

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

NOTICE OF INTENTION TO AMEND SECTIONS 13.01(b) and 13.03 (c)
OF THE NEW YORK CITY HEALTH CODE

NOTICE OF PUBLIC HEARING

In compliance with Section 1043(b) of the New York City Charter and pursuant to the authority granted to the Board of Health by Section 556 and 558 of said Charter, notice is hereby given of the proposed amendments of Section 13.01(b) and 13.03(c) the New York City Health Code.

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE (the "DEPARTMENT") WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON OCTOBER 28, 2004 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 OCTOBER 27, 2004. 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 OCTOBER 14, 2004.

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

WRITTEN COMMENTS REGARDING THE PROPOSAL MUST BE SUBMITTED TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET, CN-31, NEW YORK, NEW YORK 10013, OR BY E-MAIL TO THIS ADDRESS PUBLICCOMMENTS@HEALTH.NYC.GOV, OR BY FAX ADDRESSED TO RENA BRYANT AT (212) 788-4315, ON OR BEFORE THURSDAY, OCTOBER 28, 2004.

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

This amendment to the New York City Health Code is promulgated pursuant to Sections 558 and 1043 of the Charter. Sections 558(b) and (c) of the Charter empower the Board of Health to amend the Health Code and to include in the Health Code all matters to which the Department's authority extends. Section 1043 grants the Department rule-making authority. Further, New York State Public Health law authorizes DOHMH 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." [Public Health Law Section 580 (3)].

STATEMENT OF BASIS AND PURPOSE

Disease surveillance is a primary function of the Department and is a cornerstone to the overall health of New York City: without disease surveillance, it is difficult to determine the extent of disease and the need for intervention. Disease surveillance, and laboratory surveillance in particular, is a vital component of New York City's bioterrorism preparedness infrastructure. By closely monitoring clinical laboratory reports, the Department is able to observe and promptly investigate diseases and conditions required to be reported to the Department (including those potentially related to bioterrorism (BT) agents). To this end, it is essential that clinical laboratory reports be obtained as soon as possible once the result of the test is available. Electronic clinical laboratory submissions are critical for effective and timely interventions.

Electronic clinical laboratory reporting is of great benefit to the Department because: 1) Electronic clinical laboratory reporting enhances the Department's surveillance infrastructure and bioterrorism preparedness capabilities; 2) It brings the Department closer to the Centers for Disease Control and Prevention (CDC) electronic surveillance standards as defined in the Public Health Information Network (PHIN) initiatives; 3) It improves the completeness, timeliness, and accuracy of reports; 4) It provides an integrated system for the standardization of reporting methodologies for the reporting of mandatory reportable conditions; and 5) It allows for seamless delivery of electronic data to the Department program area's databases. In contrast, paper reporting is, in general, slow and often incomplete, and reportable conditions are often underreported. In addition, paper reports require the additional step of data entry, which is eliminated when reports are received electronically.

The Department has been accepting clinical laboratory reports in electronic format for several years as part of the Electronic Clinical Laboratory Reporting System (ECLRS) project. The Electronic Clinical Laboratory Reporting System (ECLRS) is a web-based

reporting system initially developed by the New York State Department of Health (NYSDOH) that provides laboratories with a uniform interface for reporting diseases and conditions such as tuberculosis (TB), sexually transmitted diseases (STD), communicable diseases (CD), HIV, lead, and cancer. ECLRS enables participating laboratories to use recognized standards to report positive test results over secure channels to the NYSDOH and the Department. Data confidentiality is ensured by the use of 128-bit encryption technology for both data transmission and data storage.

Both hospital-based and commercial clinical laboratories in New York City are targeted for full ECLRS implementation. Complete ECLRS implementation means that the clinical laboratory is electronically submitting every reportable condition tested in house at that laboratory. There are approximately 127 laboratories (including commercial laboratories and hospital-based laboratories) currently operating in New York City. Of the commercial laboratories in New York City, approximately 22% (14/65) have been enrolled in ECLRS; of the hospital-based laboratories, approximately 82% (51/62) have been enrolled in ECLRS. Of those facilities enrolled in ECLRS, few are submitting all reportable conditions electronically to the Department.

The Department proposes to amend Section 13.03(c) of the New York City Health Code to require that effective January 1, 2006, clinical laboratories must report to the Department electronically test results that are associated with diseases and conditions required to be reported to the Department, in a format specified by the Department.

Clinical laboratories experiencing temporary equipment failure or prolonged inaccessibility to the Internet may submit written, paper reports with the approval of the Department.

The Department is also proposing to amend the definition of clinical laboratory in Section 13.01(b) to clarify that a clinical laboratory is defined as a regulated facility pursuant to State law, holding a permit issued by the New York State Department of Health and operating within New York City or testing specimens taken from New York City residents.

The proposal is as follows:

Note – matter underlined is new

Matter in brackets [] to be deleted

RESOLVED, that subsection (b) of Section 13.01 of the New York City Health Code be and the same hereby is amended to be printed together with explanatory notes, to read as follows:

(b) Clinical laboratory 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, and operating in New York City or testing a specimen taken from a New York City resident.

Notes: This provision is being amended to clarify the definition of a clinical laboratory to include a facility regulated pursuant to the New York State Public Health Law, holding a NYS DOH license and operating within New York City or testing a specimen taken from a New York City resident.

RESOLVED, that subsection (c) of Section 13.03 of the New York City Health Code (Title 24 of the Rules of the City of New York) be and the same hereby is amended to be printed together with explanatory notes, to read as follows:

(c) Reports required pursuant to this section shall be made in a manner and form described by the Department. [The Department may require reports to be made in and in writing or prescribed forms, electronic or computer media, and] Notwithstanding any other provision of this Code, effective January 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. Written, paper reports may be submitted only in the case of temporary equipment failure or prolonged inaccessibility to the Internet and only with the specific approval of the Department. The Department may, in addition, require summary, cumulative or periodic reports on such reporting schedule as it may deem necessary.

Notes: This provision is being amended to require clinical laboratories to report to the Department electronically by January 1, 2006.

NOI-Amend 13.01 (b) and 13.03(c)