

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

NOTICE OF INTENTION
TO AMEND ARTICLE 11 OF THE NEW YORK CITY HEALTH CODE

NOTICE OF PUBLIC HEARING

In compliance with §1043(b) of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice is hereby given of the proposed amendment of Article 11 of the New York City Health Code (the "Health Code").

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE WILL HOLD A PUBLIC HEARING ON THIS PROPOSAL FROM 10 AM TO 12PM ON NOVEMBER 28, 2007 IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY NOVEMBER 27, 2007. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL BUSINESS HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY NOVEMBER 14, 2007.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 10AM. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAIL TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR ONLINE (WITHOUT ATTACHMENTS) AT <http://www.nyc.gov/html/doh/html/notice/notice.shtml> ON OR BEFORE 5:00 P.M., NOVEMBER 28, 2007. ATTACHMENTS TO ONLINE COMMENTS MUST BE MAILED OR FAXED.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A TRANSCRIPT OF THE PUBLIC HEARING WILL BE AVAILABLE FOR PUBLIC INSPECTION WITHIN A REASONABLE TIME AFTER RECEIPT, BETWEEN THE HOURS OF 9:00 A.M. AND 5:00 P.M. AT THE OFFICE OF THE SECRETARY. THE DEPARTMENT'S GENERAL POLICY IS TO MAKE WRITTEN COMMENTS AVAILABLE FOR PUBLIC VIEWING ON THE INTERNET. ALL COMMENTS RECEIVED, INCLUDING ANY PERSONAL INFORMATION PROVIDED, WILL BE POSTED WITHOUT CHANGE TO <http://www.nyc.gov/html/doh/html/comment/comment.shtml>.

STATUTORY AUTHORITY

This amendment to the New York City Health Code (“Health Code”) is promulgated pursuant to Sections 556, 558 and 1043 of the New York City Charter (“Charter”). Section 556 of the Charter grants the New York City Department of Health and Mental Hygiene (“Department”) jurisdiction to regulate matters affecting health in the City of New York. Specifically, Section 556(c)(2) of the Charter authorizes the Department to supervise the reporting and control of communicable and chronic diseases. Section 558(b) and (c) of the Charter empower the Board of Health (“Board”) to amend the Health Code and to include in the Health Code all matters to which the Department’s authority extends. Section 1043 of the Charter grants rule-making powers to the Department and the Board. In addition, New York State Public Health Law Section 580 (3)(a) authorizes the Department to, “enact or enforce additional laws, codes or regulations affecting clinical laboratories... related to the control, prevention or reporting of diseases or medical conditions....”

STATEMENT OF BASIS AND PURPOSE

The New York City (NYC) Department of Health and Mental Hygiene is proposing that the Board of Health amend § 11.03(a) of the New York City Health Code to designate as electronically reportable laboratory test results for the following diseases/conditions that can cause widespread illness in the community, have recently emerged, or have become of greater public health concern:

- Rotavirus (RV),
- Norovirus (NV) (formerly the Norwalk agent),
- Respiratory Syncytial Virus (RSV),
- Varicella (VZV),
- Methicillin Resistant *Staphylococcus aureus* (MRSA).

The Department proposes that the Board require electronic laboratory reporting to the Department of positive rotavirus, norovirus, RSV, VZV and MRSA test results; separate reporting by healthcare providers will not be required for these diseases. The Department further proposes that the Board remove from § 11.03(a) scarlet fever as a reportable disease/condition. Also, the Department proposes that the Board create a new subdivision (d) of §11.03 to require electronic laboratory reporting of antibiotic susceptibility profiles for reportable bacterial infections. Finally, the Department proposes that the Board create a new subdivision (e) to describe the manner of laboratory reporting for any of the reportable diseases/conditions listed in §11.03(a).

PROPOSED ADDITIONS TO § 11.03

The Department proposes that the Board of Health add the following diseases of increasing public health concern to § 11.03(a) of the Health Code as reportable conditions:

- **Viral infections that cause community-wide seasonal illness**
Several viral agents cause seasonal outbreaks that affect many NYC residents. Some of the most common agents are rotavirus (RV) and norovirus (NV), both major causes of seasonal gastroenteritis; and respiratory syncytial virus (RSV), a major respiratory pathogen.

Rotavirus

Rotavirus is the leading cause of severe diarrheal illness in both the developed and the developing world. It is estimated to be responsible for over 400,000 physician visits, 200,000 emergency department visits and 50,000 hospitalizations with direct and indirect costs of approximately \$1 billion in the US alone.

Seasonal epidemics occur in the late winter and can rapidly spread in day care and other group care settings. In 1998, a rotavirus vaccine was approved but was removed from the market a year later when a link between the vaccine and cases of infant intussusception were noted. A new live, oral viral reassortment vaccine (RotaTeq™) was licensed for use in the US in February 2006, and was recommended by the Advisory Committee for Immunization Practices for use in infants in August 2006.

Electronic laboratory reporting and surveillance for rotavirus is necessary in order to quantify the burden of illness in NYC, identify the onset of seasonal epidemics, track the age-specific attack rates and geographic distribution as well as quantify the magnitude and to monitor trends over time. When the new vaccine is in more widespread use, this data will be valuable in evaluating vaccine effectiveness. Knowledge of the seasonal appearance of rotavirus in NYC could additionally prove useful in crafting prevention messages.

Norovirus

The Norovirus family of viruses was first identified in 1972 during an outbreak of gastroenteritis in an elementary school in Norwalk, Ohio. Seasonal epidemics of gastroenteritis have been noted to occur in NYC through reports of outbreaks in schools, nursing homes and other institutional settings. Emergency department surveillance data suggests that large citywide outbreaks of diarrhea beginning every fall since 2001 are attributable to norovirus. In the past several years, outbreaks on cruise ships have been a common and vexing problem.

Norovirus testing is not yet available in most commercial laboratories and in anticipation that this will become available in the near future, the Department is proposing that the Board of Health amend the Health Code to include electronic reporting of positive norovirus laboratory tests. Tracking the appearance and severity of the illness through laboratory reports will help inform the medical community and support prevention messages.

Respiratory Syncytial Virus (RSV)

RSV can be a life-threatening illness in premature and low birth weight infants and is a major cause of pneumonia and lower respiratory track illness in young children. Infections in older children and adults are responsible for significant absences from school and work resulting in lost productivity.

Electronic laboratory reporting of RSV is necessary in order to quantify the burden of illness in NYC, identify the onset of seasonal epidemics, track the geographic spread, as well as quantifying the magnitude and to monitor trends over time. Knowledge of the seasonal appearance of RSV in NYC could additionally prove useful in alerting clinicians to suspect RSV in patients presenting with respiratory symptoms and implementing prevention efforts, as well as providing data to evaluate future vaccine initiatives.

Estimates from emergency department chief complaint surveillance suggest that norovirus and rotavirus combine for over 30,000 excess emergency department visits in NYC annually. RSV is increasingly recognized as a pathogen in adults resulting in hospitalizations in the elderly and absences from work. The seasonal appearance of these agents in the community is poorly understood and there is no data to assess trends and severity. Therefore, the Department proposes that the Board amend § 11.03(a) of the Health Code to include and make reportable laboratory diagnosed (by rapid and culture methods), confirmed cases of rotavirus, norovirus and respiratory syncytial virus.

- **Varicella**

Varicella (chicken pox) is caused by primary infection with Varicella Zoster Virus (VZV). Primary infection with VZV is generally mild and self-limited, but complications occur and include: secondary skin infections, pneumonia, central nervous system manifestations, and Reye syndrome. In the pre-vaccine era, hospitalization rates were 2-3 per 1,000 cases and 1 death per 60,000 cases. Persons at greater risk for complications include children < 1 year of age, persons > 15 years of age, pregnant women, and those who are immunocompromised. Prior to the availability of an effective vaccine, nearly all children developed VZV infection in early childhood; the national number of annual cases was estimated to be approximately 4 million. With licensure of a live-attenuated varicella vaccine in 1995 and subsequent introduction into the routine immunization schedule in 1996, there has been an 83%-93% reduction in cases. In addition, significant reductions in varicella mortality and hospitalization have been demonstrated, including in NYC. In 2005, an estimated 87.5% (\pm 5.4%) of children 19-35 months of age had received varicella vaccine. In spite of these gains, outbreaks of varicella have continued, especially within the primary schools. Much of this disease is due to 'break-through' disease, i.e., cases among previously vaccinated individuals. In 2006, the Advisory Committee on Immunization Practices recommended the implementation of a routine 2-dose varicella vaccination program for children, with the first dose administered at age 12 months and the second dose at age 4--6 years, with a second dose catch-up varicella vaccination for children, adolescents, and adults who previously had received 1 dose to further reduce the risk of infection. While previously, the diagnosis of varicella was most often based solely on clinical criteria, in the post-varicella vaccine era, there have been an increasing proportion of mild or atypical presentations, necessitating the increase use of varicella diagnostics.

Electronic laboratory surveillance for varicella will allow the Department to quantify the burden of illness in NYC, identify cases and outbreaks and institute control measures to prevent ongoing transmission, assess the completeness and effectiveness of vaccination, and help identify pockets of under-vaccination for intervention. Case-based reporting of varicella is recommended by both the Council of State and Territorial Epidemiologists and the Centers for Disease Control and Prevention. While most varicella infections are clinically diagnosed, it is anticipated that as cases continue to decline, laboratory diagnosis will become increasingly more important and represent the majority of cases. Therefore, the Department proposes that the Board amend § 11.03 (a) of the Health Code to include and make reportable laboratory diagnosed, confirmed cases of varicella.

- **Methicillin Resistant *Staphylococcus aureus* (MRSA)**

Case reports and outbreaks have documented the emergence of community associated (CA) MRSA in the US over the past decade. While CA-MRSA predominately causes skin and soft tissue infections (such as furuncles and abscesses), reports of clusters of pediatric deaths and necrotizing pneumonia due to CA-MRSA highlight the seriousness of this disease. Although CA-MRSA has been generally assumed to be more susceptible to antibiotics, recent trends suggest a higher level of resistance is the norm.

CA-MRSA outbreaks have occurred in prisons, sports teams, among men who have sex with men (MSM) and intravenous drug users. In 2004, the Department began an investigation of risk factors for CA-MRSA transmission among patients diagnosed at one large commercial laboratory in NYC. Preliminary results indicate an increased risk in MSM, although risk factor data collection and analysis is not yet complete. Generalization of the results of this investigation is limited because the case reports are not representative of the entire NYC population, as it only includes patients who are diagnosed at one commercial laboratory. Little is known about the risk factors for sporadic cases, particularly those occurring in children and medically underserved populations. To better understand the epidemiology of CA-MRSA in New York City and to develop targeted prevention strategies, population based surveillance is necessary.

Therefore, the Department proposes that the Board amend § 11.03 (a) of the Health Code to require electronic reporting of laboratory–confirmed Methicillin Resistant *Staphylococcus aureus* (MRSA).

- **Antibiotic sensitivity profiles for reportable bacterial diseases**

The discovery and mass production of antibiotics in the last century is responsible for the reduction in mortality of many bacterial diseases. However, many bacteria have adapted by developing resistant mechanisms rendering many antibiotics useless against them. The time it takes for industry to discover, synthesize, test, receive approval, mass produce and market new drugs is falling behind the speed at which bacteria develop resistance. Newer approaches to reducing antibiotic resistance are needed. It is important to monitor susceptibility patterns of community acquired bacterial pathogens in order to inform clinicians of the current local antibiotic resistance rates. This information when updated on a regular basis can help physicians target empiric therapeutic regimens against specific pathogens pending final susceptibility results on their patients' specimens. Furthermore, tracking antibiotic susceptibility testing (AST) results is critical to support public health initiatives to reduce antibiotic resistance in community pathogens. The data is invaluable for both designing programs to target specific bacterial diseases with high rates of resistance and communities where prevalence rates are higher, as well as assessing the impact of such programs to promote appropriate and judicious antibiotic use.

As an example, gonorrhea (GC) is a common sexually transmitted bacterial which can cause urethritis in men, and cervicitis in women. The serious sequelae of GC infection include pelvic inflammatory disease and infertility in women. There were more than 11,000 cases of gonorrhea diagnosed and reported in NYC in 2006. Over the past decades, GC has developed resistance to several commonly used antibiotic treatments, with the result that fewer drugs can be used to treat the infection. Until very recently, there were two classes of antibiotics recommended for the oral treatment of GC infection, the fluoroquinolones and the cephalosporins. In April 2007, national data were published showing increases in fluoroquinolone (FQ) resistant GC. This has led the CDC to issue national recommendations that FQ be abandoned for treating GC. In NYC, recommendations were issued in 2004 that FQ be abandoned for treating GC in certain population subgroups. Cephalosporins are now the only remaining recommended oral treatment option for GC.

Monitoring AST patterns among GC is of public health importance because if GC develops increasing resistance to available antibiotics there will need to be public health action such as recommending increased dosage or combination regimens or changes in the mode of administration (e.g., that GC be treated with an injection, rather than oral regimen).

The Department is proposing that the Board amend § 11.03 of the Health Code to require electronic laboratory reporting of antibiotic susceptibility profiles for reportable bacterial infections on all bacterial organisms that are reportable under § 11.03 and for which they perform, or refer for antibiotic susceptibility testing. This requirement includes both traditional broth and agar based methods of antibiotic susceptibility testing and newer molecular based methods that assay for the genetic determinants of antimicrobial resistance. When necessary for the protection of the public health, susceptibility data on other non-reportable organisms may be required to be reported at the discretion of the Department. Therefore, the Department proposes that the Board amend § 11.03 of the Health Code by creating a new subdivision (d) to require electronic laboratory reporting of antibiotic susceptibility profiles for reportable bacterial infections.

Finally, the Department proposes that the Board create a new subdivision (e) to describe the manner of laboratory reporting for any of the reportable diseases/conditions in §11.03(a). Clinical laboratories

shall report to the Department in a manner specified by the Department, including through the use of the electronic reporting system utilized by the New York State Department of Health .

PROPOSED DELETION FROM § 11.03

The Department proposes that the Board of Health amend § 11.03 (a) of the Health Code to remove scarlet fever from the list of reportable diseases/conditions because of the absence of a laboratory confirmed diagnosis and diminished public health concern.

The proposal is as follows:

Note - Matter in brackets [] is to be deleted.
Matter underlined is new.

RESOLVED, that Section 11.03 of Article 11 of the New York City Health Code, as set forth in Title 24 of the Rules of the City of New York, as last amended by resolution on xxxxxxxxxxxxxxxx, be and the same hereby is amended, to be printed together with explanatory notes, by adding to subdivision (a) rotavirus, norovirus, respiratory syncytial virus, varicella, *Staphylococcus aureus* methicillin resistant; by deleting scarlet fever; and, by adding new subdivisions (d) and (e) concerning electronic laboratory reporting, as follows:

§11.03 Diseases and conditions reportable.

(a) Cases and carriers affected with any of the following diseases and conditions, and persons who at the time of their death were apparently so affected, shall be reported to the Department:

Mumps

Norovirus, laboratory-confirmed (see subdivision (e) below)

Pertussis (Whooping cough)

Rabies

Respiratory Syncytial Virus, laboratory-confirmed (see subdivision (e) below)

Rickettsialpox

Rocky Mountain spotted fever

Rotavirus, laboratory-confirmed (see subdivision (e) below)

Rubella (see German measles)

Salmonella infections

[Scarlet fever]

Severe Acute Respiratory Syndrome (SARS)

Staphylococcal enterotoxin B poisoning

Staphylococcus aureus methicillin-resistant (MRSA), laboratory-confirmed (see subdivision (e) below)

Staphylococcus aureus with reduced susceptibility to Vancomycin (SARSV)

Vaccinia disease, defined as:

- (1) Persons with vaccinia infection due to contact transmission; and,
- (2) Persons with the following complications from vaccination: eczema vaccinatum, erythema multiforme major or Stevens-Johnson syndrome, fetal vaccinia, generalized vaccinia, inadvertent inoculation, myocarditis or pericarditis, ocular vaccinia, post-vaccinial encephalitis or encephalomyelitis, progressive vaccinia, pyogenic infection of the vaccination site, and any other serious adverse events (i.e., those resulting in hospitalization, permanent disability, life-threatening illness or death).

Varicella, laboratory-confirmed (see subdivision (e) below)

Vibrio species, non-cholera (including parahaemolyticus and vulnificus)

(d) Antibiotic susceptibility testing (AST) results for bacterial diseases listed under subdivision (a) of this section shall be reported by laboratories performing or referring specimens for these tests. This requirement includes traditional broth, agar and newer automated methods of AST, as well as molecular-based methods that assay for the molecular determinants of antibiotic resistance. Clinical laboratories shall report AST results to the Department in a manner specified by the Department. When necessary for the protection of the public health, the Department may request additional reporting of AST results on other infectious agents that have either increased in incidence or severity.

(e) The Department may, on its own initiative and pursuant to §13.03(c) of this Code, authorize clinical laboratories, as defined in §13.01 of this Code, to report any of the diseases/conditions listed in subdivision (a) of this section in a manner specified by the Department, including through the use of the electronic reporting system utilized by the New York State Department of Health.

Notes: The Department proposes that the Board of Health amend §11.03 of the Health Code to make electronically reportable laboratory-confirmed rotavirus, norovirus, respiratory syncytial virus, varicella, Methicillin Resistant *Staphylococcus aureus*, and by deleting scarlet fever from the reportable

disease/condition list. Those diseases that are proposed to be added to the list of reportable diseases/conditions can cause widespread illness in the community, have recently emerged, or have become of greater public health concern. The deletion of scarlet fever from the list of reportable diseases/conditions is because of the absence of a laboratory confirmed diagnosis and diminished public health concern. Also, the Department proposes that the Board create a new subdivision (d) of §11.03 to require electronic laboratory reporting of antibiotic susceptibility profiles for reportable bacterial infections. Finally, the Department proposes that the Board create a new subdivision (e) to describe the manner of laboratory reporting for any of the reportable diseases/conditions listed in §11.03(a).

NOI-Article 11-Oct 2007