

DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BOARD OF HEALTH

NOTICE OF INTENTION
TO AMEND ARTICLES 11, 45 AND 49 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 558 of said Charter, notice is hereby given of the proposed amendment of §§11.03, 11.47, 45.09 and 49.06, and repeal of §11.48 of the New York City Health Code with respect to diagnostic testing for tuberculosis.

NOTICE IS HEREBY GIVEN THAT THE DEPARTMENT OF HEALTH AND MENTAL HYGIENE WILL HOLD A PUBLIC HEARING ON THE PROPOSAL ON TUESDAY, OCTOBER 31, 2006 FROM 10:00 AM TO 12:00 PM 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 5:00 PM, MONDAY, OCTOBER 30, 2006. 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 TUESDAY, OCTOBER 17, 2006.

REGISTRATION WILL BE ACCEPTED AT THE DOOR UNTIL 10:00AM HOWEVER, PREFERENCE WILL BE GIVEN TO THOSE WHO PREREGISTER.

WRITTEN COMMENTS REGARDING THE PROPOSAL MUST BE SUBMITTED BY MAIL TO RENA BRYANT, SECRETARY TO THE BOARD OF HEALTH, 125 WORTH STREET CN-31, NEW YORK, NEW YORK 10013 OR BY E-MAIL TO: RESOLUTIONCOMMENTS@HEALTH.NYC.GOV OR BY FAX TO RENA BRYANT AT (212) 788-4315 ON OR BEFORE 5:00 P.M. ON OCTOBER 31, 2006.

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 (“Charter”). Section 556 of the Charter grants the Department of Health and Mental Hygiene (the “Department”) jurisdiction to regulate matters affecting health in the City of New York. Section 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 of the Charter grants the Department rule making powers.

STATEMENT OF BASIS AND PURPOSE

In the City of New York, the Department’s Bureau of Tuberculosis Control is responsible for carrying out the Department’s duties under the Public Health Law, Charter, Health Code and State Sanitary Code of preventing transmission of tuberculosis (TB) disease and securing treatment for persons who have or are suspected of having TB. While the Department has been highly successful during the past decade in controlling TB transmission, including transmission of disease caused by highly resistant strains of TB, the challenge for the Department is to identify and prevent further illness from developing in populations currently at highest risk for TB exposure and disease. A first step in such efforts is testing for TB infection and use of an accurate test is essential. When active disease is ruled out in a person with positive test results, the Department recommends that such persons receive treatment for latent TB infection (LTBI) to prevent future development of active disease.

The tuberculin skin test administered by the Mantoux method (TST) has been used to screen for *Mycobacterium tuberculosis* infection for over a century. However, the TST has several disadvantages and there has been much interest in developing a new test to better detect TB infection.¹ Recently a new blood-based test, QuantiFERON®-TB Gold (QFT-G; Cellestis Limited, Carnegie, Victoria, Australia), was approved by the U.S. Food and Drug Administration (FDA). The U.S. Centers for Disease Control and Prevention (CDC) released guidelines in December 2005 that stated that QFT-G can be used in all settings in which the TST is used.² QFT-G is an enzyme-linked immunosorbent assay (ELISA) that detects the release of interferon-gamma (IFN- γ) in whole blood from sensitized persons when it is incubated with mixtures of synthetic peptides that simulate proteins present in *M. tuberculosis*. QFT-G has shown similar sensitivity and better specificity than the TST.³⁻⁶ Additionally, QFT-G results are not subjective like the TST and the test only requires one patient visit. Two other blood-based TB tests, including a new version of QFT-G, are currently being reviewed by the FDA and are expected to receive approval in the near future. There has been increasing demand for QFT-G in the community and soon it likely will be offered by many non-DOHMH providers. Blood-based tests are expected to become the standard means of detecting TB infection. Therefore, it is important that the Health Code reflect the availability of these tests and the change in TB control practice.

Accordingly, it is proposed that all provisions of the Health Code that pertain to tuberculosis testing, currently only referring to skin testing, be amended to allow use of both tuberculin skin testing administered by the Mantoux method and the new FDA approved blood-

based tuberculosis diagnostic test. These provisions include §11.03 (“Diseases and conditions reportable”) and §11.47 (“Tuberculosis; reporting, examination, exclusion, removal and detention”) in Article 11 (Reportable Diseases and Conditions”); §45.09 (“Staff”) in Article 49 (“General Provisions Governing Schools and Children’s Institutions”) and §49.06 (“Mandatory tuberculosis examination”) in Article 49 (“Schools”). Amendments to provisions relating to required tuberculosis examinations for day care services staff in Article 47 were adopted by the Board of Health at its June, 2006 meeting.

Additionally, it is proposed that the tuberculosis examination requirement for home employees in §11.48 (“Home Employees; testing for tuberculosis; referral.”) be repealed, as no longer serving any substantive public health purpose. Since 1974, this provision has required that home employees, working for eight or more hours weekly in a household occupied by children aged six and under have pre-employment and annual tuberculin skin tests. The tested employee is required to present to the employer a written certification from a physician indicating that he or she is “free of tuberculosis in a communicable form.” Although §11.48 (c) requires this certification to be retained by the employee and “exhibited to a duly designated representative of the Department on request,” it is impossible to know if this testing requirement has been complied with in any regard. Moreover, the current view of the purpose of conducting screening for tuberculosis infection is to identify individuals with latent infection in order to provide treatment to prevent active tuberculosis disease. Although Department records show that there are, on average, four cases of active tuberculosis per year reported as occurring among private home employees, none of these cases were reported as a result of pre-employment or annual screening.

References

1. Menzies RI. Tuberculin Skin Testing. In: Reichman LB, Hershfield ES, eds. *Tuberculosis. A Comprehensive International Approach*. Vol 144. 2nd ed. New York: Marcel Dekker, Inc.; 2000:279-322.
2. Mazurek GH, Jereb J, Lobue P, Iademarco MF, Metchock B, Vernon A. Guidelines for using the QuantiFERON-TB Gold test for detecting Mycobacterium tuberculosis infection, United States. *MMWR Recomm Rep*. 2005;54:49-55.
3. Mori T, Sakatani M, Yamagishi F, et al. Specific detection of tuberculosis infection: an interferon-gamma-based assay using new antigens. *Am J Respir Crit Care Med*. 2004;170:59-64.
4. Kang YA, Lee HW, Yoon HI, et al. Discrepancy between the tuberculin skin test and the whole-blood interferon gamma assay for the diagnosis of latent tuberculosis infection in an intermediate tuberculosis-burden country. *JAMA*. 2005;293:2756-2761.
5. Ferrara G, Losi M, Meacci M, et al. Routine hospital use of a new commercial whole blood interferon-gamma assay for the diagnosis of tuberculosis infection. *Am J Respir Crit Care Med*. 2005;172:631-635.
6. Taggart EW, Hill HR, Ruegner RG, Litwin CM. Evaluation of an In Vitro Assay for Interferon g Production in Response to the Mycobacterium tuberculosis– Synthesized Peptide Antigens ESAT-6 and CFP-10 and the PPD Skin Test. *Am J Clin Pathol*. 2006;125:467-473.

STATEMENT PURSUANT TO SECTION 1042- REGULATORY AGENDA

This proposal was not included in the Regulatory Agenda because it is the result of recent analysis by the Department.

The proposal is as follows:

Note- matter in brackets [] to be deleted

matter underlined is new

RESOLVED, that paragraph (6) of subdivision (a) of section 11.03 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as amended by resolution adopted on the sixteenth day of June, two thousand and six, be and the same hereby is amended, to be printed together with explanatory notes, to read as follows:

§11.03 Diseases and conditions reportable.

* * *

Tuberculosis, as demonstrated by:

* * *

(6) Positive reaction to the [purified protein derivative (PPD)] tuberculin skin test administered by the Mantoux [test] method or a positive result for a U.S. Food and Drug Administration approved blood-based tuberculosis diagnostic test in a child less than five years of age, regardless of whether such person has had a BCG vaccination.

Tularemia

* * *

Notes: Subsection (a) of §11.03 was further amended by resolution adopted on XXX to add to the definition of tuberculosis a positive result in a U.S. Food and Drug Administration approved blood-based tuberculosis diagnostic test in a child under five years of age.

RESOLVED, that subsection (b) of section 11.47 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as added by resolution adopted on the ninth of March, nineteen hundred ninety-three, be and the same hereby is, amended, to be printed together with explanatory notes, to read as follows:

§11.47 Tuberculosis; reporting, examination, exclusion, removal and detention.

* * *

(b) A physician who attends a case of active tuberculosis shall examine or cause all household contacts to be examined or shall refer them to the Department for examination. The physician shall promptly notify the Department of such referral. When required by the Department, non-household contacts and household contacts not examined by a physician shall submit to examination by the Department. An examination required by this section shall include such tests as may be necessary to diagnose the presence of tuberculosis, including but not limited to [tuberculin tests] tuberculin skin tests administered by the Mantoux method or U.S. Food and Drug Administration approved blood-based tuberculosis diagnostic tests, and where indicated, laboratory examinations, and x-rays. If any suspicious abnormality is found, steps satisfactory to the Department shall be taken to refer the person promptly to a physician or appropriate medical facility for further investigation and, if necessary, treatment. Contacts shall be re-examined at such times and in such manner as the Department may require. When requested by the Department, a physician shall report the results of any examination of a contact.

* * *

Notes: Subdivision (b) of §11.47 was amended by resolution adopted on XXX to add that examinations of contacts may include either a U.S. Food and Drug Administration approved blood-based tuberculosis diagnostic test or a tuberculin skin test.

RESOLVED, that section 11.48 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as added by resolution adopted on the nineteenth of December, nineteen hundred seventy-four, be and the same hereby is, repealed.

[§11.48 Home employees; testing for tuberculosis; referral.]

RESOLVED, that the listing of section headings in Article 11 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as amended by resolution adopted on the fourth of December, two thousand one, be further amended, to be printed together with explanatory notes as follows:

Article 11

Reportable Diseases and Conditions

* * *

§11.47 Tuberculosis; reporting, examination, exclusion, removal and detention.

§11.48 Home Employees; testing for tuberculosis; referral. - Repealed

§11.49 Typhoid fever; isolation and exclusion.

* * *

Notes: Section 11.48 (“Home Employees; testing for tuberculosis; referral”) was repealed by resolution adopted on XXX. This provision required pre-employment and annual tuberculosis testing of such employees to determine if they are “free of tuberculosis in a communicable form.” The current view of the purpose of screening for tuberculosis infection is to identify individuals with latent infection in order to provide treatment to prevent active tuberculosis disease. None of the Department reports of active tuberculosis disease occurring in home employees, approximately four cases per year, resulted from pre-employment or annual screening, and the provision no longer appears to serve any substantive public health purpose.

RESOLVED, that subsection (c) of §45.09 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as amended by resolution adopted on the twelfth of December, two thousand and two, be and the same hereby is, amended, to be printed together with explanatory notes, to read as follows

§45.09 Staff

* * *

(c) A person in charge, teacher, volunteer worker or any other person who regularly associates with children shall not be permitted to work in a school, children’s institution, or public or private high school nor shall any person [who is a member of] employed by the Department of Parks and Recreation [in the Recreational Occupational Group, as defined in the Rules of the Civil Service Commission, and] who regularly associates with children under the age of sixteen years in the course of an organized recreational or play program be permitted to work with such children unless a tuberculin skin test administered by the Mantoux method (“tuberculin skin test”) or a U.S. Food and Drug Administration (“FDA”) approved blood-based tuberculosis diagnostic test is performed before he or she begins employment and thereafter at such intervals

as may be prescribed by the Department as necessary for the protection of children, subject to the following conditions.

(1) The tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test shall be administered and interpreted either by the Health Department or by a private physician. If the tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test shall be administered and interpreted by a private physician, it shall be administered and interpreted in accordance with such criteria as may be established by the Department to insure the accuracy of the results of such test. If the [person does not react to the] tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test is negative, X-ray examination will not be necessary. If the [person reacts to the] tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test is positive, [he] the person shall be X-rayed. The X-ray film shall either be taken by the Department or by a private physician. Such film shall be interpreted independently by at least two qualified interpreters of chest X-rays as defined by §1.03(q) of this Code. If an X-ray film is taken by a private physician, a report containing an interpretation of such film shall be specifically identified and submitted to the Department together with certificates on forms furnished by the Department. If the Department requires, the person shall be given further medical and laboratory examination and treatment, if deemed necessary by the Department.

(2) If the [person does not react to the] person's tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test result is negative or if the [person reacts to the] person's tuberculin skin test or FDA blood-based tuberculosis diagnostic test result is positive but a satisfactory X-ray film has been taken or a satisfactory X-ray report has been received by the Department, and he or she is deemed by the Department as not requiring further medical or laboratory examinations, a certificate of compliance shall be issued by the Department and kept on file by the school, children's institution, or public or private high school so long as the person is employed and two years thereafter.

(3) The requirement for a tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test shall not apply when a person presents satisfactory proof that he or she (a) was treated for or diagnosed as having tuberculosis in the past, or (b) had reacted positively to a tuberculin skin test or FDA approved blood-based tuberculosis diagnostic test or (c) had a BCG vaccination within the five years immediately preceding such employment, in which case a chest X-ray shall be taken in lieu thereof, in accordance with the provisions of subdivision (1) of this

subsection.

Notes: Subsection (c) was amended by resolution adopted on XXX to allow use of both FDA approved blood-based tuberculosis diagnostic and tuberculin skin tests to be used for diagnosing tuberculosis infection.

RESOLVED, that §49.06 of the New York City Health Code, set forth in title 24 of the Rules of the City of New York, as last amended by resolution adopted on the tenth of June, nineteen hundred ninety-six, be, and the same hereby is, amended to be printed with explanatory notes, to read as follows:

§49.06 Mandatory tuberculosis examination for students.

(a) As used in this section, unless the context requires otherwise:

(1) The term “certificate of tuberculosis examination” shall mean a form, acceptable to the Department which includes:

* * *

(iv) The type of [skin] tuberculosis test administered to said person;

(v) The date the [skin] tuberculosis test was administered;

(vi) The date of reading the reaction to the skin test or the date of specimen collection for a blood-based tuberculosis test;

(vii) The reaction to the skin test recorded in millimeters or the result of a blood-based tuberculosis test, and the interpretation of either test result as positive or negative;

* * *

(x) The name and address of the physician or agency administering the [skin] test for tuberculosis infection and, if necessary, the chest x-ray if different;

* * *

(9) The term “blood-based tuberculosis test” shall mean and include any blood-based test that is approved for use by the U.S. Food and Drug Administration for detecting tuberculosis infection.

[(9)] (10) The term “tuberculosis examination” shall mean and include the administration, and reading between 48 and 72 hours of administration, of a skin test or the administration of a blood-based tuberculosis test and, if there is a significant reaction to the skin test or if the blood-based test is positive, the administration and reading of a chest x-ray within 14 days of

the reading of a significant reaction to the skin test or the receipt of the positive blood-based test result.

* * *

(c) If, during the 14 day period specified in subsection (b) above, the person in parental relation to the new entrant child can furnish a certificate of tuberculosis examination showing a significant reaction to the skin test or a positive blood-based tuberculosis test result but no reading of a chest x-ray, the new entrant child may continue to attend school for an additional 14 days. If, during said additional 14 day period, the person in parental relation to the new entrant child does not furnish a certificate of tuberculosis examination showing a reading of a chest x-ray, the principal or person in charge of the school shall exclude said new entrant child from continued school attendance until such time as a complete certificate is furnished.

* * *

(f)(1) By October 30th of each year the principal or person in charge of a secondary school shall file with the Department's Bureau of Tuberculosis Control a report, covering the period of September 1 to October 15 of that year, which shall include:

* * *

(ii) the number of new entrants, by age group and country of birth, who fulfilled the requirements of this section, including the number of such children with negative skin or blood-based tuberculosis tests and the number with [significant reaction skin] positive skin or blood-based tuberculosis tests with both normal and abnormal chest x-ray readings;

Notes: Section 49.06 was further amended by resolution adopted on XXX to authorize diagnostic testing for tuberculosis infection by both a U.S. Food and Drug Administration approved blood-based test and a tuberculin skin test.

S: articles114549rev