

NOTICE OF PUBLIC HEARING

- Subject:** Opportunity to Comment on Proposed Amendment of Article 43 (School-Based Programs for Children Ages Three Through Five) and Article 47 (Day Care Services) of the New York City Health Code, found in Title 24 of the Rules of the City of New York.
- Date / Time:** October 23, 2013/10AM to 12PM
- Location:** New York City Department of Health and Mental Hygiene
Gotham Center
42-09 28th Street, 14th Floor, Room 14-45
Long Island City, NY 11101-4132
- Contact:** Roslyn Windholz
Secretary to the Board of Health
New York City Department of Health and Mental Hygiene
Gotham Center, 14th Floor, CN 31
Long Island City, NY 11101-4132
(347) 396-6078/6116

Proposed Rule

The Department of Health and Mental Hygiene is proposing that the Board of Health amend Articles 43 and 47 of the New York City Health Code to require that children under five (5) years of age receive an annual influenza vaccination and be immunized against pneumococcal disease.

Instructions

- You may pre-register to speak at the hearing by contacting Roslyn Windholz at the address or phone number above before October 23, 2013.
- The Department will also consider written comments that it receives about the proposed amendment. Written comments must be received by the Department on or before the date of the hearing. Written comments can be mailed to Roslyn Windholz at the address above. They may also be submitted by e-mail to resolutioncomments@health.nyc.gov or posted electronically (without attachments) at either <http://www.nyc.gov/html/doh/html/about/notice.shtml> or through NYC RULES at www.nyc.gov/nycrules.
- To request a sign language interpreter or any other form of reasonable accommodation for a disability at the hearing, please contact Roslyn Windholz at the phone number above by October 9, 2013.
- Copies of written comments and a transcript of oral comments received at the hearing, as soon as the hearing transcript becomes available, can be reviewed between the hours of 9:00 A.M. and 5:00 P.M. at the address above. Anyone wishing to review the comments may contact Roslyn Windholz to schedule an appointment to do so.
- Additionally, the Department's general policy is to make written comments available for public viewing on the Internet. The comments it receives, including any personal information

provided with the comment, will be posted without change to <http://www.nyc.gov/html/doh/html/about/comment.shtml>.

Statement of Basis and Purpose

Statutory Authority

These amendments to the New York City Health Code (the Health Code) are promulgated pursuant to §§558 and 1043 of the New York City Charter (the Charter). Sections 558(b) and (c) of the Charter empower the Board of Health (the Board) to amend the Health Code and to include in the Health Code all matters to which the authority of the New York City Department of Health and Mental Hygiene (the Department) extends. Section 1043 grants the Department rule-making authority.

Background

The Charter provides the Department with jurisdiction over all matters concerning health in the City of New York. The Bureau of Child Care, in the Department's Division of Environmental Health, enforces Article 47 and 43(Child Care Services) of the Health Code. Article 47 regulates all public and private group day care services for children less than six years of age. Article 43 contains health and safety standards for school-based programs for children ages three through five.

The Department is requesting the Board to amend Articles 47 and 43 to require that children attending child care services and school-based programs under the Department's jurisdiction receive annual vaccinations against influenza, and to add immunization against pneumococcal disease to the list of required pre-admission immunizations in these Articles. Full citations for reports and studies cited in the section on influenza vaccination are listed at the end of the Statement of Basis and Purpose. The Department particularly invites comments on the manner in which the influenza vaccination requirement applies to children who first enroll in a day care or school-based program mid-way through the flu season.

Influenza vaccination

Influenza causes an estimated 200,000 hospitalizations and an average of 36,000 (range 3,000-49,000) deaths annually in the United States (CDC, 2010). Approximately 20,000 hospitalizations and 30-150 deaths occur in children under 5 years of age each year. Children typically have the highest attack rates of influenza, which can be as high as 40%, and children serve as a major source of transmission within communities. Each year, an estimated 15%-42% of preschool children contract influenza, and 38 million school days are missed due to influenza illness (CDC/ National Center for Health Statistics, 1999).

Influenza strains vary from year to year. The US Food and Drug Administration annually licenses influenza vaccines for administration based on a scientific consensus identifying "virus strains likely to cause the most illness during the upcoming flu season" (generally October through April in the middle Atlantic states). (USFDA, 2012)Vaccination only protects against the strains specifically included in the approved vaccine. Therefore, immunization is only effective for the year in which it is given, and a different influenza vaccine generally needs to be administered each year. The effectiveness of influenza vaccine varies with the severity of flu season, circulating influenza viruses, vaccine composition, and the age group studied. In children less than 6 years of age, influenza vaccine efficacy, ability to prevent influenza infection, ranged from 59%-82%; effectiveness, a measure of how vaccine performed in real world settings in preventing influenza, ranged from 24%-36%.(T Jefferson, 2005; M Fujieda, 2006; Jefferson, 2008; Hoberman, 2003; Longini I, 2012) Belshe et. al. showed that live attenuated influenza vaccine (LAIV) was 55% more effective than trivalent inactivated vaccine (TIV) in preventing laboratory-confirmed influenza in children 6-59 months old (Belshe, 2007).

Influenza vaccination has been found to be safe for use in children (Hambridge SJ, 2006; Glanz JM, 2011; France EK, 2004; Bernstein DI, 1982, Skowronski DM 2006). Based on the scientific evidence, the federal Advisory Committee on Immunization Practices – which sets the standard of care for the United States – recommends that everyone 6 months of age and older receive an annual influenza vaccination. Trivalent inactivated vaccine (TIV) is licensed for use in all children >6 months of age, and live attenuated influenza vaccine (LAIV; delivered as a nasal spray) is licensed for use in children >24 months.

Vaccinating children produces “herd immunity” in the general population. This means that vaccinating children against influenza reduces the number of influenza infections in everyone else, regardless of whether they were vaccinated or not (Piedra PA, 2005). Vaccinating younger children may also protect against secondary cases (Reichert, 2001). One study looked at respiratory illness in household contacts of vaccinated and unvaccinated children attending daycare. Among study participants, vaccine efficacy in preventing proven influenza infection by measuring protective levels of antibodies was 45% for influenza B and 31% for influenza A (H3N2) during the 1996-97 influenza season. The greatest effect of vaccination was seen in household contacts 5 to 17 years of age; household contacts of vaccinated children had a 50% reduction in respiratory illnesses and an 80% reduction in febrile respiratory illness compared to unvaccinated children. Statistically significant declines in illness were not seen for household contacts of younger children or adults, though the study was limited by small sample size (ES Hurwitz, 2000). A second paper found a correlation between states with higher influenza immunization coverage among 19-35 month-olds and reduced influenza and pneumonia hospitalizations rates among adults over the age of 65 (based on claims records for Medicare eligible P&I hospitalizations) (SA Cohen, 2011). This analysis was conducted before routine pediatric influenza vaccination; summary coverage estimates rose from 8.3% in 2002-2003 to 33.5% in 2005-2006.

Despite active promotion of influenza vaccination for children, coverage rates have risen slowly in New York City. As of March 26, 2013, 61.0% of children ages 6 months through 59 months received at least one dose of influenza vaccine compared to 56.7% at the same time in 2012. This still leaves nearly 4 out of every 10 young children unprotected. Furthermore, young children are at high risk of influenza-related complications and hospitalization, making this vulnerable group especially important to protect.¹

Finally, while child day care permittees and persons in charge of schools are required by Health Code §§47.27(e) and 43.19(e) to report to the Department within 24 hours any instance of a vaccine preventable disease, the Department does not expect individual cases of seasonal influenza to be reported. Reports by schools and day care facilities will, however, continue to be required as provided in Health Code §11.03 (a) and (b) of cases of a novel strain of influenza with pandemic potential, the influenza related death of a child under 18 years of age, or an outbreak of influenza.

Pneumococcal disease immunization

¹ Seasonal influenza vaccinations are currently required for children aged 6 months through 59 months attending any child care or preschool facility in New Jersey and Connecticut. Since 2008, the New Jersey Department of Health and Senior Services has required administration of at least one dose of influenza vaccine to these children between September 1 and December 31 each year (New Jersey Administrative Code §8:57-4.19). Since 2010, the Connecticut Department of Public Health pursuant to its commissioner’s authority to establish vaccination schedules (see, Connecticut General Statutes §19a-7f) has required children aged 6 months through 59 months attending day care to receive at least one dose of influenza vaccine between September 1 and December 31 each year. Connecticut preschoolers (aged 24-59 months) are required to have one dose between August 1 and December 31 each year. Connecticut day care and preschool enrollees receiving influenza vaccine for the first time are required to have two doses of vaccine, administered at least 28 days apart. Connecticut children attending kindergarten classes are not required to have influenza vaccinations.

The Department is also requesting that the Board amend Health Code §§43.17(a)(2) and 47.25(a)(2) to add “pneumococcal disease” to the list of required immunizations. This immunization, which is required by Public Health Law §2164(2), was inadvertently omitted from these sections.

References:

Belshe, R, Edwards K, Vesikari T, et. al. Live attenuated versus inactivated influenza vaccine in infants and young children. *NEJM*. 2007;356(7):685-696.

Bernstein DI, Zahradnik JM, DeAngelis CJ, et. al. Clinical reactions and serologic responses after vaccination with whole-virus or split-virus influenza vaccines in children aged 6 to 36 months. *Pediatrics*. 1982;69:404-408.

CDC. Estimates of Deaths Associated with Seasonal Influenza - United States, 1976-2007. *MMWR*. 2010;59(33):1057-1062.

CDC/ National Center for Health Statistics. Current estimates from the National Health Interview Survey, 1999. Series 10, No 200.

Cohen G, Nettleman M. Economic impact of vaccination in preschool children. *Pediatrics*. 2000;106(5):972-976.

France EK, Glanz JM, Xu S, et. al. Safety of the trivalent inactivated influenza vaccine among children: a population-based study. *Arch Pediatr Adolesc Med*. 2004;158(11):1031-1036.

Fujieda M, Maeda A, Kondo K, et. al. Inactivated influenza vaccine effectiveness in children under 6 years of age during the 2002-2003 season. *Vaccine*. 2006;27(7):957-963.

Glanz JM, Newcomer SR, Hambidge SJ, et. al. Safety of trivalent inactivated vaccine in children aged 24 to 59 months in vaccine safety datalink. *Arch Pediatr Adolesc Med*. 2011;165(8):749-755.

Hambidge SJ, Glanz JM, France EK, et. al. Safety of trivalent inactivated influenza vaccine in children 6 to 23 months old. *JAMA*. 2006;296(16):1990-1997.

Hoberman A, Greenberg D, Paradise J, et. al. Effectiveness of inactivated influenza vaccine in preventing acute otitis media in young children. 2003;290(12):1608-1616.

Hurwitz E, Haber M, Chang A, et. al. Effectiveness of influenza vaccination of day care children in reducing influenza-related morbidity among household contacts. *JAMA*. 2000;284(13):1677-1682.

Jefferson T, Rivetti A, Harnden A, et. al. Vaccines for preventing influenza in healthy children. *Cochrane Database Syst Rev*. 2008;(2):CD004879.

Jefferson T, Smith S, Harnden A, et. al. Assessment of the efficacy and effectiveness of influenza vaccines in healthy children: systematic review. *Lancet*. 2005;365:773-780.

Longini I. A theoretic framework to consider the effect of immunizing schoolchildren against influenza: implications for research. *Pediatrics*. 2012;129(S2):S62-S67.

Piedra PA, Manjusha GJ, Kozinetz CA, et. al. Herd immunity in adults against influenza-related illnesses with use of the trivalent-live attenuated influenza vaccine (CAIV-T) in children. *Vaccine*. 2005;23(13):1540-1548.

Reichert TA, Sugaya N, Fedson DS, et. al. The Japanese experience with vaccinating schoolchildren against influenza. *NEJM*. 2001;344(12):889-896.

Skowronski DM, Jacobsen K, Daigneault J, et. al. Solicited adverse events after influenza immunization among infants, toddlers, toddlers, and their contacts. *Pediatrics*. 2006;117(6):1963-1971.

US Food and Drug Administration. News Release, FDA approves vaccines for the 2012-2013 influenza season. www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm315365.htm

The proposal is as follows:

“Shall and “must” denote mandatory requirements and may be used interchangeably.

New text is underlined; deleted material is in [brackets].

RESOLVED, that the heading and subdivision (a) of section 43.17 of Article 43 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§43.17 Health; [child admission criteria] children’s examinations and immunizations.

(a) [Admission requirements] Required examinations, screening and immunizations.

(1) *Physical examinations and screening.* Prior to initial admission to a school, all children shall receive a complete age appropriate medical examination, including but not limited to a history, physical examination, developmental assessment, nutritional evaluation, lead poisoning screening, and, if indicated, screening tests for dental health, tuberculosis, vision, and anemia.

(2) *Immunizations.*

(A) All children shall be immunized against diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella, varicella, hepatitis B, pneumococcal disease and haemophilus influenzae type b (Hib), in accordance with New York Public Health Law §2164, or successor law[, and shall have such additional immunizations as the Department may require]. Exemption from specific immunizations may be permitted [for medical contraindications] if the immunization may be detrimental to the child’s health or on religious grounds, in accordance with Public Health Law §2164.

(B) (i) Children aged from 6 months to 59 months shall be immunized each year before December 31 against influenza with a vaccine approved by the U.S Food and Drug Administration as likely to prevent infection for the influenza season that begins following July 1 of that calendar year, unless the vaccine may be detrimental to the child’s health, as certified by a physician licensed to practice medicine in this state, or the parent, parents, or guardian of a child hold genuine and sincere religious beliefs which are contrary to the practices herein required. The principal or person in charge of a school may require additional information supporting either exemption.

(ii) Except where prohibited by law, the principal or person in charge of a school may after December 31 refuse to allow any child to attend such school in excess of 14 days without acceptable

evidence of the child meeting the requirements of clause (i) of this subparagraph. A parent, guardian, or other person in parental relationship to a child denied attendance by a principal or person in charge of a school may appeal by petition to the commissioner. A child who first enrolls in a school after June 30 of any year is not required to meet the requirements of clause (i) of this paragraph for the flu season that ends before July 1 of that calendar year.

(C) A school that fails to maintain documentation showing that each child in attendance has either received each vaccination required by this subdivision or is exempt from such a requirement pursuant to paragraph A or B of this subdivision will be subject to fines for each child not meeting such requirements, as provided for under this Code.

(D) All children shall have such additional immunizations as the Department may require.

Notes: The heading and subdivision (a) of §43.17 were amended by resolution adopted XXX to add pneumococcal disease to the list of required pre-admission immunizations and to require annual immunization against influenza.

RESOLVED, that the table of section headings in Article 43 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

ARTICLE 43

SCHOOL-BASED PROGRAMS FOR CHILDREN AGES THREE THROUGH FIVE

* * *

§43.15 Corrective action plan.

§43.17 Health; [child admission criteria] children's examinations and immunizations.

§43.19 Health; daily requirements; communicable diseases.

* * *

Notes: §43.17 (Health; child admission criteria) and its heading were amended by resolution adopted XXX.

RESOLVED, that the heading and subdivision (a) of section 47.25 of Article 47 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§47.25 Health; [child admission criteria] children's examinations and immunizations.

(a) [Admission requirements] Required examinations, screening and immunizations.

(1) *Physical examinations and screening.* [All] Prior to admission, all children shall receive a complete age appropriate medical examination, including but not limited to a history, physical examination, developmental assessment, nutritional evaluation, lead poisoning screening, and, if indicated, screening tests for dental health, tuberculosis, vision, and anemia.

(2) *Immunizations.*

(A) All children shall be immunized against diphtheria, tetanus, pertussis, poliomyelitis, measles, mumps, rubella, varicella, hepatitis B, pneumococcal disease and haemophilus influenzae type b (Hib), in accordance with New York Public Health Law §2164, or successor law[, and shall have such additional immunizations as the Department may require]. Exemption from specific immunizations may be permitted if the immunization may be detrimental to the child's health or on religious grounds, in accordance with Public Health Law §2164.

(B) (i) Children aged from 6 months to 59 months shall be immunized each year before December 31 against influenza with a vaccine approved by the U.S Food and Drug Administration as likely to prevent infection for the influenza season that begins following July 1 that calendar year, unless the vaccine may be detrimental to the child's health, as certified by a physician licensed to practice medicine in this state, or the parent, parents, or guardian of a child hold genuine and sincere religious beliefs which are contrary to the practices herein required. The permittee may require additional information supporting either exemption.

(ii) The permittee may refuse to allow any child to attend a child care service in excess of 14 days without acceptable evidence of the child meeting the requirements of clause (i) of this subparagraph. A parent, guardian, or other person in parental relationship to a child denied attendance by a permittee may appeal by petition to the commissioner. A child who first enrolls in a child care service after June 30 of any year is not required to meet the requirements of clause (i) of this paragraph for the flu season that ends before July 1 of that calendar year.

(C) A school that fails to maintain documentation showing that each child in attendance has received each vaccination required by this subdivision or is exempt from such a requirement pursuant to paragraph A or B of this subdivision will be subject to fines for each child not meeting such requirements, as provided for under this Code.

(D) All children shall have such additional immunizations as the Department may require.

Notes: The heading and subdivision (a) of §47.25 were amended by resolution adopted XXX to add pneumococcal disease to the list of required pre-admission immunizations and to require annual immunization against influenza.

RESOLVED, that the table of section headings in Article 47 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

ARTICLE 47

DAY CARE SERVICES

* * *

§47.23 Supervision; staff to child ratios and group size.

§47.25 Health; [child admission criteria] children's examinations and immunizations.

§47.27 Health; daily requirements; communicable diseases

* * *

Notes: §47.25 (Health; child admission criteria) and its heading were amended by resolution adopted on XXX.

**NEW YORK CITY LAW DEPARTMENT
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212-356-4028**

**CERTIFICATION PURSUANT TO
CHARTER §1043(d)**

RULE TITLE: Vaccination Requirements for Children (Health Code Article 43)

REFERENCE NUMBER: 2013 RG 066

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

- (i) is drafted so as to accomplish the purpose of the authorizing provisions of law;
- (ii) is not in conflict with other applicable rules;
- (iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and
- (iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

/s/ STEVEN GOULDEN
Acting Corporation Counsel

Date: September 5, 2013

**NEW YORK CITY MAYOR'S OFFICE OF OPERATIONS
253 BROADWAY, 10th FLOOR
NEW YORK, NY 10007
212-788-1400**

**CERTIFICATION / ANALYSIS
PURSUANT TO CHARTER SECTION 1043(d)**

RULE TITLE: Vaccination Requirements for Children (Health Code Article 43)

REFERENCE NUMBER: DOHMH-34

RULEMAKING AGENCY: Department of Health and Mental Hygiene

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

- (i) Is understandable and written in plain language for the discrete regulated community or communities;
- (ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and
- (iii) Does not provide a cure period because it does not establish a violation, modification of a violation, or modification of the penalties associated with a violation.

/s/ Kelly Shultz
Mayor's Office of Operations

9/5/2013
Date