



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

**Notice of Public Hearing and Opportunity to Comment on
Proposed Amendment to Article 13 of the New York City Health Code**

What are we proposing? The Department of Health and Mental Hygiene (the Department) is proposing that the Board of Health (the Board) amend Article 13 (Clinical Laboratories) of the New York City Health Code (Health Code) to enhance certain reporting and disease control requirements.

When and where is the hearing? The Department will hold a public hearing on the proposed Health Code amendments from 2PM to 4PM on July 27, 2017. The hearing will be held at:

New York City Department of Health and Mental Hygiene
Gotham Center
42-09 28th Street, 3rd Floor, Room 3-32
Long Island City, NY 11101-4132
This location is wheelchair accessible.

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

- **Website:** You may submit comments to the Department through the NYC Rules website at <http://rules.cityofnewyork.us>.
- **Email:** You may email comments to resolutioncomments@health.nyc.gov
- **Mail:** You may mail 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 may fax comments to the Department at 347-396-6087.
- **By speaking at the hearing.** Anyone who wants to comment on the proposed amendments at the public hearing must sign up to speak. Speakers have up to five minutes to make their comments. You can sign up in advance of the hearing by calling Svetlana Burdeynik at 347-396-6078, or before or during the hearing in the hearing room on July 27, 2017. 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 July 27, 2017.

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 July 13, 2017.

Can I review the comments made on the proposed amendments? You may 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 the Department will be made available to the public within a reasonable period of time by the Department's Office of the General Counsel.

What authorizes the Board to make these amendments? Section 558 of the City Charter authorizes the Board to adopt and amend the Health Code and to include in the Health Code all matters to which the authority of the Department extends. Section 556 of the Charter provides the Department jurisdiction to supervise clinical laboratories and the reporting and control of communicable diseases.

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 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

Pursuant to New York Public Health Law Section 580(c), the City has the authority to regulate clinical laboratories. The Department's Division of Disease Control enforces Article 13 (Clinical Laboratories) of the Health Code, which regulates the manner in which laboratory tests must be performed and the reporting of test results.

To conduct more effective, timely, and complete disease surveillance and control in regard to Hepatitis C, the Department is proposing that the Board amend Health Code Article 13 as follows:

Hepatitis C Testing and Reporting

The Department is requesting that the Board amend Health Code §13.03(b)(3) to require laboratories to routinely perform a confirmatory RNA hepatitis C virus (HCV) test if an antibody tests is positive for hepatitis C virus.. The confirmatory test must be performed on the same specimen or a second specimen collected at the same time as the initial specimen. This requirement completes diagnostic testing and helps ensure that patients infected with HCV are aware of their status, linked to appropriate medical care and treatment, and cured, thus reducing the risk of further transmission.

Most patients are first screened for HCV via an antibody test, which shows whether the patient has ever been infected with HCV. When a patient tests positive, a confirmatory RNA test is required to establish whether the individual is currently infected with the virus. If the provider does not order the confirmatory test at the same time as the antibody test, the patient must return for an additional blood draw for the RNA test. This multi-step testing process results in treatment delays and patients being lost to care.

In 2016, only 48% of patients newly diagnosed and testing antibody positive who were reported to the Department had a confirmatory RNA test on the same specimen; and a review of 2015 data shows that 22% of New York City patients newly reported as HCV antibody positive never received confirmatory RNA testing at all. A 2016 Department survey found that 33% of 21 acute care NYC hospitals do not automatically order confirmatory RNA testing for patients with a positive antibody test.

Routine performance of a confirmatory RNA tests is aligned with Centers for Disease Control and Prevention guidelines, and will ensure that patients are accurately diagnosed, promptly treated for HCV, and receive critical related care, such as regular liver cancer screening. (Centers for Disease

Control and Prevention. Testing for HCV infection: an update of guidance for clinicians and laboratorians. *MMWR*. 2013; 62(18):362)

Statutory Authority

The authority for these proposed amendments is found in Sections 556 and 558 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 1043 grants the Department rule-making authority.

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.

Statement pursuant to Charter §1043

This proposal was not included in the Department’s Regulatory Agenda for FY 2017 because the need for the proposal was not known at the time the Regulatory Agenda was promulgated.

The proposal is as follows:

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

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

RESOLVED, that 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 read as follows:

§13.03 Report of findings, supplemental testing, and submission of isolates.

* * *

(b) (3) (A) With regard to hepatitis A, B, or C, 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 hepatitis.

[(A)] (B) 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 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.

[(B)] (C) With regard to hepatitis C[.];

(i) [all] 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. Blood bank laboratories and other laboratories that perform hepatitis C nucleic acid amplification tests on donated blood, without a positive hepatitis C antibody test, are exempt from reporting negative hepatitis C nucleic acid amplification test results for such donated blood.

(ii) If an antibody test is positive for hepatitis C virus, the laboratory must perform, or refer the specimen to another laboratory for performance of, a confirmatory RNA test on the same specimen or a second specimen collected at the same time as the initial specimen. The confirmatory RNA test must be initiated, or the specimen forwarded to another laboratory for that purpose, within 72 hours of obtaining the positive antibody test result.

* * *

**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 Hepatitis C Reporting and Testing Requirements

REFERENCE NUMBER: DOHMH-76

RULEMAKING AGENCY: Board of Health

I certify that this office has analyzed the proposed rule referenced above as required by Section 1043(d) of the New York City Charter, and that the proposed rule referenced above:

- (i) Is understandable and written in plain language for the discrete regulated community or communities;
- (ii) Minimizes compliance costs for the discrete regulated community or communities consistent with achieving the stated purpose of the rule; and
- (iii) Does not provide a cure period because it does not establish a violation, modification of a violation, or modification of the penalties associated with a violation.

/s/ Francisco X. Navarro
Mayor's Office of Operations

May 19, 2017
Date

**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 Hepatitis C Reporting and Testing Requirements

REFERENCE NUMBER: 2017 RG 022

RULEMAKING AGENCY: Board of Health

I certify that this office has reviewed the above-referenced proposed rule as required by section 1043(d) of the New York City Charter, and that the above-referenced proposed rule:

- (i) is drafted so as to accomplish the purpose of the authorizing provisions of law;
- (ii) is not in conflict with other applicable rules;
- (iii) to the extent practicable and appropriate, is narrowly drawn to achieve its stated purpose; and
- (iv) to the extent practicable and appropriate, contains a statement of basis and purpose that provides a clear explanation of the rule and the requirements imposed by the rule.

/s/ STEVEN GOULDEN
Acting Corporation Counsel

Date: May 19, 2017