

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH**

**NOTICE OF INTENTION
TO AMEND ARTICLE 13 OF THE NEW YORK CITY HEALTH CODE**

NOTICE OF PUBLIC HEARING

In compliance with §1043(b) of the New York City Charter (the “Charter”) and pursuant to the authority granted to the Board of Health by §558 of said Charter, notice is hereby given of the proposed amendment of Article 13 of the New York City Health Code (the “Health Code”).

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON OCTOBER 31, 2008 FROM 10:00A.M. TO 12:00P.M. IN THE THIRD FLOOR BOARDROOM (ROOM 330) AT 125 WORTH STREET, NEW YORK, NEW YORK 10013.

PERSONS INTERESTED IN PRE-REGISTERING TO SPEAK SHOULD NOTIFY, IN WRITING, RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK; (212) 788-5010 BY THURSDAY, OCTOBER 30, 2008. PLEASE INCLUDE A TELEPHONE NUMBER WHERE, IF NECESSARY, YOU MAY BE REACHED DURING NORMAL WORKING HOURS. SPEAKERS WILL BE LIMITED TO FIVE (5) MINUTES.

PERSONS WHO REQUEST THAT A SIGN LANGUAGE INTERPRETER OR OTHER FORM OF REASONABLE ACCOMMODATION FOR A DISABILITY BE PROVIDED AT THE HEARING ARE ASKED TO NOTIFY RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET, CN-31, NEW YORK, NEW YORK 10013; (212) 788-5010 BY FRIDAY OCTOBER 17, 2008.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 12:00PM. HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL ADDRESSED TO THE ATTENTION OF THE BOARD OF HEALTH MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, BY MAILING TO 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013, BY FAX TO (212) 788-4315, OR BY E-MAIL TO RESOLUTIONCOMMENTS@HEALTH.NYC.GOV ON OR BEFORE FRIDAY, OCTOBER 31, 2008. THE DEPARTMENT’S GENERAL POLICY IS TO MAKE WRITTEN COMMENTS AVAILABLE FOR PUBLIC VIEWING ON THE INTERNET. ALL COMMENTS RECEIVED, INCLUDING ANY

PERSONAL INFORMATION PROVIDED, WILL BE POSTED WITHOUT CHANGE TO <http://www.nyc.gov/html/doh/html/comment/comment.shtml>.

WRITTEN COMMENTS RECEIVED BY THE SECRETARY TO THE BOARD OF HEALTH AND A TRANSCRIPT OF THE PUBLIC HEARING WILL BE AVAILABLE FOR PUBLIC INSPECTION WITHIN A REASONABLE TIME AFTER RECEIPT, BETWEEN THE HOURS OF 9:00 A.M. AND 5:00 P.M. AT THE OFFICE OF THE SECRETARY.

STATUTORY AUTHORITY

These amendments to the New York City Health Code (“Health Code”) are promulgated pursuant to Sections 556, 558 and 1043 of the New York City Charter (the “Charter”). Section 556 of the Charter provides the Department of Health and Mental Hygiene (“DOHMH” or “Department”) with jurisdiction to regulate all matters affecting the health in the city of New York. Section 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 DOHMH’s authority extends. Section 1043 of the Charter grants the DOHMH rulemaking powers. In addition, §580(3) of the New York State Public Health Law specifically recognizes the authority of the City of New York, or an agency thereof such as DOHMH, to enact laws, codes or regulations affecting clinical laboratories or blood banks.

STATEMENT OF BASIS AND PURPOSE

INTRODUCTION

As part of a comprehensive review of the Health Code to assess the efficacy of its provisions in protecting the public health, the DOHMH proposes to amend current Article 13, Clinical Laboratories, to better reflect practice and the regulatory environment, assure that the revised provisions provide adequate legal tools to effectively ensure the reporting of presumptive and positive laboratory findings for any notifiable disease, condition, outbreak, unusual manifestation of disease or unusual disease listed or referenced in Section 11.03 or in Article 13. Pursuant to this review and assessment of the Health Code, the DOHMH proposes that the Board amend certain of the provisions of current Article 13 as provided for below.

Section 13.01

Subdivisions (a) and (c) would be deleted. Instead, a new definition of “laboratory” or “clinical laboratory”, which terms are used interchangeably, will make clear that those terms also include a blood bank. Separate definitions of “laboratories” and “blood bank” are not necessary since the term “blood bank” is not used in the article. Furthermore, the laboratory testing that blood banks in New York State are required to perform must, pursuant to state regulations, be done in state licensed laboratories. Therefore, the reporting and other requirements of Article 13, which are imposed on clinical laboratories, will also apply to blood banks. The definition of “clinical

laboratory” would be amended to make consistent reference to New York City and to the New York State Public Health Law as used in the Health Code.

Section 13.03

Subdivision (a) would be amended to clarify that only the laboratory that actually tests a clinical specimen must report positive findings, but that a laboratory that refers a specimen to another laboratory for analysis must provide all the information that the testing laboratory will need to fully comply with the reporting requirements. The subdivision would also be revised to clarify that reports of presumptive and positive laboratory findings for all notifiable diseases or conditions, or any other reportable findings, are to be submitted within 24 hours of the clinical laboratory obtaining the results, and that, in addition, reports of presumptive or confirmed laboratory findings for diseases, conditions or occurrences which are urgently reportable pursuant to §11.03(b)(1) or (c) of this Code must be reported immediately by telephone. Subdivision (a) would also be amended to provide greater specificity with regard to which data elements must be reported, including the reporting of race, ethnicity and gender if these data elements are known to the laboratory. Pregnancy status would be specified as reportable if known and if clinically relevant to a positive laboratory result; for example a positive hepatitis B surface antigen or a positive syphilis test result. It should be noted that the Department has programs in place with regard to both these conditions which offer outreach services to affected women in order to mitigate perinatal and congenital transmission. Subdivision (a) would be further amended to specify as reportable quantitative results for any positive or reactive serologic test results related to reportable diseases specified by the Department, and to incorporate the substance of former subdivision (d) of section 11.03 regarding the reporting of antibiotic susceptibility testing results.

Subdivision (b) would be revised to add reporting requirements with regard to laboratory tests related to syphilis and hepatitis.

Subdivision (c) would be amended to delete an outdated reference to July 1, 2006, and to incorporate the substance of former subdivision (e) of section 11.03 allowing laboratories to report to the Department through an electronic reporting system utilized by the New York State Department of Health.

Section 13.05

Subdivision (a) would be amended to update the cross reference to Article 11’s confidentiality provision.

Subdivision (b) would be amended to clarify that negative direct smears to detect acid fast tuberculosis bacilli are not reportable to the Department, but must be reported to the physician, or other person ordering the test, within 24 hours, to update laboratory tuberculosis testing and reporting requirements, including a requirement to perform nucleic acid amplification testing.

Section 13.07 (formerly §13.04)

This section, related to hemoglobin A1C reports, would be renumbered, and subdivision (a) would be amended to clarify that reports are to be submitted within 24 hours of the clinical laboratory obtaining the results.

Subdivision (c) would be modified to clarify that the requirements of subdivision (a) of §13.03, as well as the provisions of paragraphs (1) through (6) of that subdivision, are applicable to hemoglobin A1C reports.

Subdivision (d) would be amended to allow the disclosure of information to the patient's "treating health care providers" as opposed to "treating medical providers" as is currently set forth in the Code. The term "health care provider" is a more generally recognized term that is defined in the state Public Health Law as encompassing both "health care practitioners" and "health care facilities".

The proposal is as follows:

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

RESOLVED, that, effective February 1, 2009, the sections and section headings for Article 13 of the New York City Health Code be and the same hereby are revised, to be printed together with introductory notes to read as follows:

Article 13

Clinical Laboratories

§13.01 Definitions

§13.03 Report of positive findings

[§13.04 Reporting of Hemoglobin A1C]

§13.05 Testing for tuberculosis

§13.07 Reporting of Hemoglobin A1C

Introductory Notes:

As part of a comprehensive review of the Code to assess the efficacy of the articles in protecting the public's health, Article 13 was amended to better reflect public health practice and technology, and assure that the revised provisions provide adequate legal and investigative tools to protect the public's health, including the reporting of positive or reactive laboratory findings indicating the presumptive or confirmed presence of any notifiable disease, condition or occurrence listed or referenced in Section 11.03 or this Article 13, and to update laboratory testing and reporting requirements for tuberculosis and syphilis.

RESOLVED, that, effective February 1, 2009, §§13.01, 13.03 and 13.05 be and the same hereby are amended, to be printed together with explanatory notes to read as follows:

§13.01 Definition[s].

When used in this article [:(a) Laboratories means clinical laboratories and blood banks.

(b)] “laboratory” or [Clinical] “clinical laboratory” shall mean a facility, including a blood bank, regulated pursuant to Public Health Law, Title V, Article 5, holding a permit issued by the New York State Department of Health, and operating in [New York] the City or testing a specimen taken from a [New York] City resident.

[(c) Blood bank shall mean a facility regulated pursuant to Public Health law, Title V, Article 5 and holding a permit issued by the New York State Department of Health.]

Notes:

This section was amended by resolution adopted on [].

§13.03 Report of positive findings.

(a) The director of a clinical laboratory conducting an examination of a specimen submitted for analysis shall report to the Department, within 24 hours of obtaining results, all positive or reactive laboratory findings which indicate the presumptive or confirmed presence of any disease or condition required to be reported by subdivision (a) of §11.03 of this Code, and also any laboratory findings which are otherwise required to be reported pursuant to this section or this Article; provided that findings indicating the presumptive or confirmed presence of diseases or conditions required to be reported pursuant to paragraph (1) of subdivision (b) of §11.03, as well as outbreaks or suspected outbreaks, unusual manifestations of disease or conditions and unusual diseases required to be reported pursuant to subdivision (c) of §11.03, shall also be reported to the Department immediately by telephone. A clinical laboratory which refers a specimen to another laboratory for examination shall provide to the testing laboratory all of the information the testing laboratory will need to fully comply with the reporting requirements set forth in this Article or this Code. Reports shall [state the particulars required by §11.05 and shall include] contain all of the information and data elements

required by the reporting forms or electronic reporting format approved by the Department, including but not limited to:

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

(2) The medical record number if known, identification number or code assigned to the person, if any, and other personal identifiers as may be required by the Department.

(3) The name, [and] address and telephone number of the physician or other authorized [person] health care practitioner [or clinical laboratory] who submitted the specimen, the health care facility, if any, that submitted the specimen, and the clinical laboratory that referred the specimen, if any.

(4) The name and address of the clinical laboratory which performed the test.

(5) The date the test or tests results were first available.

(6) The name(s) of test or tests performed.

(7) The positive or reactive results (including [titer of the] quantitative results related to positive or reactive serologic [test for syphilis] tests for reportable diseases or conditions specified by the Department if quantitative [test] testing was performed).

(8) The antibiotic susceptibility testing results for bacterial diseases listed under subdivision (a) of §11.03 of this Code. This requirement includes traditional broth, agar and newer automated methods of antibiotic susceptibility testing, as well as molecular-based methods that assay for molecular determinants of antibiotic resistance.

(b)(1) With regard to tuberculosis, reports shall also include all laboratory findings which indicate presumptive 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. Such reports shall specify the laboratory methodology used and shall state whether the specimen was susceptible or resistant to each anti-tuberculosis drug at each concentration tested.

(2) With regard to syphilis, any treponemal or non-treponemal results, whether qualitative or quantitative, which are positive or reactive shall be reported to the Department within 24 hours of obtaining any such positive or reactive results. In addition, any negative or non-reactive results, or any quantitative results, on syphilis tests associated with the aforementioned positive or reactive results, and performed by the same laboratory, shall be separately reported to the Department by the laboratory performing the associated syphilis tests within 24 hours of obtaining such results. If a laboratory has been referred a specimen to perform only tests associated with a positive syphilis result obtained at the referring laboratory, and such associated syphilis tests have yielded only negative or non-reactive results, then, notwithstanding anything to the contrary in subdivision (a) of this section, only the referring laboratory shall report said negative or non-reactive results to the Department within 24 hours of obtaining the results. If a laboratory obtains negative or non-reactive results on a specimen submitted for syphilis testing and refers a specimen for further syphilis to another laboratory, and such further syphilis tests yield positive or reactive results, then, notwithstanding anything to the contrary in subdivision (a) of this section, in addition to the testing laboratory reporting such positive or reactive results, the referring laboratory shall report both the negative or non-reactive results obtained by it and also the positive or reactive results of any such further syphilis testing.

(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.

(c) Reports required pursuant to this [section] article shall be made in a manner and form prescribed by the Department. Notwithstanding any other provision of this Code, [effective July 1, 2006,] clinical laboratories shall report to the Department using electronic or computer media prescribed by the Department in a format specified by the Department, including through the use of the electronic reporting system utilized by the New York State Department of Health. Written paper reports may be submitted for a limited period of time only in the case of extenuating circumstances, temporary equipment failure, or prolonged inability to access the Internet, and only with the specific

approval of the Department. In addition, the Department may, on its own initiative, allow written, paper reports to be submitted if electronic reporting is not possible in a particular circumstance, as a result of a deficiency in the Department's or the State Health Department's electronic reporting system. The Department may, in addition, require summary, cumulative or periodic reports on such reporting schedule as it may deem necessary.

Notes:

This section was amended by resolution adopted on [].

§13.05 Testing for tuberculosis.

A clinical laboratory authorized to perform tests for tuberculosis, including the growth of cultures from clinical specimens for the isolation of mycobacteria, shall adhere to the following minimum requirements:

(a) Within 24 hours of observing growth of a culture or subculture of *M. tuberculosis* complex, a portion of the initial culture or subculture from any specimen from which *M. tuberculosis* complex has been isolated shall be submitted to the Department for DNA or other molecular analysis.

[(i)] (1) A laboratory which submits a specimen to the Department for drug susceptibility testing shall be deemed to have complied with [subsection] subdivision (a) of this section unless otherwise notified by the Department.

[(ii)] (2) The Department's records relating to such DNA analysis shall be confidential in accordance with [§11.07] §11.11 of this Code.

(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 [direct] concentrated smears for AFB are performed on clinical specimens (e.g., sputum) the results shall not be reported to the Department unless positive. Negative [direct] smears shall be [concentrated and] 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). 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 or a laboratory designated by the Department; and

(2) Conventional cultures of clinical specimens shall be initiated within 24 hours after receipt, shall be examined for growth at least once each week after inoculation and, upon observing adequate suspicious growth, an acid fast smear examination shall be performed. Identification of M. tuberculosis complex shall be completed within four (4) working days after adequate suspicious growth is first observed; and

(3) Cultures of clinical specimens [by radiometric methodology] shall be completed within fifteen (15) working days after growth is first indicated. Identification of M. tuberculosis complex shall be completed within four (4) working days after adequate suspicious growth is first observed; and

(4) If direct drug susceptibility testing is performed it shall be initiated within 24 hours or the next scheduled workday after obtaining a smear positive for acid fast bacilli, and, if indirect drug susceptibility testing of pure cultures is performed, it shall be initiated [within seven workdays after] as soon as growth typical of M. tuberculosis is observed [or its speciation]; and

(5) If the time periods provided in paragraphs 1 through 4 above cannot be adhered to by the receiving laboratory, then specimens shall be forwarded to another clinical laboratory within 24 hours [or the next scheduled workday] after receipt of a specimen [or the determination by the receiving laboratory that such time period cannot be met]; and

(6) For other laboratory techniques and methodologies, [including but not limited to radiometric techniques,] examination schedules recommended by the manufacturer of each such methodology shall be adhered to; and

(7) The result of any test or examination related to tuberculosis including but not limited to those specified in this section shall be reported to the physician or other person authorized to request clinical laboratory tests, or the forwarding laboratory, if any, within 24 hours of the test result or finding.

Notes:

This section was amended by resolution adopted on [].

RESOLVED, that, effective February 1, 2009, §13.04, Reporting of Hemoglobin A1C, be amended and renumbered as §13.07 to read as follows:

§ 13.07. Reporting of Hemoglobin A1C.

(a) All clinical laboratories, as defined under §13.01 of this Article, that report laboratory test results electronically to the Department and which use a file up-load method, shall electronically report to the Department all laboratory results for Hemoglobin A1C tests, as defined in [subsection] subdivision (b) of this section, within 24 hours of obtaining such results.

(b) The “Hemoglobin A1C” laboratory test represents an index of blood glucose control measuring average blood sugar over the past 90 days, and shall mean the following for the purposes of this section: HgbA1c; HgbA1c by HPLC; HbA1c; Glycohemoglobin A1C; Gycolhaemoglobin; Glycohemoglobin; Glycated Hgb; Glyco-Hb; GHb; Ghb. As defined in this section, “Hemoglobin A1C” shall not mean the following: Hgb; Hemoglobin; Hb; Hb without reference to glycated or glycosylated or A1C; or Glycohemoglobin total.

(c) Reports required by subsection (a) shall contain the information required in §13.03 (a)[(1) through (6)] of this Article and of paragraphs (1) through (6) thereof.

(d) Hemoglobin A1C test results and other identifying information reported to the Department pursuant to this section shall be confidential and shall not be disclosed to any person other than the individual who is the subject of the report or to such person’s treating [medical] health care providers. If the subject of the report is a minor, information can be disclosed to the subject’s parent or legal guardian.

Notes: Section 13.07 was renumbered without substantive change from its predecessor, former section 13.04, by resolution adopted on [].

