

NOTICE OF PUBLIC HEARING

Subject: Opportunity to Comment on Proposed Amendment of Article 11 (Reportable Diseases and Conditions) and Article 13 (Clinical Laboratories) of the New York City Health Code found in Title 24 of the Rules of the City of New York

Date / Time: July 26, 2012 / 10 A.M. to 12 P.M.

Location: New York City Department of Health and Mental Hygiene
2 Gotham Center, 15th Floor, Room 15-12
42-09 28th Street
Long Island City, NY 11101-4132

Contact: Rena Bryant (347) 396-6071
New York City Department of Health and Mental Hygiene
Board of Health
Office of the Secretary to the Board
2 Gotham Center, 14th Floor, Room 14-15, Box 31
Long Island City, NY 11101-4132

Instructions

- Prior to the hearing, on or before 5pm, July 26, 2012, you may submit written comments about the proposed amendment by mail to Rena Bryant at the address above, by email at resolutioncomments@health.nyc.gov online (without attachments) at www.nyc.gov/html/doh/html/notice/notice.shtml or electronically through NYC RULES at www.nyc.gov/nycrules
- To request a sign language interpreter or other form of reasonable accommodation for a disability at the hearing, please contact Rena Bryant at the phone number above by July 12, 2012.
- Copies of written comments and a summary of oral comments received at the hearing will be available within a reasonable time after receipt between the hours of 9:00 A.M. and 5:00 P.M. at the contact address above.

Proposed Amendments

- The Department of Health and Mental Hygiene is proposing that the Board of Health amend:
 1. Article 11 of the Health Code, to require that physicians obtain specimens for herpes simplex virus (HSV) testing from infants with vesicular skin lesions who are suspected of having HSV infection, and
 2. Article 13 to require that clinical laboratories detecting HSV in any specimens from infants 60 days of age or less forward a portion of the specimen and any derived materials to the State Department of Health laboratories.

STATEMENT OF BASIS AND PURPOSE

Statutory Authority

These amendments to the New York City Health Code (the “Health Code”) are issued in accordance with §§556, 558 and 1043 of the New York City Charter (the “Charter”).

- Section 556 of the Charter provides the Department of Health and Mental Hygiene (the “Department”) with authority to regulate all matters affecting health in the City of New York.
- 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 over which the Department has authority.
- Section 1043 of the Charter gives the Department rulemaking powers.

Basis and purpose of the amendments

One of the most important duties of any public health agency is to investigate and control communicable diseases. As the local health officer for the City of New York (NYC), the Commissioner of the Department is required “to make such an investigation as the circumstances may require for the purpose of verifying the diagnosis, ascertaining the source of infection...to collect and submit, or cause to be collected and submitted, for laboratory examination such specimens as may furnish necessary or desirable information in determining the source of infection or in assisting diagnosis: ...” New York State Sanitary Code §2.6 [10 NYCRR Chapter 1].

Similarly, Health Code §11.03(e) provides that upon receiving a report of a disease or condition required to be reported, the Department may conduct any surveillance, epidemiological and laboratory investigation necessary to verify diagnosis, ascertain sources or causes of infection, identify additional cases, and implement public health measures to control the disease and prevent further morbidity or mortality. These provisions authorize the Department to require collection of specimens for laboratory examination for testing to be performed by the Department or as designated by the Department.

Neonatal Herpes

Neonatal herpes is an uncommon but serious infection with a high case fatality rate; since 2006, 15 NYC neonates have died from herpes. In 2006, Health Code §11.03 was amended to make neonatal herpes simplex virus (HSV) infection a reportable disease. There are approximately 15 laboratory-confirmed cases reported each year, and 2-4 additional cases that meet a case definition for probable infection but are not laboratory-confirmed. The Department believes that the number of confirmed cases is an underestimate, because health care providers fail to obtain specimens for herpes virus detection, do not send specimens to laboratories that can perform the necessary testing, and obtain specimens after starting anti-viral treatment, which can reduce the likelihood of detecting virus in a specimen.

State Sanitary Code §2.5 provides that a “physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory of the State Department of Health, for examination of such specimens as may be designated by the State Commissioner of Health, together with data concerning the history and clinical manifestations pertinent to the examination: ... Herpes infection in infants aged 60 days or younger (neonatal) ...”

Nucleic Acid Amplification Tests (NAAT)

Nucleic acid amplification tests (NAAT) are a form of molecular testing. They are more sensitive than cultures for the detection of HSV infection. However, few health care providers and hospitals have ready access to laboratories that are able or authorized to perform NAAT on swabs from skin vesicles, and opportunities for laboratory-confirmation of herpes infection have been missed. The New York State Department of Health Wadsworth Center laboratories have the ability to perform NAAT and other molecular analyses.

Highly sensitive NAAT testing of suspected neonatal herpes specimens benefits individual cases and public health in three ways:

- (1) It enables confirmation of the diagnosis, and reassures physicians and parents that, given the serious threat to the neonate's life posed by a herpes infection, treatment for herpes should be started and continued despite the risks associated with such treatment.
- (2) Public health officials can more accurately document disease incidence.
- (3) Public health officials can prioritize cases for investigation to determine how transmission occurred and how it can be prevented in the future.

Amendment of Article 11

The Department is proposing that the Board amend Article 11 to add a new §11.10 requiring health care providers to obtain swab specimens from vesicular skin lesions in a neonate presenting with possible HSV infection before or when starting treatment of the infant with anti-viral drugs, and submitting the specimens to the NYS Department of Health Wadsworth Center laboratory, for diagnostic testing. State Sanitary Code §2.5 provides that a "physician in attendance on a person affected with or suspected of being affected with any of the diseases mentioned in this section shall submit to an approved laboratory, or to the laboratory of the State Department of Health, for examination of such specimens as may be designated by the State Commissioner of Health, together with data concerning the history and clinical manifestations pertinent to the examination [in cases of]: ... Herpes infection in infants aged 60 days or younger (neonatal) ..." The State Sanitary Code clearly states the authority of the State Commissioner of Health to require submission of such specimens, and the Department believes that a similar provision is necessary in the City's Health Code. The Department does not intend that this requirement result in delaying necessary treatment.

Amendment of Article 13

The Department is also proposing that the Board amend Article 13 to add a new §13.09 to require that clinical laboratories detecting HSV in any specimen from infants sixty days of age or less submit a portion of such specimens and derived materials to the Wadsworth Center for further testing as needed. NYC neonatal herpes surveillance data, collected since 2006 when the disease was made reportable, are used for local and national provider education and to support investigations to determine if cases are related. However, even when infection is laboratory-confirmed as HSV infection, viral type (indicating whether infection is due to HSV type 1 or HSV type 2) is unknown approximately 15% of the time. Data regarding viral type will help the Department understand factors associated with infection, factors associated with virulence of each type, and the impact that future vaccines are likely to have on neonatal HSV infection.

The resolution is as follows:

Matter to be deleted is in brackets []

New matter is underlined

RESOLVED, that Article 11 (Reportable Diseases and Conditions) of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be amended, adding a new §11.10, to be printed together with explanatory notes as follows:

§11.10 Neonatal herpes simplex. At or before initiating treatment for a suspected case of herpes simplex virus infection occurring in a child aged 60 days or less, the health care provider ordering treatment shall collect specimens from one or more vesicles or from any skin lesions suggestive of herpetic disease. Unless otherwise directed by the Department, all such specimens shall be sent by the provider to the New York State Department of Health Wadsworth Center laboratories for diagnostic testing using molecular methods, and a report of the results shall be forwarded to the Department.

Notes: §11.10 was added to Article 11 by resolution adopted XXX. It requires physicians and other health care providers to obtain specimens from vesicular skin lesions on infants suspected of having neonatal herpes simplex virus at or before starting anti-viral treatment to enable prompt and accurate diagnosis. It also requires such health care provider to submit the specimens to New York State Department of Health for testing.

RESOLVED, that the Table of Section Headings in Article 11 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be amended, adding a new §11.10, to be printed together with explanatory notes as follows:

ARTICLE 11

REPORTABLE DISEASES AND CONDITIONS

§11.01 Definitions.

* * *

§11.09 Blood Lead Reporting and Children's Blood Lead Registry.

§11.10 Neonatal herpes simplex.

§11.11 Confidentiality of reports and records.

* * *

Notes: Article 11 was amended by resolution adopted XXX to add a new §11.10 that requires physicians and other health care providers to obtain specimens from vesicular skin lesions on infants suspected of

having neonatal herpes simplex virus at or before starting anti-viral treatment to enable prompt and accurate diagnosis, and submit the specimens to the New York State Department of Health for testing.

RESOLVED, that Article 13 (Clinical Laboratories) of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be amended, adding a new §13.09, to be printed together with explanatory notes as follows:

§13.09 Neonatal herpes simplex specimens.

When a clinical laboratory detects herpes simplex virus in a specimen collected from a child 60 days of age or less, the laboratory shall send the original specimen and any derived materials to the New York State Department of Health Wadsworth Center laboratories for further testing as needed. A copy of the test results shall be sent to the Department.

Notes: §13.09 was added to Article 13 by resolution adopted XXX. It requires clinical laboratories to forward portions of specimens from infants in which herpes simplex virus is detected to NYS Department of Health for testing as needed.

RESOLVED, that the Table of Section Headings in Article 13 of the New York City Health Code, found in Title 24 of the Rules of the City of New York, be amended, adding a new §13.09, to be printed together with explanatory notes as follows:

ARTICLE 13

CLINICAL LABORATORIES

§13.01 Definitions.

* * *

§13.07 Reporting of Hemoglobin A1C.

§13.09 Neonatal herpes simplex specimens.

Notes: Article 13 was amended by resolution adopted XXX to add a new §13.09 that requires clinical laboratories to forward portions of specimens from infants in which herpes simplex virus is detected to the New York State Department of Health Wadsworth Center laboratories for further testing as needed.

**NEW YORK CITY LAW DEPARTMENT
DIVISION OF LEGAL COUNSEL
100 CHURCH STREET
NEW YORK, NY 10007
212-788-1087**

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

RULE TITLE: Testing for Neonatal Herpes

REFERENCE NUMBER: 2012 RG 047

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: May 31, 2012

**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: Testing for Neonatal Herpes
REFERENCE NUMBER: DOHMH-19
RULEMAKING AGENCY: DOHMH-19**

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/ Francisco Navarro
Mayor's Office of Operations

May 31, 2012
Date