

▲ New York Blood Center

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October 30, 2008

Department of Health and Mental Hygiene
Board of Health
125 Worth Street CN-31
New York, NY 10013

Attention: Rena Bryant, Secretary to the Board of Health

Re: **Article 13 of the New York City Health Code**

New York Blood Center ("NYBC") is one of the nation's largest community blood centers, collecting blood from nearly 500,000 people annually. NYBC respectfully submits these comments in response to the recent proposal by the New York City Department of Health and Mental Hygiene ("DOHMH") to amend Sections 13.01 and 13.03 of the New York City Health Code (the "Health Code"). These proposed amendments expand the definition of a "clinical laboratory" to include blood banks. The proposed amendments further require that only the laboratory that actually tests a specimen report positive findings to DOHMH, and that the clinical laboratory that refers the specimen to the testing laboratory for analysis provide to the testing laboratory all information needed to fully comply with the reporting requirements set forth in the Health Code. NYBC is concerned that, if implemented, these amendments could compromise the efficiency of current reporting practices of blood banks and result in increased time and operations costs to blood collection facilities.

NYBC currently outsources all of its serological communicable disease testing of blood donations to Blood Systems Laboratory, a New York State licensed testing laboratory located in Scottsdale, Arizona. This laboratory performs blood donation testing for a number of blood collection centers in the United States. On average, Blood Systems Laboratory tests samples from between 1,500 to 2,000 donations per day for NYBC. In accordance with blood collection industry standards and U.S. Food and Drug Administration ("FDA") guidance, the samples sent to this testing laboratory are identified using only an ISBT or Codabar donation identification barcode.¹ These unique identifiers are recorded in the donor's record at the blood bank and become the primary modality used to electronically track samples for reporting purposes, as well as to appropriately notify donors of test results, assess donors for inclusion in donor referral registries, or withdraw donated units from inventory. Once the blood bank receives the test results back from the testing laboratory, the blood bank performs appropriate

¹ See AABB Standards for Blood Banks and Transfusion Services, 25th Ed. (2008), and FDA Guidance, United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 218 version 2.0.0 (2005).

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notifications within the required time frame regarding any donor with a reportable test result. It is standard practice for blood banks such as NYBC to report positive findings directly to the relevant branch of the Department of Health ("DOH"). This reporting is performed via ECLRS, HIV DOH manual reporting, or the NYS Communicable Diseases report form DOH389. These existing reporting practices have proven to be efficient and effective in allowing blood banks to comply with reporting requirements on the state, county, and city levels.

As the testing laboratory does not bill donors or their insurance for blood donation testing, there is no need for the clinical laboratory to be in possession of donors' identifying information along with their testing results. If the proposed amendments to the Health Code are implemented, NYBC would have to supply the testing laboratory with the relevant identifiers for all of the samples submitted for testing so that the laboratory could report the positive test results in a timely manner. Putting systems in place to perform electronic transmission of data to the testing laboratory would result in significant time and expense to NYBC without any added benefit or efficiency to the public health reporting system. NYBC would have to design and validate new electronic interfaces in order to accurately transmit this data to the testing laboratory. NYBC also would need to coordinate this effort with the testing laboratory, which does not currently have the electronic systems in place to receive and maintain such data. The testing laboratory may be unable or unwilling to undertake such system changes, or may charge a premium for testing services in exchange for the time and expense of implementing these new data transmission systems. Ultimately, the increased expense to NYBC and the testing laboratory of creating and maintaining such systems would be passed onto our hospital customers and could result in an increase in the cost of our blood products.

Under the current system, there is no risk that duplicate reports of positive infectious disease testing results would be submitted since only the blood bank, and not the testing laboratory, has access to the donor's identifying information. Further, FDA regulations require blood centers to comply with current good manufacturing practices ("cGMPs").² This adherence to cGMPs helps to ensure the accuracy and efficiency of our reporting.

In conclusion, NYBC believes that the current reporting structure has operated efficiently and effectively, and will continue to meet the needs of the DOHMH, while helping to maintain an adequate and safe blood supply. NYBC is not aware of any concerns or objections from either state or city authorities with regard to the accuracy or reliability of blood banks' current reporting practices. Because changes to these practices under the proposed amendments to the Health Code could compromise the accuracy and efficiency of reporting, as well as increase operations costs, we are requesting that these amendments be revised to allow blood banks that outsource donation testing to continue to directly report required communicable disease testing results to DOH and DOHMH.

² Sec 21 C.F.R. Part 606

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Resolution Comments

From: Perry F. Smith [pfs01@health.state.ny.us] **Sent:** Thu 10/30/2008 9:22 AM
To: Resolution Comments
Cc: Hwa-Gan Chang; David K. DiCesare; F. Bruce Coles; Margaret J. Oxtoby; Barbara J. Wallace; Lou Smith; Jennifer Baumgartner
Subject: Re: Fw: NYC Health Code Proposed Revisions to Article 13/ Comments can be made by October 31. Also a public hearing on October 31.

Attachments:

Please see the following comments that we have about the proposed NYC regulations. Thanks.

Perry F. Smith, MD
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David K.
 DiCesare/DEPI/CCH
 /OPH/DOH

To

10/29/2008 01:22 PM Perry F.
 Smith/DEPI/CCH/OPH/DOH@NYSDOH
 cc

Hwa-Gan
 Chang/DEPI/CCH/OPH/DOH@NYSDOH
 Subject

Fw: NYC Health Code Proposed
 Revisions to Article 13/ Comments
 can be made by October 31. Also a
 public hearing on October 31.

The following are comments which we feel need to be made about the proposed revisions listed from the announcement below.

Section 13.03 - Pregnancy status would be specified as reportable if known and if clinically relevant to a positive laboratory result...

- Due to current informatics technology (IT) constraints, it should be noted that the only way to electronically submit the pregnancy status of a patient is through a comment or note. There currently is no such element with Health Level 7 file structures to report a pregnancy, and therefore, there is also no such data field within the NYS electronic

reporting system to hold this information other than in a note or comment.

Section 13.03 - 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.

- Due to current IT constraints, it should be noted that many of the electronic interfaces between referring and testing facilities do not have the capability of transmitting all of the information requested within this document as much of the information is maintained outside of the laboratory system at the referring facility where the interface with the testing facility is connected. It is not currently known if the interface between facilities can be modified to extract the requested data through another system at the requesting facility, and if so, the cost that would be required to make this connection.

Dave DiCesare
NYS ELR Co-ordinator
ECLRS Help Desk
(866) 325-7743

----- Forwarded by David K. DiCesare/DEPI/CCH/OPH/DOH on 10/29/2008 12:42 PM -----

Hello,

As someone interested in NYC public health policy and laboratory reporting, we are sending you a link to the proposed revisions to Article 13 of the NYC Health Code. As part of a comprehensive review of the Health Code, 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. The entire Notice of Public Hearing and proposal can be found at: <http://home2.nyc.gov/html/doh/downloads/pdf/notice/article-13-intention-08.pdf> You will see in the Notice that comments can be made by October 31, 2008 on line or by email. The public hearing date is October 31, 2008 as well. All of the details regarding how to comment or testify at a hearing are in the Notice.

Thank you, Jennifer

Jennifer Baumgartner
City Research Scientist/ECLRS Project Manager
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Resolution Comments

From: Wollock, Andrea J [Andrea.J.Wollock@questdiagnostics.com] **Sent:** Thu 10/30/2008 11:55 AM
To: Resolution Comments
Cc:
Subject: Comments: Article 13 Amendments, New York City Health Code
Attachments:

RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH

Dear Ms. Bryant:

Quest Diagnostics Incorporated is the leading provider of diagnostic testing, information and services that patients and doctors need to make better healthcare decisions. The company offers the broadest access to diagnostic testing services through its national network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. We appreciate the opportunity to provide comments on Article 13 amendments to the New York City Health Code.

We wish to comment on only one section of the new amendments (see below).

Section 13.05(b)(7) Testing for tuberculosis.

"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."

Comment: Although we are in agreement with the medical community that identification and isolation of individuals with *Mycobacteria tuberculosis* (MTB) is crucial for helping to ensure the disease is not transmitted to others, this testing will initially be problematic to the laboratory. Currently we find that the collection of respiratory specimens is less than optimal for the amount of testing to be performed. We see that the volume of specimen submitted for acid-fast smear and culture is usually close to our minimum requirement. The necessity to split the sample for the additional nucleic acid amplification test would most likely provide a quantity not sufficient to provide adequate culture sensitivity. In addition, since New York City would be the only jurisdiction with this requirement, laboratories performing tuberculosis testing for a larger geographic area would face a significant operational burden. Segregating NYC specimens, to ensure different handling, would require additional time and staff.

Please feel free to contact me with any questions or concerns. My contact information is at the bottom of this email.

Thank you,

Andrea Wollock

Andrea J. Wollock | Director, State Government Affairs | Quest Diagnostics | 815 Connecticut Avenue, 40th Floor, New York, NY 10022 | Tel: 212-261-0201 | Fax: 212-261-0202 | Email: Andrea.J.Wollock@questdiagnostics.com

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