

DEPARTMENT OF HEALTH
BOARD OF HEALTH

NOTICE OF ADOPTION OF AMENDMENTS TO SECTIONS 13.01(b) AND 13.03 (c)
OF THE NEW YORK CITY HEALTH CODE

In compliance with Section 1043(b) of the New York City Charter (the ACharter@), a Notice of Intention to amend Sections 13.01 (b) and 13.03 (c) of the New York City Health Code and a notice of public hearing was printed in the City Record on Friday, September 22, 2004. A public hearing was held on October 28, 2004. Three written comments were received, and the Department further amended the proposal based on the comments. The Board of Health at its December 7, 2004 meeting adopted the following:

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 is amending Section 13.03(c) of the New York City Health Code to require that effective July 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, prolonged inability to obtain access to the Internet, or other extenuating circumstances, may submit paper reports for a limited period of time, but only with the specific approval of the Department. In addition, the Department may on its own initiative allow paper reports in a particular circumstance as a result of a deficiency in the Department's electronic reporting system.

The Department also amended 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 amendments are 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 was 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 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. 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 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 provision was amended to require clinical laboratories to report to the Department electronically by July 1, 2006.