



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

**Notice of Public Hearing and Opportunity to Comment
on Proposed Amendments to the New York City Health Code**

What are we proposing? The Department of Health and Mental Hygiene is proposing that the Board of Health amend Articles 11 and 13 of the Health Code, deleting, amending and adding requirements for reporting of certain communicable diseases by health care providers and clinical laboratories and clarifying various provisions related to the authority of the Department. This proposal was not included in the Department's Regulatory Agenda for 2013-2014, because the Department did not anticipate this amendment at the time.

When and where is the hearing? The New York City Department of Health and Mental Hygiene will hold a public hearing on the proposed rule. The public hearing will take place at 2:00 PM until 4:00 PM on April 23, 2014. The hearing will be at
New York City Department of Health and Mental Hygiene
Gotham Center, 42-09 28th Street, 14th Floor, Room 14-43
Long Island City, NY 11101-4132

How do I comment on the proposed amendments to the Health Code? Anyone can comment on the proposed amendments by:

- **Website.** You can submit comments to the Department through the NYC rules Web site at <http://rules.cityofnewyork.us>
- **Email.** You can email written comments to resolutioncomments@health.nyc.gov
- **Mail.** You can mail written comments to:
New York City Department of Health and Mental Hygiene
Gotham Center – 42-09 28th Street, CN 31
Long Island City, NY 11101-4132
- **Fax.** You can fax written comments to New York City Department of Health and Mental Hygiene at 347-396-6088
- **Speaking at the hearing.** Anyone who wants to comment on the proposed amendments at the public hearing must sign up to speak. You can sign up before the hearing by calling Svetlana Burdeynik at 347-396-6078. You can also sign up in the hearing room before or during the hearing on April 23, 2014. You can speak for up to five minutes.

Is there a deadline to submit written comments? Written comments must be received on or before 5:00 p.m. on April 23, 2014.

Do you need assistance to participate in the hearing? You must tell us if you need a reasonable accommodation of a disability at the Hearing. You must tell us if you need a sign language

interpreter. You can tell us by mail at the address given above. You may also tell us by telephone at 347-396-6078. You must tell us by April 9, 2014.

Can I review the comments made on the proposed amendments? You can review the comments made online at <http://rules.cityofnewyork.us/> on the proposed amendments by going to the website at <http://rules.cityofnewyork.us/>. All written comments and a summary of the oral comments received by DOHMH will be made available to the public within a reasonable period of time by the DOHMH Office of the General Counsel.

What authorizes the Board of Health to make these amendments? Section 558 of the City Charter authorizes the Board of Health to adopt and amend the Health Code and to include in the Health Code all matters to which the authority of the Department extends. This proposed amendment was not included in the Department's regulatory agenda for this Fiscal Year because it was not contemplated when the Department published the agenda.

Where can I find the Health Code and the Department's rules? The Health Code and the rules of the Department of Health and Mental Hygiene are in title 24 of the Rules of the City of New York.

What rules govern the rulemaking process? The Board of Health must meet the requirements of §1043 of the City Charter when creating or changing the Health Code. This notice is made according to the requirements of City Charter §1043.

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. Further, New York State Public Health law §580(3) permits 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 or to the control or abatement of public health nuisances."

Background

The Charter provides the Department with jurisdiction over all matters concerning health in the City of New York. The Department's Division of Disease Control conducts disease surveillance and control activities for most of the diseases listed in Article 11 of the New York City Health Code (Health Code). The Department's Divisions of Epidemiology, Healthcare Access and Improvement, Health Promotion and Disease Prevention, and Environmental Health also conduct surveillance and control activities for various reportable diseases and conditions. The Department is also required to comply with various provisions of Chapter 1 of the New York State Sanitary Code (the Sanitary Code), found in Title 10 of the Codes, Rules and Regulations of the State of New York (NYCRR), with respect to control of communicable diseases.

The lists of reportable diseases in the Health Code and Sanitary Code are periodically modified in response to emerging infections and changing priorities for disease surveillance and control.

In addition to reportable disease surveillance, the Department has successfully implemented several different and complementary syndromic surveillance systems to improve outbreak detection capacity as well as provide situational awareness of a wide variety of public health conditions, both routinely and during emergencies.

Since implementation of the Article 13 requirement that clinical laboratories report electronically (approved by the Board in 2006), the Department has greatly enhanced its capacity for receiving more complete and timely reports on notifiable diseases to monitor disease trends and conduct effective investigations.

To conduct more effective, timely and complete disease surveillance and control, the Department is proposing that the Board of Health amend various provisions of Health Code Articles 11 and 13 as follows:

- A. Amend Health Code § 11.03(a) to update the current list of reportable diseases:
 - 1) Change reporting of “Severe Acute Respiratory Syndrome” to “severe or novel coronavirus” – also changed in paragraph (1) of subdivision (b)
 - 2) Delete reporting requirement for Kawasaki syndrome
 - 3) Delete requirement to report “viral and aseptic meningitis” from reporting of meningitis
- B. Amend Health Code § 11.03(d) to add pharmacy sales of both prescription and over the counter medications as new sources for syndromic surveillance.
- C. Amend Health Code §11.03(e) to clarify the authority of the Department to obtain information necessary for public health investigations.
- D. Amend Health Code §§11.15 and 11.19 to lower the age for exclusion of children with enteric infections in daycare from less than six years of age to less than five years of age.
- E. Amend Health Code § 11.17 to clarify Department authority to order health care providers to isolate individuals with certain communicable diseases that may pose imminent and significant threats to public health until action can be taken by the Commissioner or designee.
- F. Amend Health Code §13.03(a) (1) to add data elements to be included on all laboratory reports.
- G. Amend Health Code §13.03(b)(1) to require reporting of results of all TB tests (negative or positive) of subsequent samples from patients with a prior positive acid fast bacilli (AFB) smear or test for M. tuberculosis complex (e.g., culture or nucleic acid amplification [NAA]).
- H. Amend Health Code § 13.03(b)(3) to add to hepatitis C reporting all positive and negative hepatitis C (HCV) nucleic acid tests (NAT) laboratory test results. The Department will require only laboratories that electronically submit through the Electronic Clinical Laboratory Reporting System (ECLRS) to report negative HCV NAT laboratory test results through ECLRS. Healthcare providers will not be required to report these results.

- I. Amend Health Code § 13.03(b)(3) to require reporting of all hepatitis B virus (HBV) test results (positive, negative and indeterminate) for hepatitis B surface antigen (HBsAg) and hepatitis B surface antibody (anti-HBs), both qualitative and quantitative, for children ages 168 days to 1,825 days (six months of age up to the fifth birthday). The Department will require only laboratories that electronically submit through the Electronic Clinical Laboratory Reporting System (ECLRS) to report negative HBV laboratory test results through ECLRS. Healthcare providers will not be required to report these results.
- J. Amend Health Code § 13.05(b)(1) and add a new paragraph (8) to require reporting of results of all subsequent tests on specimens from persons with a prior positive AFB smear or positive test for M. tuberculosis complex by culture or NAA .

Reasons for these changes

- A) **Changes to the reportable disease list in Health Code §11.03.** The Department is requesting the Board to amend Health Code §11.03 (a) and (b) as follows:
 - 1) **Change reporting of “Severe Acute Respiratory Syndrome (SARS)” to “severe or novel coronavirus.”** The 2003 epidemic of Severe Acute Respiratory Syndrome (SARS) was due to a novel coronavirus that emerged from mainland China and then spread internationally. In response, the Department added SARS to the list of reportable diseases in Health Code §11.03 to monitor for the re-emergence and potential introduction of this virus into New York City. In 2013, a different coronavirus emerged in the Middle East and resulted in several importations into Europe and hospital outbreaks in both the Middle East and Europe. As of February 7, 2014, there have been 182 cases, including 79 deaths worldwide. The syndrome caused by this novel coronavirus has been named Middle East Respiratory Syndrome or MERS. To enable the Department to monitor for the introduction of SARS-related, MERS-related, and other novel or severe coronaviruses, the Department is requesting the Board to change “SARS” in §11.03(a) to “severe or novel coronavirus”. Both suspect and confirmed cases of this disease will also be listed in Health Code § 11.03 (b) (1) as being immediately reportable.
 - 2) **Delete Kawasaki syndrome.** Kawasaki syndrome is a rare but serious rash illness that most commonly occurs in children less than 5 years of age. The etiologic agent(s) responsible for Kawasaki syndrome remain unknown despite intensive investigations during prior outbreaks, and the disease does not appear to be spread from person to person. From 2002 to 2012, there has only been a median of 20 cases (range 2 to 35 cases) of Kawasaki syndrome reported in New York City per year. There is no public health response to an individual case other than confirming that the case meets clinical criteria. Kawasaki syndrome is not currently listed as reportable in either the State Sanitary Code or the Centers for Disease Control and Prevention (CDC) National Notifiable Disease Surveillance System. As the Health Code § 11.03 (a) requires reporting of suspected or confirmed outbreaks of any disease or condition (defined as 3 or more cases), the Department would still respond to reports of outbreaks of Kawasaki syndrome after it is removed from the list. There is no reason, however, to continue to make individual cases reportable. Therefore, the Department is requesting the Board to remove Kawasaki syndrome from the list of reportable diseases.
 - 3) **Delete viral and aseptic meningitis.** Viral meningitis is a clinical syndrome that can be caused by a wide variety of viruses, most of which do not represent a public health

concern, especially for single cases. Aseptic meningitis is when a patient has the clinical syndrome of meningitis, but the laboratory identifies no microorganisms. Most cases of aseptic meningitis are due to viruses. Arboviral diseases, including arboviral meningitis, are currently listed and reportable separately in Health Code § 11.03 (a) and will remain reportable given the need to monitor for diseases like West Nile virus to ensure prompt detection and control of mosquito borne viruses in New York City. There is no public health response to an individual case for most other causes of viral or aseptic meningitis. For many, the specific etiologic agent remains unknown once more common causes of bacterial or viral meningitis are ruled out by laboratory testing. Neither viral nor aseptic meningitis are currently listed in the CDC's National Notifiable Disease Surveillance System. The New York State Department of Health has also indicated they intend to request that the State Public Health and Health Planning Council remove this disease from the State Sanitary Code at some time in the future. However, even if deleted from the Health Code list, until the disease is deleted from the State Sanitary Code, it will remain reportable in New York City. Lastly, as Health Code §11.03(a) requires reporting of suspected or confirmed outbreaks of any disease or condition (defined as 3 or more cases), the Department would still respond to clusters of viral or aseptic meningitis even after this disease is removed from the list. Therefore, the Department is requesting the Board to remove viral and aseptic meningitis from the list of reportable diseases.

B) Amend Health Code §11.03 (d) adding pharmaceutical sales to the types of data that may be collected in conducting syndromic surveillance. In 2008, the Board adopted Health Code 11.03(d), authorizing the Department to collect and monitor certain types of de-identified electronic health care data (e.g., emergency department and clinic visits) to ascertain the existence of and monitor the progress of an outbreak. This type of surveillance, known commonly as “syndromic surveillance,” relies on a wide array of electronic data sources and analytical techniques. Emergency department visit logs and over-the-counter pharmacy sales are examples of health encounter data sources that are routinely collected, available in electronic format, and able to be transmitted in a timely manner for public health monitoring. The Department has been using syndromic surveillance in various formats for the past 12 years as a complement to traditional notifiable disease surveillance to monitor for public health conditions, including seasonal surveillance for influenza-like illness, gastroenteritis, and injuries and mental health issues during and after emergencies (e.g., Hurricane Sandy in 2012).

Since 2002, the Department has received data on pharmaceutical sales on a voluntary basis from a large retail chain in New York City. In 2013, a second pharmacy chain was added to the Department's system, again on a voluntary basis. The Department recognizes the additional value that pharmacy sales data provide to the other syndromic data sources currently listed in Health Code § 11.03(d). Pharmacies may be the first and only contact with the health care system for individuals with early or mild symptoms of disease, and pharmaceutical sales data have demonstrated usefulness in outbreak detection. One example was a marked increase in sales of over-the-counter antidiarrheal medication that was retrospectively recognized as one of the first indicators of a large outbreak of cryptosporidiosis in Milwaukee in 1993 due to contamination of the municipal water supply.¹

¹Mac Kenzie WR, Hoxie NJ, Proctor ME, Gradus MS, Blair KA, Peterson DE, et al. A massive outbreak in Milwaukee of cryptosporidium infection transmitted through the public water supply. *NEJM* 1994; 331(3): 161-167.

In August 2003, the Department used syndromic pharmacy data to detect an increase in diarrheal illness associated with a citywide power outage.²

Accordingly, the Department is proposing that the Board add retail pharmacies to the list of facilities in Health Code § 11.03(d) from which reports will be required and to list both over-the-counter and prescription medications as data elements that will be requested. Such reports must be made electronically and in a form, manner, and frequency as specified by the Department. The data collected will not include any personal identifiers. Specific variables that will be requested from pharmacies include, but may not be limited to, the following: date of sale, product name, National Drug Code, store address/zip code, store ID, quantity/size, birth year of purchaser (prescription drug only), promotion item and Universal Product Code (over the counter medications only). Pharmacies not equipped to maintain sales data electronically will be exempted from this requirement. It should be noted that Health Code §71.09 currently makes pharmacies' and other entities' records subject to inspection by the Department in connection with public health investigations and provides that all information obtained from such records is to be kept confidential by the Department.

C) Amend Health Code §11.03(e) to clarify the Department's authority to obtain medical information for public health investigations. Currently, this provision authorizes the Department to obtain additional information concerning any report made by required reporters listed in Health Code §11.05(a) or other individuals required to submit reports in accordance with other applicable law. However, this limits the Department's authority to obtain information necessary for public health investigations when information about a public health problem originates not with a required reporter of a case or condition, but with other individuals or entities. In dangerous dog investigations, for example, the health care provider treating the bite victim is required to report the bite pursuant to Health Code §11.03(a) and (e). However, other sources may also report on the bites, such as the person bitten, the owner of the dog, a police officer, a bystander, or local media. In the course of such an investigation, the Department may learn about other bites inflicted by a particular dog that were not reported by a treating health care provider. Medical information about the other bite victim's injuries is also vital to such an investigation. As currently drafted, §11.03(e) could limit the ability of the Department to obtain necessary medical information regardless of whether the case was reported in accordance with §11.03(a). The Department is proposing that the Board amend this provision to clarify its authority to obtain necessary medical information for public health investigations. Although New York City Charter §555 (b) authorizes the Commissioner to issue subpoenas to compel production of witnesses, records, and other documents in any proceeding before the Commissioner, there are so many reported diseases and conditions being investigated at any one time, that requiring subpoenas to be issued is unnecessarily cumbersome. It should also be noted that HIPAA authorizes disclosure of medical information for public health purposes to public health agencies, such as the Department, without patient consent. In most reportable disease and condition investigations, it is important to be able to investigate and intervene appropriately, based on the best available information, as quickly as possible to prevent further transmission of a communicable disease or injuries from poisonings or other conditions the Department has the duty to investigate.

Another reason to amend this provision is the emergence of organizations that manage the exchange of health information in a defined geographic area for outpatient clinics, provider

²Marx MA, Rodriguez CV, Greenko J, et al. Diarrheal illness detected through syndromic surveillance after a massive power outage: New York City, August 2003. *Am J Public Health.* 2006;96(3):547-53.

offices, hospitals, laboratories, and other healthcare entities, currently referred to as regional health information organizations (RHIOs) or Qualified Entities (QEs). With the increasing use of electronic health records and health information exchanges, the Department recognizes health information exchange organizations as potential sources of information necessary for investigations of reportable diseases and conditions listed in Health Code §11.03.

Accordingly, the Department is requesting the Board to add a requirement to §11.03(e) that affords the Department access to electronically stored patient health information by entities such as health information exchange organizations for any confirmed or suspected cases, contacts, or carriers of reportable diseases that is necessary for the Department to conduct its surveillance and epidemiologic investigations, including in response to suspected or confirmed outbreaks.

- D) Amend Health Code §§11.15 and 11.19 to change the age of exclusion for children with enteric infections in daycare and pre-kindergarten from under six years of age to under five years of age.** Health Code §11.15 currently requires exclusion of a child under the age of six or staff member who has contact with children under the age of six in a school, day care facility, camp, or other congregate care setting who has been diagnosed with one of the following gastrointestinal illnesses: amebiasis, Campylobacteriosis, cholera, Cryptosporidiosis, *E. coli* O15:H7 or other Shiga toxin producing *Escherichia coli* (STEC) infections, Giardiasis, Hepatitis A, Paratyphoid fever, Salmonellosis (other than typhoid), Shigellosis, Typhoid fever, and Yersiniosis.

The Department is proposing that the Board lower the age criteria from under six to under five years, so that control efforts are focused on the children at highest risk in daycare or pre-kindergarten settings. Outbreaks or person-to-person spread are much less common among children who are toilet trained and no longer require diaper care. Excluding children from kindergarten requires children to miss educational services and a parent or caregiver to stay home from work creating a significant burden for families. Changing the threshold from under 6 years to under 5 years will allow the Department to focus enforcement efforts in children attending daycare or pre-kindergarten settings, and not children attending kindergarten or elementary school where the risk of disease transmission is less. For the same reasons, the Department is proposing that the change in excluding children only under age five also be made applicable to cases of paratyphoid and typhoid fever in §11.19.

- E) Amend Health Code § 11.17 to clarify the Department’s authority to order the isolation of persons with communicable diseases that may pose an imminent and significant threat to public health.** Subdivision (a) of Health Code §11.17 (Control measures; duty to isolate; and isolation, quarantine and examination orders) requires that suspected or confirmed cases and carriers of specific contagious infectious diseases and “any other contagious disease that in the opinion of the Commissioner may pose an imminent and significant threat to the public health ... shall be isolated in a manner consistent with recognized infection control principles and isolation procedures in accordance with State Department of Health regulations or guidelines.” The Health Code provision does not explicitly impose a duty upon the physicians attending these cases or carriers to isolate them until the Commissioner or designee takes further action. The proposed amendment clarifies that physicians attending to these patients are required to isolate them.

A similar provision in the State Sanitary Code § 2.27 imposes a duty upon attending physicians to isolate persons with “highly communicable diseases,” pending public health action. It refers to Sanitary Code § 2.1 for a definition of “highly communicable diseases.” However, Sanitary Code § 2.1 lists only certain reportable diseases and does not indicate that

there may be other emergent diseases of public health concern that are not listed. The proposed amendment to Health Code § 11.17(a) will clarify that physicians attending patients with diseases listed in Health Code § 11.17, as well as those with emergent diseases that are not currently reportable, are required to isolate them pending further action by the Department.

- F) Amend Health Code §13.03(a) to require additional data elements to be submitted with electronic laboratory reports of notifiable diseases and conditions.** Electronic laboratory reporting has greatly improved the timeliness and completeness of reportable disease surveillance. As more health care information is now available with enhancements and improved linkages in electronic health record systems, it is possible to obtain more complete information on the case-patient and the health care provider who requested testing to facilitate case investigations. The Department is requesting that the Board add the following data elements to the list of information that should accompany all electronic laboratory reports, if known, in Health Code §13.03:

- Patient email
- Patient mobile phone number
- Provider email
- Provider fax number
- Provider mobile phone number
- Provider National Provider Identification (NPI) number
- Facility National Provider Identification (NPI) number

In addition, paragraph (1) of Health Code §13.03(a) currently requires the pregnancy status to be indicated if known and if clinically relevant (e.g., for hepatitis B and syphilis). Although the laboratory may not know the patient's pregnancy status based on information provided by the requesting health care provider, the laboratory would know that a pre-natal panel of laboratory tests was ordered. Therefore, the Department is proposing to amend this provision to require information about pregnancy either when pregnancy status is known and indicated or when pregnancy is probable (e.g., a pre-natal panel is ordered).

These additional data elements will enhance the Department's disease surveillance efforts by improving its ability to contact patients and/or providers to obtain additional information required for a case investigation.

- G) Amend Health Code §13.03(b)(1) and §13.05 to require reporting of all tuberculosis test results of subsequent samples for patients with either an initial positive acid fast bacilli (AFB) smear or positive culture or other test for *M. tuberculosis* complex.** The Department is proposing that the Board amend Health Code §13.03(b)(1) to require the reporting of all subsequent test results for a patient with a previous positive test result for AFB smear, nucleic acid amplification (NAA), mycobacterial culture, or other test for *M. tuberculosis* complex. Currently negative results are only reported when results are from samples with an AFB positive smear. This amendment will enable the Department to more quickly rule out a suspected diagnosis of TB and discontinue unnecessary treatment and to better monitor treatment.

Cases and suspect cases of TB disease residing in New York City are managed by the Department, sometimes in partnership with private providers. Currently, laboratories are required to report to DOHMH all results from biological samples found positive for AFB,

cultures and NAA tests positive for *M. tuberculosis* complex, drug susceptibility tests performed on *M. tuberculosis* complex cultures, pathology findings indicative of TB, and any culture or NAA result associated with an AFB-positive smear sample even if negative. Current reporting is not, however, timely enough to identify persons who were suspected as having TB, started treatment, and later found not to have TB disease, nor is it adequate enough to track TB patients' response to treatment.

Test results on initial samples collected from patients are used to diagnose TB disease and determine infectiousness. Test results from subsequent samples collected after an initial positive sample are used to monitor a patient's response to treatment. Receiving timely test results, either positive or negative, is critical for these purposes.

Current required test results are reported electronically or via fax to the Department when they become available. To obtain negative test results that are not currently reportable, Department staff must visit hospitals to perform chart reviews and visit or call providers and laboratories. Getting a negative result can take multiple attempts over months. Patients suspected of TB are placed on treatment until TB diagnosis is ruled out, which is generally based on laboratory test results. Reducing the time to obtain negative test results can reduce the time the patient is on unnecessary treatment. More importantly, negative results are critical for monitoring patients on treatment. In general, patients on appropriate treatment are expected to have negative culture results within 60 days of treatment. Extending treatment may be necessary if patients do not have a documented negative culture conversion. Having negative results automatically reported to the Department will decrease the time it takes for patients to be deemed non-infectious and will assist the Department in determining the optimal treatment length for TB patients.

H) Amend Health code §13.03(b)(3) to require reporting of negative hepatitis C virus (HCV) nucleic acid tests (NAT) (electronic laboratory reporting only). The Department is proposing that the Board amend Health Code §13.03(b)(3) to require reporting of all HCV NAT results. This provision currently specifies only that HCV (and other hepatitis) reports made by clinical laboratories be accompanied by results of alanine aminotransferase testing (ALT). The addition of required reporting of NAT results will support the Department's 2013 plan³ to reduce illness and death from HCV. One component of this plan involves strengthening the Department's capacity to manage and utilize data for evidence-based policies and practice. By receiving reports of both positive and negative test results for HCV NAT, the Department will be able to estimate the number of persons tested, the burden of chronic HCV infection in New York City, the number of persons treated for and cured of chronic HCV infection, and monitor changes over time, similar to what is currently authorized for human immunodeficiency virus (HIV) infection.

As many as 146,500 New York City residents may have chronic HCV. The disease is most prevalent in New York City neighborhoods with high poverty. Most persons living with HCV have few symptoms of illness until 10 to 30 years after initial infection, when life-threatening health complications, including cirrhosis and liver cancer, can develop. The annual number of deaths associated with HCV has been increasing yearly and, since 2007, has exceeded deaths associated with HIV in the United States. Highly effective HCV antiviral treatments have

³ Hepatitis C in New York City: State of the Epidemic and Action Plan. Available at <http://www.nyc.gov/html/doh/downloads/pdf/cd/hepC-action-plan.pdf>

recently been approved, and more are expected in the coming years, making it likely that liver failure, cancer, and death from HCV can be averted in the future.

Antibody screening tests for HCV are recommended for all persons born between 1945 and 1965 and for patients with risk factors, including any history of injection drug use or receipt of a blood transfusion before 1992. However, 15-25% of patients who test HCV antibody positive have no detectable HCV nucleic acid in their blood, indicating that they do not have HCV infection. This is usually because they either resolved a prior HCV infection or had a false-positive HCV antibody test. Therefore, it is recommended that all patients with a positive HCV antibody test undergo HCV NAT testing to determine infection status.

The Department found that, from 2009 to 2012, 27% of patients with a positive HCV antibody never received an HCV NAT test, while an additional 9% only received NAT testing after the Department sent a reminder to the clinician that NAT testing is recommended.

Currently, both the Sanitary Code and Health Code § 11.03 mandate reporting by health care providers and others of persons who are cases and carriers of HCV. Laboratories must report positive HCV antibody screening tests and all positive confirmatory assays, e.g., recombinant immunoblot assay (RIBA) or NAT, that result from laboratory analysis of specimens in accordance with the “Laboratory Reporting of Communicable Diseases, 2010” guidance issued by the Department and the New York State Department of Health. With nearly 10,000 new cases of HCV reported each year, the Department does not currently have sufficient staff resources to conduct individual case investigations by chart review and patient and provider interviews to determine infection and treatment status. If the Department received results of both positive and negative tests for HCV NAT, this would provide more useful information for tracking the HCV epidemic in New York City. First, it would be possible to accurately classify patients as chronically infected by determining which antibody-positive patients are infected (NAT positive) versus not infected (NAT negative). Second, it would be possible to evaluate HCV testing patterns and focus outreach efforts toward providers who are not following HCV NAT testing recommendations. Third, by making all HCV NAT results reportable, the Department would also be able to estimate the proportion of patients who are receiving care for their diagnosis. For example, patients with only an antibody test but no NAT test would presumably not be in care. Patients who are NAT positive, but become NAT negative over time, would be presumed to be on treatment and, if the negative NAT tests are sustained, to be cured. The Department would be able to use these data to target interventions to those neighborhoods that have persistently higher levels of HCV viral loads based on HCV NAT results. These data could also be used to identify and prioritize linkage to care for persons who have been diagnosed with chronic HCV but have been lost to medical follow-up. Finally, these data will help the Department evaluate and, as needed, enhance our policies and programs on HCV prevention and control.

Therefore, the Department is requesting the Board to include a requirement for laboratories to report negative HCV NAT test results through the Department’s electronic reporting mechanism set forth in Health Code § 13.03(c).

- I) Amend Health code §13.03(b)(3) to require reporting of negative hepatitis B virus (HBV) test results for children for children ages 168 days to 1,825 days (six months of age up to the fifth birthday).**The addition of required reporting of HBsAg (hepatitis B surface antigen) and anti-HBs (hepatitis B surface antibody) test results for children ages six months to five years of age will support the Department’s efforts to help prevent perinatal

HBV among children born to HBV-infected mothers and to conduct surveillance for this nationally notifiable disease. Children born to HBV-infected mothers are at high risk of acquiring this infection. If infected, 90% will develop chronic hepatitis infection, placing them at risk for cirrhosis and hepatic carcinoma at an early age.

Each year, the Department case manages approximately 1,800 babies born to HBV positive pregnant women in New York City. Through individual patient education and case management, the Department helps to ensure that the newborns receive HBV immune globulin and HBV vaccine within 12 hours of birth and two more doses of HBV vaccine by six months of age to prevent HBV infection. These high-risk children should have post-vaccination serology testing performed at nine months of age to assess if they are infected, susceptible, or immune. Interpretation requires the test results for both HBsAg and anti-HBs. Children who are found to be infected have to be referred to a specialist for evaluation and treatment. Children who are found susceptible after the first immunization series have to immediately begin a second three dose series of HBV vaccination.

Currently, the Department contacts the pediatric provider who administered the HBV vaccinations to provide reminders and to obtain post-vaccination serology testing results. This activity consumes approximately 25% of staff time. In addition, the Department is frequently unable to obtain all test results due to not being able to locate the family or the pediatric provider. The Department does not obtain test results for approximately 40% of the 1,800 babies managed annually. By requiring reporting of all test results for HBsAg and anti-HBs for children ages six months to five years, the Department will receive post-vaccination serology test results more efficiently and completely. The Department will be better able to manage cases lost to follow-up either by the Department or by other health jurisdictions, which may have cases that have moved to New York City.

The resolution 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 list of reportable communicable diseases in subdivision (a) of §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, is amended, to be printed with explanatory notes to read as follows:

§11.03 Diseases and conditions of public health interest that are reportable.

* * *

Influenza-related deaths of a child less than 18 years of age

[Kawasaki syndrome]

Legionellosis

* * *

Melioidosis

Meningitis, [including aseptic, viral and] other bacterial causes (specify type)

Meningococcal, invasive disease

* * *

Salmonellosis

Severe [Acute Respiratory Syndrome (SARS)] or novel coronavirus

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

* * *

Notes: Subdivision (a) of §11.03 was amended by Board of Health resolution adopted XXX to delete Kawasaki syndrome and viral meningitis as reportable diseases and to change reporting of Severe Acute Respiratory Syndrome [SARS] to Severe novel coronavirus, a broader category, in view of emergent strains of coronaviruses other than SARS.

RESOLVED, that the list of immediately reportable communicable diseases in paragraph 1 of subdivision (b) of §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, is amended, to be printed with explanatory notes to read as follows:

* * *

Rubella (German measles)

[SARS] Severe or novel coronavirus

Smallpox

* * *

Notes: The list of immediately reportable diseases in paragraph (1) of subdivision (b) of §11.03 was amended by Board of Health resolution adopted XXX to change reporting of Severe Acute Respiratory Syndrome [SARS] to severe or novel coronavirus, a broader category, in view of emergent strains of coronaviruses other than SARS.

RESOLVED, that subdivision (d) of §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, is amended, to be printed with explanatory notes to read as follows:

(d) *Authority for syndromic surveillance.*

(1) Health care providers and others. To ascertain the existence or monitor the progress of an outbreak, or the occurrence of unusual manifestations of disease, or of unusual diseases or conditions of public health interest, the Department may require reports by emergency departments, urgent care facilities, hospitals and clinics, and health information organizations which are comprised of such health care providers, as such terms are defined in Article 28 of the New York State Public Health Law or regulation promulgated thereunder, of all patient visits during each 24-hour period. Such reports shall be made electronically and in a form, manner and frequency as may be specified by the Department. Reports required by this subdivision may include age, gender, date and time of visit, zip code of residence, chief complaint, diagnosis or diagnosis code, disposition, radiographic results, laboratory results and a unique identification number adequate to access the patient's medical record if deemed necessary by the Department to investigate a suspected outbreak. In the event of a suspected or confirmed outbreak, and upon request by the Department, the identity of a patient shall be promptly reported to the Department.

(2) Retail pharmacies. To ascertain the existence or monitor the progress of an outbreak, or the occurrence of unusual manifestations of disease, or of unusual diseases or conditions of public health interest, the Department may require from retail pharmacies reports of sales of specified over the counter and prescription medications when the data from such sales are maintained in an electronic form. Such reports must be made electronically and in a form, manner and frequency as may be specified by the Department. The data collected will not include any personal identifiers. Specific variables to be requested from pharmacies may include, but need not be limited to: date of sale, product name, National Drug Code, store address/zip code, store ID, quantity/size, birth year of purchaser (prescription drug only), promotion item and Universal Product Code (over the counter medications only).

Notes: Subdivision (d) of §11.03 was amended by Board of Health resolution adopted XXX to add retail pharmacies to the various entities required to submit reports used for syndromic surveillance.

RESOLVED, that subdivision (e) of §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, is amended, to be printed with explanatory notes to read as follows:

(e) Information needed for investigations. Upon receipt of a report submitted pursuant to this section or any other provision of this article or other applicable law the Department may conduct such surveillance, epidemiologic and laboratory investigation activities as it shall deem necessary to verify the diagnosis, ascertain the source or cause of infection, injury or illness, identify additional cases, contacts, carriers or others at risk, and implement public health measures to control the disease or condition and prevent additional morbidity or mortality. Such investigations may include, but are not limited to, collecting or requiring collection of such clinical or environmental specimens for laboratory examination as the Department considers necessary, including the collection of specimens or isolates from clinical laboratories for testing by the Department or as designated by the Department. When deemed necessary for the protection of public health, in the course of conducting an investigation of a disease or condition made reportable to the Department by this article or other applicable law, the Department may require any person [required to submit a report pursuant to this article or other applicable law, or an agent of such person,] or any entity maintaining or managing health-related electronic records to provide reasonably necessary [additional] information [not otherwise required to be reported by this Code,] including but not limited to information on household contact and non-household contact names and contact information, clinical signs and symptoms, treatment, including records of treatment, laboratory, radiological, or other diagnostic procedures as specified by the Commissioner or designee.

Notes: Subdivision (e) was amended by resolution adopted XXX to clarify the Department's authority to obtain medical records necessary for epidemiologic and case investigations of reportable diseases and conditions, including records maintained in electronic data bases.

RESOLVED, that §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, is amended, to be printed with explanatory notes to read as follows:

§11.15 Control measures; duty to exclude; exclusion orders.

(a) Any individual required to be isolated pursuant to provisions of this Article, and certain cases, suspect cases, contacts and carriers, 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 of the following diseases who is a food handler shall be excluded until 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 0157:H7 and other Shiga toxin producing Escherichia coli (STEC) infections

Salmonellosis (other than typhoid)

Shigellosis

Yersiniosis

(2) A case or carrier of the following diseases who is an enrollee or attendee under the age of [six] five or staff member who has contact with children under the age of [six] five in a school, day care facility, camp or other congregate care setting with children under the age of [six] five; or a health care practitioner in a hospital or medical facility who provides oral care shall be excluded until 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 and other Shiga toxin producing Escherichia coli (STEC) infections

Shigellosis

(3) A case or carrier of the following diseases who is an enrollee or attendee under the age of [six] five or staff member who has contact with children under the age of [six] five in a school, day care facility, camp or other congregate care setting with children under the age of [six] 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 of the diseases listed in this paragraph who is a food handler; an enrollee or attendee under the age of [six] five or staff member who has contact with children under the age of [six] five in a school, day care facility, camp or other congregate care setting with children under the age of [six] five; or a health care practitioner in a hospital or medical facility who provides oral care, shall be excluded until 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 or household contact of Hepatitis A who is a food handler; an enrollee or attendee under the age of [six] five or staff member who has contact with children under the age of [six] five in a school, day care facility, camp or other congregate care setting with children under the age of [six] 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 a risk to others.

(b) An owner or person in charge of a work place, school, day care, camp or other congregate setting with children under the age of [six] five, shelter or other congregate residential setting, or any other institution, facility or place specified in this section or this article, shall not knowingly or negligently permit a case, suspect case, contact or carrier to work in or attend such place when required by this article to be isolated or excluded.

(c) The Department may, in accordance with the provisions of subdivision (k) of §11.23 of this Article, order any case, contact, or carrier, or suspected case contact or carrier of a contagious disease to be excluded from any setting when necessary for the protection of public health.

Notes: §11.15 was amended by Board resolution adopted XXX changing the age for exclusion of children with enteric diseases from under six to under five years of age, and the individuals caring for such children in congregate settings, after the Department determined that six year old children posed a much less significant public health risk than those under five.

RESOLVED, that subdivision (a) of §11.17 of Article 11 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, is amended, to be printed with explanatory notes to read as follows:

§11.17 Control measures; duty to isolate; and isolation, quarantine and examination orders.

(a) In a hospital, clinic, nursing home or other medical facility, it shall be the duty of the attending physician to isolate a case, carrier, suspect case, or suspect carrier of diphtheria, rubella (German measles), influenza with pandemic potential, invasive meningococcal disease, measles, monkeypox, mumps, pertussis, poliomyelitis, pneumonic form of plague, [SARS] severe or novel coronavirus, vancomycin intermediate or resistant *Staphylococcus aureus*(VISA/VRSA), smallpox, tuberculosis (active), vaccinia disease, viral hemorrhagic fever or any other contagious disease that in the opinion of the Commissioner may pose an imminent and significant threat to the public health, [shall be isolated] in a manner consistent with recognized infection control principles and isolation procedures in accordance with State Department of Health regulations or guidelines pending further action by the Commissioner or designee.

Notes: Subdivision (a) was amended by resolution adopted XXX to clarify the duty of providers to isolate persons with specified and emergent contagious diseases of public health concern until the Commissioner takes further action.

RESOLVED, that subdivisions (a) and (b) of §11.19 of Article 11 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, is amended, to be printed with explanatory notes to read as follows:

§11.19 Typhoid and paratyphoid fever; exclusion.

(a) A case of typhoid or paratyphoid fever who is a food handler; an enrollee or attendee under the age of [six] five or staff member who has contact with children under the age of [six] five in a school, day care facility, camp or other congregate care setting with children under the age of [six] five; a health care practitioner in a hospital or medical facility who provides oral care; a resident of a congregate homeless facility or shelter or any other congregate residential setting; or any other person who in the opinion of the Department represents a risk to the health of the public, shall be excluded until the end of the febrile period and until four stool specimens are submitted to the Department, found to be free of typhoid and paratyphoid bacteria, and until

released from exclusion by the Department. Stool specimens shall be submitted as specified herein. The initial two specimens shall be taken no less than 48 hours after the cessation of antibiotic therapy and 24 hours apart. A second set of two specimens shall be taken thirty (30) days later, and no less than 24 hours apart. The case shall be instructed not to prepare food for other members of the household or others, nurse the sick, or care for children until it is determined that the patient is non-infectious and a non-carrier as per subdivision (c) of this section. Members of the household shall be advised by the physician in attendance of precautions to be taken to prevent further spread of the disease and shall be informed as to the appropriate specific preventive measures.

(b) A household contact who is a food handler; an enrollee or attendee under the age of [six] five or staff member of a school, day care facility or other congregate care setting with children under the age of [six] five; a health care practitioner in a hospital or medical facility who provides oral care; or any other person who in the opinion of the Department represents a risk to the health of the public, shall be excluded until two successive stool specimens, taken no less than 24 hours apart are examined by the Department and found free of typhoid and paratyphoid bacilli.

Notes: §11.19 was amended by Board resolution adopted XXX changing the age for exclusion of children with typhoid and paratyphoid fever from under six to under five years of age, and the individuals caring for such children in congregate settings, after the Department determined that six year old children posed a much less significant public health risk than those under five.

RESOLVED, that the section heading, paragraph 1 of subdivision (a), and paragraphs 1 and 3 of subdivision (b), of §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, are amended, to be printed with explanatory notes to read as follows:

§13.03 Report of [positive] findings

(a) * * *

(1) The full name, date of birth and address of the person from whom the specimen was taken; the race, ethnicity and gender of such person, if known; the pregnancy status of such person, if the pregnancy status is known or probable (e.g., if a pre-natal panel was ordered) and if it is clinically relevant to the positive laboratory results, for example, a positive hepatitis B surface antigen or a positive syphilis test result; the specimen source; and the date the specimen was

collected; patient email and mobile phone number, if known; provider email, fax number, mobile phone number and National Provider Identification (NPI) number if known; and facility National Provider Identification (NPI) number.

(b) * * *

(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, [and] all drug susceptibility testing results and all subsequent test results on samples from any patient who had a previous positive AFB smear or a positive M. tuberculosis complex test result (e.g., culture or NAA). [Such] 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.

* * *

(3) With regard to hepatitis A, B, C, D, E or any other suspected infectious viral hepatitides, reports shall also include the results of alanine aminotransferase testing (ALT) if performed on the same specimen that tests positive for any of the reportable viral hepatitides. With regard to hepatitis C, all hepatitis C nucleic acid amplification test results, including both positive and negative results, must be reported electronically in accordance with subdivision (c) of this section. With regard to hepatitis B, all hepatitis B surface antigen and hepatitis B surface antibody test results, including positive, negative, and indeterminate, for children ages 168 days to 1,825 days (six months of age up to the fifth birthday) must be reported electronically in accordance with subdivision (c) of this section.

Notes: Paragraph (1) of subdivision (a) of §13.03 was amended by Board of Health resolution adopted XXX to clarify reporting of pregnancy status and to require additional fields facilitating investigations of cases whose specimens are being analyzed and the providers submitting specimens, and the section heading was amended to more accurately reflect section content. Paragraph (1) of subdivision (b) of §13.03 was amended by Board of Health resolution adopted XXX to require submission to the Department of all reports of tests performed on specimens of persons with prior positive tuberculosis test results.

Paragraph (3) of subdivision (b) of §13.03 was amended by Board of Health resolution adopted XXX to require reporting of all hepatitis C nucleic acid, all hepatitis B surface antigen, and all

hepatitis B surface antibody test results to enable the Department to more accurately identify and monitor persons with the disease.

RESOLVED, that paragraph 1 of subdivision (b) of §13.05 of Article 13 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, is amended, and that a new paragraph 8 of such subdivision be added, to be printed with explanatory notes to read as follows:

§13.05 Testing for tuberculosis.

* * *

(b) (1) Smears performed to detect acid fast bacilli (AFB) shall be examined within 24 hours after receipt of the specimen in the laboratory, and when concentrated smears for AFB are performed on clinical specimens (e.g., sputum) [the] all positive results shall [not] be reported to the Department [unless positive]. Negative smears shall be reported to the physician or other person authorized to request laboratory tests, or the forwarding laboratory, if any, within 24 hours pursuant to §13.05(b)(7) and must also be reported to the Department if the smear is from a patient with a previously reported positive AFB smear. All respiratory specimens which test acid-fast smear positive and are from patients who have not previously been diagnosed with tuberculosis shall have nucleic acid amplification testing performed. If a laboratory examining the specimen does not have the ability to perform nucleic acid amplification testing, it shall submit an appropriate specimen to the Department for testing by the Department of a laboratory designated by the Department[; and].

* * *

(8) A negative result of any laboratory test or examination related to tuberculosis must also be reported to the Department within 24 hours of the test result being known if the test is conducted on a specimen from a patient with any prior positive laboratory test related to tuberculosis.

Notes: Paragraph (1) of subdivision (b) was amended, and a new paragraph (8) was added by Board resolution adopted XXX to require reporting of all test results on specimens of persons who had previous positive AFB and M. tuberculosis complex test results identified by culture or nucleic acid amplification.

**NEW YORK CITY LAW DEPARTMENT
DIVISION OF LEGAL COUNSEL
100 CHURCH STREET
NEW YORK, NY 10007
212-356-4028**

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

RULE TITLE: Amendment of Reporting Requirements for Communicable Diseases
(Health Code Articles 11 and 13)

REFERENCE NUMBER: 2014 RG 013

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: March 5, 2014

**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: Amendment of Reporting Requirements for Communicable Diseases
(Health Code Articles 11 and 13)

REFERENCE NUMBER: DOHMH-40

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/ Ruby B. Choi
Mayor's Office of Operations

March 5, 2014
Date