-school and school-aged children. Consequently, it is of the utmost importance, that this cohort maintains a high rate of vaccination coverage to prevent disease outbreaks. Historically, both nationwide and in New York State, school vaccination laws/requirements have been instrumental in helping to achieve high rates of immunization among school-aged children and consequently, in helping to prevent many diseases.

The development of school entry laws typically begins with public health recommendations made by the Advisory Committee on Immunization Practices (ACIP). ACIP provides advice and guidance to the Secretary of the U. S. Department of Health and Human Services, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. ACIP makes their recommendations based on evidence presented to them by both medical and other health care professional organizations. Their recommendations shape national immunization policy and are usually adopted by such professional organizations such as the American Association of Pediatrics, the American Association of Family Physicians, and the American College of Physicians. ACIP recommendations form the standard of care for immunization practices in the US, and school entry laws need to follow these standards as closely as possible. New York State regulations need to be modified to be current with immunization practices.

Necessity for Regulation Updates:

New York State's immunization rates for school-aged children have remained high, due in large part to school entry vaccination requirements. New York State has over 650 school districts and over 15,000 schools, including day cares, elementary, secondary, private, and public schools. Overall, immunization rates are consistently over 90 percent throughout the state and also in most individual schools; however, variations do exist. For instance, although the overall rate for religious exemptions in NYS is .53%, the exemption rates by grade group per county vary greatly. For children enrolled in grade 1, religious exemption rates range from 0% to 13.51%. This variation can be explained in part by the inhabitants of a given county. Counties with Amish and Mennonite communities tend to have higher religious exemption rates. The majority of schools in Amish and Mennonite communities do not offer kindergarten or high school grades, only enrolling children in grades 1 through 8. Therefore, the immunization rates for counties with large Amish and Mennonite communities have higher religious exemption rates for grades 1 through 8. There are other schools, where children with religious exemptions tend to cluster.

When a significant proportion of individuals in a community are immunized, those persons serve as a protective barrier against the likelihood of transmission of disease in the community, thus indirectly protecting those who are not fully immunized. This protection is referred to as "community immunity" or "herd immunity." If a large proportion of a community decides to not be vaccinated, the protection levels that

initially existed via herd immunity decline, and disease transmission increases. The importance of high immunization rates in NYS remains paramount, despite the sometimes low rates of disease in the US.

The purpose of the proposed regulatory changes is to update regulations so that they comply with current immunization recommendations and knowledge. Over time, through routine vaccine use, it has become obvious that changes in the schedule are necessary to maximize the protection of children and the community. The dangers of under-vaccination have been dramatically demonstrated by the number of outbreaks of diseases that have not been seen in developed countries in large numbers for many years. In addition, a rise in the number of outbreaks related to high rates of exemption to immunization in certain communities around the country, have illustrated the need for stronger school entry requirements.

The changes to these regulations include updating the school entry and attendance immunization requirements to comply with current recommendations of the official schedule as approved by ACIP and other major medical professional societies. These include: increasing the required number of doses of diphtheria, tetanus and acellular pertussis (DTaP) and varicella vaccines, clarifying the age appropriate vaccinations required with polio, hepatitis b, *haemophilus influenzae* type b, and pneumococcal vaccines, clarifying that appropriate spacing of vaccines is essential for efficacy, and clarifying definitions and key parts of the regulations, such as what constitutes immunity and how to determine the time a student can be in process of receiving their vaccines.

Since 2007, ACIP has recommended two doses of varicella (chicken pox) vaccine, one dose at 12 to 18 months of age and a second dose at 4-6 years of age. This was based on the fact that one dose of varicella vaccine seemed to allow an unacceptable number of breakthrough case of varicella disease. Exact rates of varicella disease are not known for New York State, but national studies have shown a steady decline in the number of cases of the disease as immunization has become more widespread.

All affected children will be required to adhere to the proposed school entry regulations on and after July 1, 2014.

Associated Costs:

The proposed regulatory changes are not expected to result in substantial costs to the state or local 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 \$10 billion from direct costs. The CDC estimates that every dollar spent on immunization saves \$18.43, producing societal aggregate savings of \$42 billion. Potential savings to Medicaid and other payers are also expected secondary to the prevention of cases of disease.

The Vaccines for Children Program (VFC), a federal entitlement program, provides vaccine for eligible children. In addition, the “317” federal grant supports purchase of

vaccine for administration at no cost to children at local health departments, and also supports immunization delivery, surveillance, communication and education. Private insurance, the VFC Program and the “317” grant will cover the cost of most of the additional vaccines required for school entry to eligible individuals. The State, however, may be required to use additional funds for the purchase and administration of vaccine to meet the revised school entry requirements for those individuals who are underinsured and/or participate in the State Children’s Health Insurance Program (SCHIP).

The NYSDOH Bureau of Immunization currently operates the New York State Immunization Information System (NYSIIS), which will aid in the recording of immunizations and has the ability to identify and generate notifications to students who are not in compliance with school immunization entry/attendance requirements. Currently 2,425 educational institutions in NYS are actively utilizing NYSIIS. These institutions are currently able to search for a given student’s immunization history, review it and determine compliance with current school entry requirements. These features are already a part of NYSIIS and thus the expansion of immunization requirements will not result in any additional costs for the State.

The NYSDOH will need to provide education on and promote the regulatory changes that will go into effect in the fall of 2014. The NYSDOH has contact information for all schools in NYS and currently communicates with schools across the state on a regular basis. The expansion of school immunization requirements and the need for education of all affected schools will not be a burden to the State as this communication takes place on

a frequent basis already. Funds necessary for educational/media campaigns will be made available from the existing Department of Health budget.

The cost to local governments and school districts is difficult to estimate, but should be minimal. School staff already collect immunization records and make sure that students comply with school entry requirements. The great majority of students will already be in compliance with the recommended schedule because this is the standard of care and most physicians and other health care providers comply with the recommendations.

Administrative staff at public schools will be responsible for assuring that each student is in compliance with the revised school entry requirements at the time of registration.

School staff will be able to utilize NYSIIS to check and record immunization records, a cost saving measure that was not available the last time regulations were changed.

Administrative procedures already in place will be utilized to notify students of immunization requirements and to notify deficient students of the need to comply. Given that schools are already checking, recording and notifying deficient students, the costs of implementing these regulations will likely be minimal.

Additional costs for the administration of vaccine by local health departments to meet the revised school entry requirements in the county health department clinics will likely be incurred. A substantial portion of the costs of organizing additional county health departments' clinic services will be eligible for reimbursement through State public health local assistance or from third party payers.

It is difficult to determine what, if any, additional expenses may be incurred by these measures to private parties, however, costs are predicted to be minimal. Given that the revised school entry requirements incorporate the currently recommended ACIP immunization schedule, many medical practices have already been recommending and administering these vaccines to their patients. It is possible that the new regulations will prompt an initial increase in patient flow to update all children's vaccine status in accordance with the new school entry requirements. This could require some additional staffing time and/or 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.

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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. 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).

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, in order to prevent the transmission of disease and accompanying morbidity and mortality. Current regulations are out-of-date and need to be amended to comply with currently accepted medical practice and recommendations. The legislative objective of PHL § 2168 is to establish a comprehensive database of complete, accurate and secure immunization records. Current regulations also need to be amended to address statutory changes to PHL § 2168 and to account for the implementation of NYSIIS that has occurred since 2008.

Needs and Benefits:

The Centers for Disease Control and Prevention (CDC) declared vaccination to be one of the ten greatest public health achievements of the twentieth century.¹ The introduction and widespread use of vaccines have profoundly reduced the occurrence of many serious infectious diseases. Prior to vaccines, thousands of children each year, living in the United States (US), could expect to die or be left with life-long disabilities as a result of contracting diseases that are now preventable by vaccination, such as smallpox, poliomyelitis, rubella, measles, diphtheria and pertussis. The worldwide eradication of smallpox and the near-eradication of poliomyelitis can be directly attributed to vaccination. Similarly, once commonly encountered and often deadly diseases such as diphtheria and rubella are becoming a rarity in the US as a result of the routine use of vaccination against these and other infectious diseases. Many of these now vaccine-preventable diseases, due to their person-to-person mode of transmission, have historically occurred at very high rates in pre-school and school-aged children. Consequently, it is of the utmost importance, that this cohort maintains a high rate of vaccination coverage to prevent disease outbreaks. Studies have in fact shown that when parents comply with school entry laws, corresponding disease in the community decreases proportionally.²

Historically, both nationwide and in New York State, school vaccination laws/requirements have been instrumental in helping to achieve high rates of

immunization among school-aged children and consequently, in helping to prevent many diseases. Mandated vaccination for school entry has uniformly increased state vaccination rates for required vaccines.³ In 1999, the Task Force on Community Preventive services concluded, after a review of all available studies on the effectiveness of school entry vaccination laws, that they are both effective at reducing disease rates and outbreaks as well as increasing overall vaccination coverage.⁴ States that currently have school mandates for adolescent hepatitis B vaccine have rates almost twice that of states without such mandates.³ One recent study investigated the impact on adolescent vaccination rates by comparing states which have a vaccine requirement for middle school entry versus states which have only an vaccine education requirement.⁵ Only the requirement for vaccination, not the education-only mandate was associated with higher coverage. These laws, which have clearly been shown to increase vaccination rates in a community, are of vital importance to provide both individual and community protection against disease.

In 2007, New York State became one of the first states to require the combined tetanus, diphtheria and pertussis (Tdap) vaccination prior to sixth grade entry. The school mandate at the middle school level in New York State for Tdap vaccine was found to be associated with a greater than two-fold increase in tetanus, diphtheria and pertussis vaccination rates in one New York City cohort.⁶ This school entry requirement has not only significantly increased Tdap vaccination rates, but has also increased rates, though not as substantially, for other recommended vaccines (such as MCV4) not included in the requirement.⁶

When a significant proportion of individuals in a community are immunized, those persons serve as a protective barrier against the likelihood of transmission of disease in the community, thus indirectly protecting those who are not fully immunized. This protection is referred to as “community immunity” or “herd immunity.” The optimal level of herd immunity varies by disease type (see Table A).

Table A: Estimated Herd Immunity thresholds for vaccine preventable diseases

Disease		Herd immunity threshold
Diphtheria		85%
Measles		83–94%
Mumps		75–86%
Pertussis		92–94%
Polio		80–86%
Rubella		80–85%

Reference: [History and Epidemiology of Global Smallpox Eradication](#) From the training course titled "Smallpox: Disease, Prevention, and Intervention". The CDC and the [World Health Organization](#). Slide 16-17.

If a large proportion of a community decides to not be vaccinated, the protection levels that initially existed via herd immunity decline, and disease transmission increases. Such a scenario occurred in 1989 to 1991 when nationwide, low measles vaccination rates led to outbreaks of measles throughout the US. These outbreaks resulted in greater than 55,000 cases of measles and 123 measles-associated deaths. In addition, some of the cases occurred as a result of vaccine failure from one dose of measles vaccine. As a direct result, two measles vaccines were recommended and later required for school entry in NYS. This is an excellent illustration of how school entry/attendance requirements must be updated at regular intervals to ensure that the most recent scientific and epidemiologic knowledge is translated into everyday practice, therefore resulting in the optimization of immunization practices.

The importance of high immunization rates remains paramount, despite the sometimes low rates of disease in the US. Low immunization rates have led to significant outbreaks, such as the pertussis outbreak (over 9100 cases) which occurred in California in 2010, and resulted in the death of 10 infants. The study by Omer et al, published in the American Journal of Epidemiology in 2008 shows that there is a significant overlap between clusters of low exemption rates and pertussis cases in Michigan.⁷ In 2011 the US saw the most cases of measles since 1996; 222 cases were reported for the year, with the average number of cases usually around 60/year. A Los Angeles Times article clearly made this point that low immunization rates contributed heavily to the measles outbreak in California as per data obtained from the California Department of Public Health.⁸ New York State too has experienced the reoccurrence of vaccine preventable diseases. In

2010, New York had over 660 cases of mumps and 720 cases of pertussis. In 2011, there were over 930 cases of pertussis. To date in 2012, New York has seen more than 2,000 cases of pertussis.

In addition, vaccine preventable diseases have been occurring on a global scale, due to lax school entry laws in some countries. The United Kingdom has had several years of outbreaks of both mumps and measles, including hospitalizations and deaths, and in 2011, France experienced an extremely large outbreak of measles with over 20,000 cases. Canada has had outbreaks of mumps and measles, the great majority of which are due to cases of individuals who were not immunized and who travelled to and from several European countries where measles epidemics are occurring. Several recent editions of the Morbidity and Mortality Weekly Report (MMWR) provide details on cases of measles imported and spread in the US.^{9, 10, 11}

The development of school entry laws typically begins with public health recommendations made by the Advisory Committee on Immunization Practices (ACIP). ACIP provides advice and guidance to the Secretary of the U. S. Department of Health and Human Services, the Assistant Secretary for Health, and the CDC on the control of vaccine-preventable diseases. ACIP makes their recommendations based on evidence presented to them by both medical and other health care professional organizations. Their recommendations shape national immunization policy and are usually adopted by such professional organizations such as the American Association of Pediatrics, the American Association of Family Physicians, and the American College of Physicians.

ACIP recommendations form the standard of care for immunization practices in the US, and school entry laws need to follow these standards as closely as possible. New York State regulations have not been modified to keep current with immunization practice and are therefore, less effective in preventing communicable diseases.

The Advisory Committee on Immunization Practices (ACIP)

The ACIP sets the immunization schedule that is the national standard of care. The ACIP was established under Section 222 of the Public Health Service Act (42 U.S.C. § 217a). The committee is governed by the provisions of the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees.

The Secretary of the Department of Health and Human Services (DHHS), and, by delegation, the Director of the Centers for Disease Control and Prevention (CDC), are authorized to assist states and their political subdivisions in the prevention and control of communicable diseases; to advise the states on matters relating to the preservation and improvement of the public's health; and to make grants to states and, in consultation with the state health authorities, to agencies and political subdivisions of states to assist in meeting the costs of communicable disease control programs.

The ACIP provides advice and guidance to the Secretary of the DHHS, the Assistant Secretary for Health, and the Director of the CDC, regarding the most appropriate selection of vaccines and related agents for effective control of vaccine-preventable

diseases. The guidance covers the appropriate use of the vaccine and may include recommendations for administration of immune globulin preparations and/or antimicrobial therapy shown to be effective in controlling the same disease. For each recommended vaccine, the committee advises on population groups and/or circumstances in which a vaccine or related agent is recommended. The committee develops guidance on the appropriate route, dose and frequency of administration of the vaccine, associated immune globulin, or antimicrobial agent. The committee also provides recommendations on contraindications and precautions for use of the vaccine and related agents and provides information on recognized adverse events. Committee deliberations on the appropriate use of vaccines to control diseases in the U.S. include consideration of population-based studies such as efficacy, cost benefit, and risk benefit analyses. The ACIP sets the childhood immunization schedule that is used throughout the US and that details which vaccines are recommended, and at which ages and at what intervals they shall be given.

The committee consists of 15 members, including the Chair. Members and the Chair are selected by the Secretary of DHHS, from authorities who are knowledgeable in the fields of immunization practices and public health, have expertise in the use of vaccines and other immunobiologic agents in clinical practice or preventive medicine, have expertise with clinical or laboratory vaccine research, or have expertise in assessment of vaccine efficacy and safety. The committee includes a person or persons knowledgeable about consumer perspectives and/or social and community aspects of immunization programs. “Stringent measures and rigorous screening are used to avoid both real and apparent

conflicts of interest, and no special interest or lobbying groups provide any material support to ACIP or its members. The committee recommends licensed new vaccines to be incorporate into the routine immunization schedule, recommends vaccine formulations, and reviews older vaccines to consider revising its recommendations.”¹²

Immunization rates in New York State:

New York State’s immunization rates for school-aged children have remained high, due in large part to school entry vaccination requirements. New York State has over 650 school districts and over 15,000 schools, including daycares, elementary, secondary, private, and public schools. Overall, immunization rates are consistently over 90 percent throughout the state and also in most individual schools; however, variations do exist. For instance, although the overall rate for religious exemptions in NYS is .53%, the exemption rates by grade group per county vary greatly. For children enrolled in grade 1, religious exemption rates range from 0% to 13.51%. This variation can be explained in part by the inhabitants of a given county. Counties with Amish and Mennonite communities tend to have higher religious exemption rates. The majority of schools in Amish and Mennonite communities do not offer kindergarten or high school grades, only enrolling children in grades 1 through 8. Therefore, the immunization rates for counties with large Amish and Mennonite communities have higher religious exemption rates for grades 1 through 8. There are other schools, where children with religious exemptions tend to cluster.

Immunization rates for school aged children are assessed through a statewide survey conducted by the NYSDOH each year as required by PHL § 2164. The statewide survey assesses the immunization rates of children in grades pre-kindergarten through 12. The immunizations required vary by age and grade group. For example, children enrolling in kindergarten are required to be immunized against diphtheria, tetanus, pertussis, polio, measles, mumps, rubella, hepatitis B, and varicella. Children enrolling in grade six are required to be immunized against diphtheria, polio, measles, mumps, rubella, hepatitis b, and varicella. They are also required to receive a booster dose of tetanus and diphtheria toxoid-containing vaccine and acellular pertussis vaccine (Tdap).

Immunization rates are also assessed by the National Immunization Survey (NIS) conducted yearly by the CDC. According to the NIS immunization rates in New York State have remained high, but have not increased.¹³ New York State must update its existing school entry requirements to reflect national recommendations and measurement strategies as well as to maintain the high immunization rates currently in existence.

The purpose of the proposed regulatory changes is to update regulations so that they comply with current immunization recommendations and knowledge. Over time, through routine vaccine use, it may become obvious that changes in the schedule are necessary to maximize the protection of children and the community. The dangers of under-vaccination have been dramatically demonstrated by the number of outbreaks of diseases that have not been seen in developed countries in large numbers for many years. In addition, a rise in the number of outbreaks related to high rates of exemption to

immunization in certain communities around the country, have illustrated the need for stronger school entry requirements. Recently, Washington, Vermont and California have all passed laws requiring parents to receive additional information about vaccination before a child can receive an exemption. All of these states have been the sites of large outbreaks of vaccine preventable diseases.

The changes to these regulations include updating the school entry and attendance immunization requirements to comply with current recommendations of the official schedule as approved by ACIP and other major medical professional societies. These include: increasing the required number of doses of diphtheria, tetanus and acellular pertussis (DTaP) and varicella vaccines, clarifying the age appropriate vaccinations required with polio, hepatitis b, *haemophilus influenzae* type b, and pneumococcal vaccines, clarifying that appropriate spacing of vaccines is essential for efficacy, and clarifying definitions and key parts of the regulations, such as what constitutes immunity and how to determine the time a student can be in process of receiving their vaccines.

Since 2007, ACIP has recommended two doses of varicella (chicken pox) vaccine, one dose at 12 to 18 months of age and a second dose at 4-6 years of age. This was based on the fact that one dose of varicella vaccine seemed to allow an unacceptable number of breakthrough case of varicella disease. Exact rates of varicella disease are not known for New York State, but national studies has shown a steady decline in the number of cases of the disease as immunization has become more widespread. Additional regulations are in the process of being developed, that will make varicella a reportable disease in New York

State. This will enable tracking and monitoring of disease rates as a second dose is implemented as a requirement for school entry.

Costs to State Government including the Department of Health:

The proposed regulatory changes are not expected to result in substantial costs to the state government but instead will likely result in cost savings to the state. For instance, an outbreak of measles in spring 2011 in Salt Lake County, Utah, despite a rapid response, resulted in outbreak costs of approximately \$300,000 for infection control measures by two local hospitals and the local and state health departments.¹⁴

Routine childhood immunizations have been estimated to result in a cost savings of approximately \$10 billion from direct costs.¹⁵ The CDC estimates that every dollar spent on immunization saves \$18.43, producing societal aggregate savings of \$42 billion.¹⁶

Potential savings to Medicaid and other payers are also expected secondary to the prevention of cases of disease.

The Vaccines for Children Program (VFC), a federal entitlement program, provides vaccine for eligible children. In addition, the “317” federal grant supports purchase of vaccine for administration at no cost to children at local health departments, and also supports immunization delivery, surveillance, communication and education. Private insurance, the VFC Program and the “317” grant will cover the cost of most of the additional vaccines required for school entry to eligible individuals. The State, however, may be required to use additional funds for the purchase and administration of vaccine to

meet the revised school entry requirements for those individuals who are underinsured and/or participate in the State Children's Health Insurance Program (SCHIP).

The NYSDOH Bureau of Immunization currently operates the New York State Immunization Information System (NYSIIS), which will aid in the recording of immunizations and has the ability to identify and generate notifications to students who are not in compliance with school immunization entry/attendance requirements.

Currently 2,425 educational institutions in NYS are actively utilizing NYSIIS. These institutions are currently able to search for a given student's immunization history, review it and determine compliance with current school entry requirements. These features are already a part of NYSIIS and thus the expansion of immunization requirements will not result in any additional costs for the State. NYSIIS is currently reaching out to all educational organizations in the State to educate them on this vital feature which will undoubtedly increase its usage.

The NYSDOH will need to provide education on and promote the regulatory changes that will go into effect in the fall of 2014. The NYSDOH has contact information for all schools in NYS and currently communicates with schools across the state on a regular basis. The expansion of school immunization requirements and the resultant need for education of all affected schools will not be a burden to the State as this communication takes place on a frequent basis already. Funds necessary for educational/media campaigns will be made available from the existing Department of Health budget.

Costs to Local Governments:

The cost to local governments and school districts is difficult to estimate but should be minimal. School staff already collects immunization records and makes sure that students comply with school entry requirements. The great majority of students will already be in compliance with the recommended schedule since this is the standard of care and most physicians and other health care providers comply with the recommendations. Schools will have to add a few immunizations to their information collection protocols. Administrative staff at public schools will be responsible for assuring that each student is in compliance with the revised school entry requirements at the time of registration. School staff will be able to utilize NYSIIS to check and record immunization records, a cost saving measure that was not available the last time regulations were changed. Administrative procedures already in place will be utilized to notify students of immunization requirements and to notify deficient students of the need to comply. Given that schools are already checking, recording and notifying deficient students, the costs of implementing these regulations will likely be minimal.

Additional costs for the administration of vaccine by local health departments to meet the revised school entry requirements in the county health department clinics will likely be incurred. A substantial portion of the costs of organizing additional county health departments' clinic services will be eligible for reimbursement through State public health local assistance or from third party payers.

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 incorporate the currently recommended ACIP immunization schedule, many medical practices have already been recommending and administering these vaccines to their patients. It is possible that the new regulations will prompt an initial increase in patient flow to update all children's vaccine in accordance with the new school entry requirements. This could require some additional staffing time and/or 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:

State School districts are already required, as part of the requirements of New York State Public Health Law section 2164, to verify all student's immunization histories and to submit the gathered information on an annual basis to the state via the School Immunization Survey.

Paperwork:

New York State Public Health Law Section 2164 requires that all public, private and parochial child caring centers, day care agencies, nursery schools, and all kindergartens, elementary, intermediate and secondary schools complete and submit an annual school immunization survey. Most schools submit their immunization survey data online with the exception of smaller day care agencies that submit a paper survey. The revised school entry regulations only alter the number of doses of vaccines required for school entrance which consequently will not increase the normal amount of the State's paperwork associated with the immunization survey process. Similarly because schools are already required to maintain student immunization records and submit a yearly immunization survey to the State, 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 laws are created by individual states. Under the federal constitution, all decisions relating to childhood school entry laws are part of the states' traditional police power. Thus, there is no federal standard with regard to school entry regulations.

Compliance Schedule:

All affected children will be required to adhere to the proposed school entry regulations on and after July 1, 2014.

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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-caring centers, 9,338 day care agencies, 642 nursery schools, 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. This information includes immunizations received, and/or history of disease, and/or serology performed, and or medical and/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 kindergartens, 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 mandated 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 mandate.

Compliance Costs:

The cost to facilities to meet this mandate is estimated to be negligible, because facilities 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 technically 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 New York City (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:

The Advisory Committee on Immunization Practices (ACIP) is the body that creates the recommended immunization schedule for children on an annual basis and is the authority in determining the vaccinations types and intervals in which children should be immunized. The proposal to require children to be up to date on their immunizations as specified by the schedule set forth by the ACIP is a generally accepted as the standard of practice. However, the regulations do provide an exception when a medical contraindication or religious exemption exists. It does not include an exception for any other philosophical, social or economic reason because such exceptions substantially undermine the effectiveness of the health initiative. With respect to minimizing the

economic impact on the schools, many, if not all schools already have mechanisms in place to verify immunization requirements.

Small Business and Local Government Participation:

Small businesses and local governments would be positively impacted by these regulations in that with improved immunization compliance in school settings, the likelihood of vaccine preventable disease outbreaks, and their resultant negative effects on local communities, would be lessened, if not eliminated.

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. It will require additional documentation, record-keeping and other compliance requirements on public or private entities, but it is not expected to adversely affect rural areas.

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 Department received one set of comments during the public comment period from the New York City Department of Health and Mental Hygiene (“NYCDOHMH”).

Comment:

In proposed § 66-1.2(a)(2), the Citywide immunization registry is defined to include “those persons 19 years and older with written consent in accordance with the New York City Health Code.” Because the requirement for written consent was removed pursuant to a recent State legislative change, the word “written” should be deleted.

Response:

Regulatory language has been revised to incorporate this change.

Comment:

Proposed § 66-1.2 (a)(7) defines school as “any agency or entity required by law or regulation to verify immunization status for participants.” Because the applicable existing laws and regulations do not specifically refer to verification, it is recommended that the reference to verification be removed. Proposed § 66-1.2(a)(8)(v) also refers to schools and incorporates this definition.

Response:

The regulations were not revised to include this change. Applicable existing law at Public Health Law (PHL) § 2168(8)(d)(i) does refer to school verification of immunization status for eligibility for admission.

Comment:

The definition of who is an authorized user of the registry should be expanded to encompass the person who administers the vaccine.

Response:

The regulations were not revised to include this change. Authorized users of the registry already include an ordering provider's "designee." One type of individual who could be an ordering provider's designee is the individual administering the vaccine.

Comment:

The reference to "CIR" in §66-1.2(d)(1)(i) regarding allowance for a time-limited deferral on electronic data submission to the registry should be stricken. NYCDOHMH does not provide deferrals to such electronic submission.

Response:

Regulatory language has been revised to incorporate this change.

Comment:

In §66-1.3(c), add the word "recognized" before the term "medical contraindication."

Response:

The regulations were not revised to include this change as the term "medical contraindication" is clear and does not require further modification.

Comment:

In § 66-1.3(c), revise regulations so that the "local health authority" has the authority to require additional information supporting an exemption.

Response:

The regulations were not revised to include this change. Under PHL § 2164(7), the responsibility to exclude a non-compliant student from school lies with the principal, teacher, owner or person in charge of the school. As such, the principal or person in charge of the school has the authority to require additional information relevant to making this decision.

Comment:

In §66-1.3(c), revise the regulation so that the local health authority has the authority to order a school to exclude a child who has not complied with immunization requirements.

Response:

The regulations were not revised to include this change. Under PHL § 2164(7), the authority to exclude a non-compliant student from school lies with the principal, teacher, owner or person in charge of the school.

Comment:

In §66-1.6, revise the regulation to clarify that a record issued by the New York State Immunization Information System or Citywide Immunization Registry may be accepted as a certificate of immunization.

Response:

Regulatory language has been revised to incorporate this change.