NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

Notice of Adoption of Amendments to Articles 11 and 13 of the New York City Health Code

In accordance with §1043(b) of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health (the "Board") by §558 of the Charter, a notice of intention to amend Articles 11 and 13 of the New York City Health Code (the "Health Code") was published in the City Record on September 20, 2017 and a public hearing was held on October 25, 2017. Two written comments were received; no witnesses testified at the public hearing. In consideration of the comments, one change was made to the original proposal. At its meeting on March 13, 2018, the Board adopted the following resolution.

Statement of Basis and Purpose

The Department's Division of Disease Control conducts disease surveillance and control activities for most of the diseases listed in Article 11 (Reportable Diseases and Conditions) of the Health Code. The Division of Disease Control also enforces Article 13 (Clinical Laboratories) of the Health Code, which regulates how laboratory tests must be performed and the reporting of test results. In addition, the Department must comply with various provisions of Part 2 of the New York State Sanitary Code, found in Title 10 of the New York Codes, Rules and Regulations, with respect to control of communicable diseases.

To conduct more effective, timely, and complete disease surveillance and control, the Board is amending Health Code Articles 11 and 13 as follows:

Hepatitis B Reporting

The Board is amending Health Code §13.03(b)(3)(B) (previously §13.03(b)(3)(A)) to require laboratories to report all hepatitis B virus (HBV) DNA test results, including negative results. The Health Department previously required laboratories to report only positive HBV DNA results, in addition to other positive HBV test results.

HBV DNA testing is performed on individuals who have tested positive for HBV. HBV DNA tests measure viral load and whether the patient has chronic (active) HBV, requiring treatment. For patients already diagnosed with chronic HBV, DNA test results provide important information regarding infectiousness, treatment eligibility, and risk for development of liver cancer. For patients being treated for HBV, DNA test results provide information regarding treatment outcome (i.e., the extent to which the patient cleared the infection).

The number of HBV cases is rising nationally and in New York City. More than 100,000 New Yorkers are estimated to be living with chronic HBV, with 8,439 new cases diagnosed in 2016, an increase of 18.8% since 2013. The majority of individuals infected with HBV as adults will clear the virus on their own, but many New Yorkers will develop chronic HBV. Chronic HBV can lead to serious health issues, including cirrhosis and liver cancer. All persons with chronic HBV infection require linkage to care and regular monitoring for liver damage and other complications; a subset require treatment with antiviral medications.

Without negative HBV DNA test results, the Health Department would have limited knowledge regarding whether patients who have tested positive for HBV are receiving appropriate follow-up testing and treatment. Mandated reporting of negative HBV DNA test

results will allow the Health Department to estimate the proportion of New Yorkers infected with HBV who are appropriately tested and linked to care; identify gaps in access to care; develop targeted interventions to increase linkage to care and improve provider knowledge of HBV testing and treatment guidelines; and increase monitoring to reduce HBV-related morbidity and mortality.

In consideration of a comment received, the proposed amendment has been modified to exempt blood bank laboratories and other laboratories that perform hepatitis B DNA tests on donated blood from the requirement to report negative and indeterminate hepatitis B DNA test results for such donated blood.

Carbapenem-resistant Enterobacteriaceae Reporting

The Board is amending Health Code §11.03(a) to require laboratories to report carbapenem-resistant Enterobacteriaceae (CRE), an emerging bacterial threat. CRE are a family of bacteria that are difficult to treat because they have high levels of resistance to many antibiotics including carbapenem antibiotics. Carbapenem antibiotics are often used as the last line of treatment for infections caused by highly resistant bacteria, including those in the Enterobacteriaceae family.

As explained by the Centers for Disease Control and Prevention (CDC): "The emergence and dissemination of carbapenem resistance among Enterobacteriaceae in the United States represents a serious threat to public health. These organisms cause infections that are associated with high mortality rates and they have the potential to spread widely. Decreasing the impact of these organisms will require a coordinated effort involving all stakeholders including healthcare facilities and providers, public health, and industry."[1] CDC has designated CRE an "urgent" threat, the highest threat level in its list of antibiotic resistant threats in the United States.[2]

CRE infections are common in hospitals, nursing homes, and other healthcare settings. Patients whose care requires devices like ventilators, urinary catheters, or intravenous catheters, and patients who are taking long courses of certain antibiotics are most at risk for CRE infections.[3] In 2015, hospitals in NYS reported 3,618 CRE cases via the CDC's National Healthcare Safety Network (NHSN); 1,727 of these were reported by the 51 participating New York City facilities.[4] As only hospitals submit CRE data to the NHSN, the number of CRE infections in New York is probably significantly larger.

Mandated reporting will provide vital epidemiological information regarding incidence and evolution of CRE and assist in the identification of new strains, clusters, and outbreaks. This will enable the Department to help ensure infection control precautions are being taken. Mandated reporting of CRE is also aligned with recently released Council of State and Territorial

[1] Centers for Disease Control and Prevention, National Center for Emerging and Zoonotic Infectious Diseases. Facility Guidance for Control of Carbapenem-resistant Enterobacteriaceae (CRE). November 2015 Update – CRE Toolkit. https://www.cdc.gov/hai/pdfs/cre/cre-guidance-508.pdf.

[2] Centers for Disease Control and Prevention. Antibiotic Resistant Threats in the United States, 2013. https://www.cdc.gov/drugresistance/pdf/ar-threats-2013-508.pdf.

[3] Centers for Disease Control and Prevention. Carbapenem-resistant Enterobacteriaceae in Healthcare Settings. CDC website. https://www.cdc.gov/hai/organisms/cre/index.html.

[4] NYS Healthcare Associated Infections in New York State, 2015. Part 2: Technical Report. March 2017.

Epidemiologists guidelines.[5] Based on a 2016 survey, 27 jurisdictions require some form of CRE reporting.[6]

Minor changes to other parts of §11.03(a) are being made for purposes of consistency.

Statutory Authority

The Board's authority to promulgate these proposed amendments is found in Sections 556, 558, and 1043 of the New York City Charter (the "Charter"). Sections 558(b) and (c) of the Charter empower the Board to amend the Health Code and to include all matters to which the Department's authority extends. Section 556 of the Charter provides the Department with jurisdiction to protect and promote the health of all persons in the City of New York. Section 1043 grants the Board rule-making authority.

The rule is as follows:

Note: New material is underlined. [Deleted material is in brackets.]

"Shall" and "must" denote mandatory requirements and may be used interchangeably unless otherwise specified or unless the context clearly indicates otherwise.

RESOLVED, that subdivision (a) of section 11.03 of Article 11 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended, to be printed together with explanatory notes to read as follows:

(a) Cases and carriers affected with any of the following diseases and conditions of public health interest, and persons who at the time of their death were apparently so affected, must be reported to the Department as specified in this article:

Amebiasis

Anaplasmosis (Human granulocytic anaplasmosis)

Animal bite, or exposure to rabies

Anthrax

Arboviral infections, acute (including but not limited to the following viruses: chikungunya virus, Zika virus, dengue virus, Eastern equine encephalitis virus, Jamestown Canyon virus, Japanese

[5] Council of State and Territorial Epidemiologists. Infectious Disease Committee Position Statement 17-ID-04: Public Health Reporting and National notification of Carbapenemase Producing Carbapenem-Resistant Enterobacteriaceae for *E. coli, Klebsiella* spp. and *Enterobacter* spp. July 2017.
[6] Council of State and Territorial Epidemiologists. State Reportable Conditions Assessment (SRCA). http://srca.querytool.cste.org/.

encephalitis virus, La Crosse virus, Powassan virus, Rift Valley fever virus, St. Louis encephalitis virus, Western or Venezuelan equine encephalitis virus, West Nile virus and yellow fever)

Babesiosis

Botulism (including infant, foodborne and wound botulism)

Brucellosis (undulant fever)

Campylobacteriosis

Chancroid

Chlamydia trachomatis infections

Cholera

Creutzfeldt-Jakob Disease

Cryptosporidiosis

Cyclosporiasis

Diphtheria

Drownings, defined as the process of experiencing respiratory impairment from submersion/immersion in liquid whether resulting in death or not

Ehrlichiosis (Human monocytic ehrlichiosis)

Encephalitis

Enterobacteriaceae, carbapenem-resistant (CRE), laboratory-confirmed (reporting requirement applicable to laboratories only)

Escherichia coli 0157:H7 infections

Falls from windows in multiple dwellings by children sixteen (16) years of age and under

Food poisoning occurring in a group of two or more individuals, including clusters of diarrhea or other gastrointestinal symptoms; or sore throat which appear to be due to exposure to the same consumption of spoiled, contaminated or poisonous food, or to having eaten at a common restaurant or other setting where such food was served. Also includes one or more suspected cases of neurologic symptoms consistent with foodborne toxin-mediated, including but not limited to botulism, combroid or ciguatera fish poisoning, or neurotoxic or paralytic shellfish poisoning.

Giardiasis

Glanders

Gonococcal infection (gonorrhea)

Granuloma inguinale

Hantavirus disease

Hemolytic uremic syndrome
Hemophilus influenzae (invasive disease)
Hepatitis A; B; and C
Herpes simplex virus, neonatal infections (in infants 60 days or younger)
Hospital associated infections as defined in Title 10 New York Codes, Rules and Regulations (NYCRR) Section 2.2 (New York State Sanitary Code) or its successor law, rule or regulation
Influenza, novel strain with pandemic potential
Influenza, laboratory-confirmed ([only required through the Department's electronic reporting mechanism set forth in § 13.03(c) of this Code] reporting requirement applicable to laboratories only)
Influenza-related deaths of a child less than 18 years of age
Legionellosis
Leprosy
Leptospirosis
Listeriosis
Lyme disease
Lymphocytic choriomeningitis virus
Lymphogranuloma venereum
Malaria
Measles (rubeola)
Melioidosis
Meningitis, bacterial causes (specify type)
Meningococcal, invasive disease
Monkeypox
Mumps
Norovirus, laboratory-confirmed ([only required through the Department's electronic reporting mechanism set forth in § 13.03(c) of this Code] reporting requirement applicable to laboratories only)
Pertussis (Whooping cough)
Plague
Poisoning by drugs or other toxic agents, including but not limited to lead poisoning consisting of a blood lead level of 10 micrograms per deciliter or higher (see also §11.09(a) of this Code); carbon monoxide poisoning and/or a carboxyhemoglobin level above 10%; and including confirmed or suspected pesticide poisoning as demonstrated by:

(1) Clinical symptoms and signs consistent with a diagnosis of pesticide poisoning; or

(2) Clinical laboratory findings of blood cholinesterase levels below the normal range; or

(3) Clinical laboratory findings or pesticide levels in human tissue above the normal range.

Poliomyelitis

Psittacosis

Q fever

Rabies

Respiratory syncytial virus, laboratory-confirmed ([only required through the Department's electronic reporting mechanism set forth in § 13.03(c) of this Code] reporting requirement applicable to laboratories only)

Ricin poisoning

Rickettsialpox

Rocky Mountain spotted fever

Rotavirus, laboratory-confirmed ([only required through the Department's electronic reporting mechanism set forth in § 13.03(c) of this Code] reporting requirement applicable to laboratories only)

Rubella (German measles)

Rubella syndrome, congenital

Salmonellosis

Severe or novel coronavirus

Shiga toxin-producing *Escherichia coli* (STEC) (which includes but is not limited to *E. coli* O157:H7)

Shigellosis

Smallpox (variola)

Staphylococcal enterotoxin B poisoning

Staphylococcus aureus, methicillin-resistant, laboratory-confirmed ([only required through the Department's electronic reporting mechanism set forth in § 13.03(c) of this Code] reporting requirement applicable to laboratories only)

Staphylococcus aureus, vancomycin intermediate and resistant (VISA and VRSA)

Streptococcus, Group A (invasive infections)

Streptococcus, Group B (invasive infections)

Streptococcus pneumoniae invasive disease

Syphilis, all stages, including congenital

Tetanus

Toxic shock syndrome

Trachoma

Transmissible spongiform encephalopathy

Trichinosis

Tuberculosis, as demonstrated by:

(1) Positive culture for *Mycobacterium tuberculosis* complex; or

(2) Positive DNA probe, polymerase chain reaction (PCR), or other technique for identifying *Mycobacterium tuberculosis* from a clinical or pathology specimen; or

(3) Positive smear for acid-fast bacillus, with final culture results pending or not available, on either a microbacteriology or a pathology specimen; or

(4) Clinically suspected pulmonary or extrapulmonary (meningeal, bone, kidney, etc.) tuberculosis, such that the physician or other health care professional attending the patient has initiated or intends to isolate the patient or initiate treatment for tuberculosis, or to continue or resume treatment for previously incompletely treated disease, or, if the patient is not available, that the physician or other health care professional would initiate isolation or treatment if the patient were available; or

(5) Biopsy, pathology, or autopsy findings in lung, lymph nodes or other tissue specimens, consistent with active tuberculosis disease including, but not limited to presence of acid-fast bacilli, caseating and non-caseating granulomas, caseous matter, tubercles and fibro-caseous lesions; or

(6) Positive reaction to the purified protein derivative (PPD) Mantoux test, blood-based tests positive for tuberculosis infection, or other recognized diagnostic test positive for tuberculosis infection in a child less than five years of age, regardless of whether such child has had a BCG vaccination.

Tularemia

Typhoid fever

Vaccinia disease, defined as

(1) Persons with vaccinia infection due to contact transmission; and

(2) Persons with the following complications from smallpox 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 ([only required through the Department's electronic reporting mechanism set forth in § 13.03(c) of this Code] reporting requirement applicable to laboratories only)
Vibrio species, non-cholera (including *parahaemolyticus* and *vulnificus*)
Viral hemorrhagic fever
Yersiniosis

Note: Section 11.03(a) was revised by the Board on March 13, 2018, to require laboratories to report CRE.

RESOLVED, that subparagraph (B) of paragraph (3) of subdivision (b) of section 13.03 of Article 13 of the New York City Health Code, set forth in Title 24 of the Rules of the City of New York, be amended, to be printed together with explanatory notes to read as follows:

(B) With regard to hepatitis B, all DNA test results must be reported, including positive, negative, and indeterminate results. In addition, all hepatitis B surface antigen and hepatitis B surface antibody test results, including positive, negative, and indeterminate, for children ages 0 days to 1,825 days (birth up to the fifth birthday) must be reported electronically in accordance with subdivision (c) of this section when patient age is known. Blood bank laboratories and other laboratories that perform hepatitis B DNA tests on donated blood are exempt from reporting negative and indeterminate hepatitis B DNA test results for such donated blood.

Note: Section 13.03(b)(3)(B) was revised by the Board on March 13, 2018, to require reporting of all DNA test results for hepatitis B, including positive, negative, and indeterminate results.