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 Section 1043 of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health (the "Board") by Section 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 June 19, 2019, and a public hearing was held on July 22, 2019. No individuals testified at the public hearing; three written comments were received. After consideration of those comments one change was made for clarity. At its meeting on October 8, 2019, the Board adopted the following resolution.

Statement of Basis and Purpose

Statutory Authority

The Board's authority to codify 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 Department rule-making authority.

Background

The Department is responsible under the Charter for supervising matters affecting the health of New Yorkers. Through its Division of Disease Control, the Department conducts disease surveillance and control activities for most of the diseases listed in Article 11 (Reportable Diseases and Conditions) of the Health Code. The same Division also enforces Article 13 (Clinical Laboratories) of the Health Code, which regulates the performance of laboratory tests 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 (NYCRR), with respect to the control of communicable diseases.

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

Tuberculosis Infection Reporting

The Board is amending Health Code Sections 11.03(a) and 13.03(b)(1) to require laboratories to report all test results for tuberculosis (TB) infection, including negative results. Prior to the adoption of these amendments, the Health Code required reporting only of test results and other information attendant to active TB disease, and tests positive for TB infection and related information for children under five years old.

TB is a disease caused by the bacterium *Mycobacterium tuberculosis*, which is spread person-to-person through the air. Most commonly, TB disease affects the lungs, but it can also affect other parts of the body. Individuals who have a positive test for TB infection but do not have symptoms or other test results consistent with active TB disease are diagnosed with latent TB infection (LTBI). Persons with LTBI are asymptomatic and cannot transmit the infection to others. It is estimated that approximately 10 percent of individuals with LTBI will develop active TB disease at some point in their life. Treating LTBI is the only way to significantly reduce the risk of developing active disease and thus is a vital component of TB prevention efforts.

There is no reliable data on the prevalence of LTBI in the United States or New York City. National estimates from the National Health and Nutrition Examination Survey study, when combined with New York City population data, result in an estimate of approximately 700,000 people with LTBI in the City. However, data from the Department's TB clinics suggests there could be as many as 1.8 million people in New York City with LTBI. Based on these estimates, there is a large reservoir of TB infection in New York City, some of which will result in future cases of active TB disease.

While the Department has made major strides in reducing the number of active TB cases in New York City – from 3,755 at the height of the TB epidemic in 1992 to 559 in 2018 – the number of TB cases has largely plateaued in the last 10 years. The Department is working to expand its efforts to identify and treat people with LTBI to further reduce the burden of TB in New York City, and reporting of test results for TB infection will help focus that effort.

Reporting of tests for TB infection will give the Department a better understanding of the prevalence of TB infection in order to better direct public health resources. Also, the data collected will provide information about testing practices, which will help inform provider outreach. Reports of laboratory tests negative for TB infection will provide the Department with a more complete picture of testing practices and allow for better estimates of testing prevalence to inform the Department's programming.

In addition, the Board has made minor related language changes to Health Code § 11.21(a) for consistency.

In response to public comments received, the language of the Department's proposal as to this provision has been revised to clarify that laboratories must report all test results, including negatives, for tests for TB infection only, and not tests performed in connection with diagnosing or monitoring active TB disease, such as mycobacteria culture tests.

Syphilis Amendment Proposal

The Board is adding a new Section 11.33 to the Health Code to require healthcare providers to test pregnant persons for syphilis at 28 weeks of pregnancy, or as soon thereafter as reasonably possible but no later than at 32 weeks of pregnancy, and that test results and a treatment plan be documented.

Syphilis is a sexually transmitted infection caused by the bacterium *Treponema pallidum*. Untreated syphilis during pregnancy can result in devastating health outcomes, including stillbirth. Infants with congenital syphilis may manifest abnormalities of the central nervous system, bones and joints, teeth, eyes, and skin. In New York City, the number of congenital syphilis cases increased 186% between 2017 (7 cases) and 2018 (20 cases). Twenty is the largest number of congenital syphilis cases reported in the City in over ten years and included one syphilitic stillbirth at 31 weeks. In general, New York City has much higher rates of primary, secondary, and early latent syphilis as compared to the U.S. population. In 2017, the rate of syphilis at all stages was 95.33 per 100,000 in NYC vs. 31.4 cases per 100,000 nationally. Syphilis is increasing among New York City women; from 2017 to 2018, the number of primary, secondary, and early latent syphilis cases among NYC women increased 44%, from 219 to 315 cases.

Congenital syphilis can be prevented by timely treatment of maternal syphilis. However, symptoms of maternal syphilis during pregnancy may not be apparent, so serologic screening during pregnancy is critical. New York State mandates syphilis screening at the first prenatal care examination (NYS Public Health Law § 2308) and at delivery (10 NYCRR § 69-2.2). Increasingly, the Department has documented congenital cases resulting from maternal syphilis infections acquired subsequent to screening negative earlier during pregnancy; this accounted for 11 cases (55%) of congenital syphilis cases in 2018. At least half of these cases may have been averted by screening women at 28 weeks of pregnancy.

The Board adopts the Department's proposal to require an additional syphilis test at 28 to 32 weeks of pregnancy to identify pregnant people who become infected subsequent to initial mandatory screening, which will enable treatment, improve the health of the pregnant person, and prevent potentially grave health outcomes attendant to vertical transmission. Requiring documentation of test results and a treatment plan will help ensure appropriate follow-up care. Twenty-eight weeks is the most appropriate time for third trimester re-screening because other screening tests are routinely performed at 28 weeks, and because screening at this time would allow sufficient time to treat pregnant people who have syphilis prior to delivery. These changes now align the Health Code with laws in several other states that require third trimester syphilis testing of all pregnant persons.

Exclusion of Cases and Carriers of Enteric Pathogens

The Board is amending Health Code § 11.15(a) to provide the Department with the discretion to end "exclusion" of people infected with enteric pathogens when doing so is appropriate under the circumstances.

Under the Health Code, individuals infected with or carrying certain enteric pathogens were required to be excluded from certain settings where there was an elevated risk of disease

transmission. Thus, cases and carriers who are food handlers or health care workers have to be excluded from their place of work, and staff and attendees of schools, child care programs, camps, and other facilities attended by children under five years of age had to be excluded from those facilities. Under the current provision, the Health Code provides that exclusion can end only when the excluded person no longer has symptoms and the Department had received two or three (depending on the pathogen) successive negative stool specimens demonstrating that transmission is no longer likely and that the excluded person's illness is no longer a public health concern.

The enteric diseases addressed in Health Code § 11.15 – Campylobacteriosis, Cholera, *Escherichia* (*E.*) *coli* 0157:H7 and other Shiga toxin-producing *E. coli* (STEC) infections, Salmonellosis (other than typhoid), Shigellosis, Yersiniosis, Amebiasis, Cryptosporidiosis, and Giardiasis – are transmitted via the fecal-oral route. People infected with or carrying enteric pathogens who are food handlers, health care workers providing oral care or feeding, child care workers, or child care attendees can shed the organism in their stool and transmit the infection to others if they have poor hand hygiene practices. Exclusion can last from days to months.

The number of people identified requiring exclusion has increased significantly in recent years. In 2018, there were 187 exclusions ranging in duration from 1 to 135 days, with a mean length of 22 days, as compared to 69 exclusions in 2015. The increase in exclusions is due to improved surveillance practices and increased use of culture-independent diagnostic tests (CIDT), a testing method that is more sensitive than other types of traditional tests, leading to more positive test results. Stool samples can be positive by a CIDT but negative by traditional tests, such as bacterial culture, indicating that although the organism's DNA is detectible, it may not be alive and capable of being transmitted. However, under the Health Code provision prior to the adoption of these changes, individuals have to be excluded based on the positive CIDT result while awaiting for multiple follow-up culture results. Also, some individuals shed the organism in the stool for many weeks or months even after symptoms have ended, and experience suggests that the risk of transmission in that circumstance is low. As there are no clear national guidelines on exclusion, exclusion requirements of jurisdictions vary. Many jurisdictions, including New York State, are less strict than New York City without any measured increase in disease transmission.

For these reasons the Department proposes a more flexible approach that takes into consideration the circumstances of a particular case, including the type of infection, the type of test used to detect the pathogen, the presence or absence of symptoms, the individual's treatment with antimicrobial drugs, the individual's job responsibilities, and the likelihood of infectiousness based on the length of time since symptom onset. The adoption of this proposal still allows the Department to exclude people with enteric pathogens until consecutive negative test results are received if, in the view of Department experts, there remained a public health threat. However, the Department would have the discretion to allow people to return to work or school sooner if their illness no longer poses a risk to others.

In addition, the Board is adopting is minor language changes to this provision for consistency and clarity, and to correct typographical errors.

Campylobacter Testing and Reporting

The Board is amending Health Code § 13.03(b) to no longer require laboratories to perform culture testing on all specimens found to be positive for *Campylobacter* by CIDT. Culture testing involves a laboratory using a specimen to grow the pathogen; a sample of the pathogen grown by culture is termed an "isolate".

In January 2017, the Health Code was amended to require follow-up culture tests on the following enteric pathogens: *Campylobacter*, *Listeria monocytogenes*, *Salmonella*, *Shigella*, *Vibrio*, *Yersinia*, and Shiga toxin-producing *Escherichia coli*. The laboratory must report the results of the culture and submit any resulting isolates to the Department. The Department proposed the amendment to enable it to obtain information about the pathogens not available from CIDT and used to assist in outbreak detection and response.

Campylobacter bacteria can be transmitted to people through contaminated food and liquid or contact with certain animal feces. It causes diarrhea, fever, and abdominal cramps and, in rare cases, more serious illness. Compared to other enteric pathogens, *Campylobacter* is difficult to isolate and found relatively frequently, particularly given an increase in positive test results stemming from more expansive use of CIDT. Further, other enteric pathogens that are required to be cultured per the Health Code, including *Salmonella* and Shiga toxin-producing *Escherichia coli*, have more significant public health consequences than *Campylobacter*, including that they are more likely to be part of local and multi-state disease outbreaks.

The Department has determined that appropriate monitoring of *Campylobacter* can occur without routine culture testing and isolate submission. Given the high number of *Campylobacter* reports (approximately 2500 cases in New York City in 2018), the Department generally has been able to investigate only clusters, as opposed to isolated cases. Accordingly, the Department does not make use of most of the isolates received from laboratories. The Department can request additional testing and isolates from laboratories in the event of a suspected cluster or outbreak, rather than requiring laboratories to perform the additional testing as a matter of course. The Department believes this approach better balances laboratory burden and public health needs.

In addition, in order to address questions raised by reporting laboratories, the Board is adopting minor language changes to clarify that reports must be sent to the Department.

Accordingly, the Board amends Health Code Articles 11 and 13 as follows:

Note: New material is <u>underlined</u>. 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 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, shall be reported to the Department as specified in this article:

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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] <u>tuberculin skin test administered using the Mantoux method</u>, 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. <u>This reporting requirement is applicable to healthcare providers only. The related reporting requirement for laboratories is set forth in paragraph (7) below.</u>

<u>(7) Blood-based test for tuberculosis infection, or other later developed diagnostic test for tuberculosis infection, for all persons regardless of age. This reporting requirement is applicable to laboratories only. The related reporting requirement for healthcare providers is set forth in paragraph (6) above.</u>

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RESOLVED, that subdivision (a) of section 11.15 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 read as follows:

(a) Any individual required to be isolated pursuant to provisions of this Article, and certain [cases, suspect cases, contacts and carriers] <u>individuals infected with or carrying, suspected to be infected with or carrying, or having contact with people infected with or carrying certain</u>

organisms that cause disease, as indicated in this subdivision, shall be excluded by the operator, employer or person in charge of the applicable institution, facility or place as set forth in this subdivision.

(1) [A case or carrier] An individual infected with or carrying an organism that causes any of the following diseases who is a food handler shall be excluded until the individual no longer has symptoms and, as determined by the Department, no longer has an illness that is a risk to others. For the exclusion to be terminated, the excluded individual must provide the Department with clinical evidence of the absence of disease, which, as determined by the Department, may include two negative stool samples, taken not less than 24 hours apart and no less than 48 hours after resolution of symptoms, [are submitted to the Department and until determined by the Department to no longer be a risk to others;] provided that, if the individual has received antimicrobial therapy, the first stool sample shall be taken no less than 48 hours after the last dose:

Campylobacteriosis

Cholera

[E. coli 015:H7] *E. coli* O15:H7 and other Shiga [toxin producing Escherichia coli] toxin-producing *Escherichia coli* (STEC) infections

Salmonellosis (other than typhoid)

Shigellosis

Yersiniosis

(2) [A case or carrier] An individual infected with or carrying an organism that causes any of the following diseases who is an enrollee or attendee under the age of five or staff member who has contact with children under the age of five in a school, day care facility, camp or other congregate care setting with children under the age of five; or a health care practitioner in a hospital or medical facility who provides oral care shall be excluded until the individual no longer has symptoms and, as determined by the Department, no longer has an illness that is a risk to others. For the exclusion to be terminated, the excluded individual must provide the Department with clinical evidence of the absence of disease, which, as determined by the Department, may include two negative stool samples, taken not less than 24 hours apart and no less than 48 hours after resolution of symptoms, [are submitted to the Department and until determined by the Department to no longer be a risk to others;] provided that, if the individual has received antimicrobial therapy, the first stool sample shall be taken no less than 48 hours after the last dose[;] :

Cholera

[E. coli 015:H7] *E. coli* O15:H7 and other Shiga [toxin producing Escherichia coli] toxin-producing *Escherichia coli* (STEC) infections

Shigellosis

(3) [A case or carrier] An individual infected with or carrying an organism that causes any of the following diseases who is an enrollee or attendee under the age of five or staff member who has contact with children under the age of five in a school, day care facility, camp or other

congregate care setting with children under the age of five; or a health care practitioner who provides oral care, shall be excluded until the individual no longer has symptoms, unless the Department determines that there is a continuing risk to others:

Campylobacteriosis

Salmonellosis (other than typhoid)

Yersiniosis

(4) [A case or carrier]An individual infected with or carrying an organism that causes any of the diseases listed in this paragraph who is a food handler; an enrollee or attendee under the age of five or staff member who has contact with children under the age of five in a school, day care facility, camp or other congregate care setting with children under the age of five; or a health care practitioner in a hospital or medical facility who provides oral care, shall be excluded until the individual no longer has symptoms and, as determined by the Department, no longer has an illness that is a risk to others. For the exclusion to be terminated, the excluded individual must provide the Department with clinical evidence of the absence of disease, which, as determined by the Department, may include three negative stool samples, taken not less than 24 hours apart and no less than 48 hours after resolution of symptoms, [are submitted to the Department and until determined by the Department to no longer be a risk to others;] provided[, however,] that, if the individual has received antimicrobial therapy, the first stool sample shall be taken no less than 48 hours after the last dose:

Amebiasis

Cryptosporidiosis

Giardiasis

(5) [A case]An individual, or a household contact of an individual, with Hepatitis A who is a food handler; an enrollee or attendee under the age of five or staff member who has contact with children under the age of five in a school, day care facility, camp or other congregate care setting with children under the age of five; or a health care practitioner in a hospital or medical facility who provides oral care, shall be excluded until determined by the Department to no longer [be] have an illness that is a risk to others.

RESOLVED, that paragraph (5) of subdivision (a) of section 11.21 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 read as follows:

(5) *Reports for children less than five years of age.* When a child less than five years of age has a positive test for tuberculosis infection, the physician who attends the child, or the person in charge of a hospital, dispensary or clinic giving treatment to the child, must submit to the Department reports of all qualitative and quantitative diagnostic tests for tuberculosis infection for such child, including reports of all [bloodbased] blood-based tests and [purified protein derivative (PPD) Mantoux tests] tuberculin skin tests (TST) administered using the Mantoux method (including induration where a [PPD] TST is performed); all radiological examinations (including chest x-rays, computerized tomography scans, and magnetic resonance imaging

scans); and initiation of treatment for latent tuberculosis infection, in a manner prescribed by the Department.

RESOLVED, that paragraph (1) 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 read as follows:

(1) With regard to tuberculosis, reports shall also include all laboratory findings which indicate presumptive or confirmed presence of tuberculosis, the results of smears found positive for acid fast bacilli (AFB), all results including negatives and species identification on samples which had positive smears, all results including negative and indeterminate results of blood-based or other later-developed laboratory [test results positive] tests for tuberculosis infection [for children less than five years of age], all drug susceptibility testing results and all subsequent test results on samples collected within one year from any patient who had a previous positive AFB smear or a positive *Mycobacterium tuberculosis* complex test result (e.g., culture or NAA). Reports shall specify the laboratory methodology used and shall state if applicable whether the specimen was susceptible or resistant to each anti-tuberculosis drug at each concentration tested.

RESOLVED, that paragraph (4) 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 read as follows:

(4) If a culture-independent diagnostic test or other laboratory test demonstrates the possible presence of [*Campylobacter*,] *Listeria monocytogenes*, *Salmonella*, *Shigella*, *Vibrio*, or *Yersinia* in a patient specimen, the laboratory must perform, or refer the specimen to another laboratory for performance of, culture on the original specimen to isolate the organism. The culture must be initiated, or the specimen forwarded to another laboratory, within 72 hours of obtaining the positive culture-independent diagnostic test or other laboratory test result. The laboratory that performed the culture-independent diagnostic test or other positive test for one of the listed enteric pathogens must report the results of the subsequent culture test, whether positive or negative and whether performed by it or another laboratory, to the Department within 24 hours of obtaining the result. The laboratory that performed the culture must submit the resulting isolates, if any, to the Department in a manner and form prescribed by the Department. In the case of Shiga toxin-producing *Escherichia coli*, the laboratory must submit (i) an isolate or (ii) a Shiga toxin-positive broth (if available) and stool to the Department in a manner and form prescribed by the Department.

RESOLVED, that 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 include a new Section 11.33 to read as follows:

§11.33 Congenital Syphilis

(a) Every physician attending pregnant persons in the City of New York shall in the case of every person so attended take or cause to be taken a sample of blood of such person at 28

weeks of pregnancy, or as soon thereafter as reasonably possible, and in no event later than at 32 weeks of pregnancy, and submit such sample to a laboratory for standard serological testing for syphilis.

(b) Every other person permitted by law to attend pregnant persons in the state, but not permitted by law to take blood tests, shall cause a sample of the blood of any pregnant person under his or her care to be taken by a duly licensed physician at 28 weeks of pregnancy, or as soon thereafter as reasonably possible, and in no event later than at 32 weeks of pregnancy. Such sample shall be submitted to a laboratory for standard serological testing for syphilis.

(c) All syphilis test results, and a treatment plan for persons testing positive, must be prominently recorded in each pregnant person's medical record within one week of receipt of the test results. All test results must be reported to the Department in accordance with the Health Code.

(d) Nothing in this section shall be construed to supplant or otherwise interfere with applicable requirements to perform syphilis testing during pregnancy and at birth pursuant to the New York State Public Health Law and Title 10 of the New York Codes, Rules and Regulations (New York State Sanitary Code), or any successor laws, rules, or regulations.