CHAPTER 17: LAWS GOVERNING TUBERCULOSIS IN NEW YORK CITY

INTRODUCTION

This chapter summarizes the laws and regulations applicable to tuberculosis (TB) control in New York City (NYC).

Reporting of TB and several aspects of TB control practices are governed by various New York State (NYS) and NYC laws, namely: the NYS Sanitary Code (contained in Volume 10 of the New York Codes, Rules and Regulations [NYCRR]), the NYS Public Health Law, and the NYC Health Code. Further, pursuant to the NYC Charter, legal mandates are at times issued by way of mayoral Executive Order.

These laws balance individuals' privacy and civil liberty interests with public health concerns directed at controlling the spread of TB.

This section describes laws related to:

1. Confidentiality and disclosure of patient information
2. Reporting requirements
3. Investigation, isolation, exclusion requirements, and enforcement mechanisms for non-adherent patients

CONFIDENTIALITY AND DISCLOSURE OF PATIENT INFORMATION

Protection of patient confidentiality is of utmost importance to public health and patient care. Maintenance of confidentiality promotes cooperation among patients, their families, and their communities with TB testing, treatment, prophylaxis, and contact investigations. The loss of patient confidentiality undermines trust between the Health Department and NYC residents, potentially hindering the ability of the Health Department to protect the public's health.

LAWS GOVERNING THE CONFIDENTIALITY OF PATIENT INFORMATION

The Health Department is legally required to treat all patient information received from patients and healthcare providers with the highest level of confidentiality.

The NYC Health Code requires the Health Department to keep confidential all medical, epidemiologic, and surveillance reports and records that contain individually identifiable patient information reported to or maintained by the Health Department, and limits disclosure of identifiable information to authorized persons to protect the health of an individual or the public [NYC Health Code §§ 3.25(a)(1), 11.11(a)]. NYC law also requires aggregate data to be prepared in a manner that does not reasonably enable patient identification [NYC Health Code § 11.11(a)(2)]. The NYC Health Code allows individuals to consent in writing to the disclosure of their own medical records to themselves, their treating provider, or to a court, provided that information regarding other individuals, including contacts, is excluded from the disclosure [NYC Health Code §§ 3.25(a)(2), 11.11(b)].

NYS Public Health Law § 2221 provides for the confidentiality of patient TB records maintained by physicians, government agencies, and others, allowing them to be shared only with State or local health authorities, such as the Health Department, and requiring such health authorities to maintain confidentiality except where disclosure is authorized by law. Violation of this provision is a misdemeanor offense [NYS Public Health Law § 2230].

The confidentiality of patient information is also extensively regulated by the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA). HIPAA established a national legal standard for protecting the privacy of protected health information (PHI) from disclosure by certain entities. HIPAA defines PHI as any health or medical information that can identify or be linked to a specific individual [45 CFR § 160.103]. PHI may be transmitted or maintained in any form or medium (electronically, on

paper, or orally), but excludes certain educational and employment records, and records of a person who has been deceased for more than fifty years [45 CFR § 160.103]. HIPAA gives individuals the right (with a few limited exceptions) to access and obtain a copy of their own PHI, authorize the sharing of their PHI, and request amendments to their medical records [45 CFR §§ 164.508, 164.524, 164.526].

HIPAA's confidentiality mandates are limited to "covered entities," defined as healthcare providers who transmit billing and payment information in electronic form (e.g., most doctors, hospitals, laboratories, and pharmacies), health plans (e.g., Medicare, Medicaid, and private health insurance companies), and healthcare clearinghouses (i.e., entities that perform billing services) [45 CFR § 160.103]. HIPAA delineates very limited circumstances under which covered entities can share PHI without patient consent (e.g., information needed for treatment of the patient or for payment purposes) [45 CFR § 164.506].

The NYC Health Department is a hybrid entity under HIPAA; it operates both as a public health authority and as a provider of healthcare through Health Department clinics, including Bureau of TB Control (BTBC) clinics. Information collected by the Health Department as a public health authority, which is not a "covered entity" under HIPAA, is exempt from HIPAA, but is still governed by State and local confidentiality law. Health Department clinics, as HIPAA "covered entities," must comply with HIPAA's confidentiality and disclosure requirements.

DISCLOSURE OF PATIENT INFORMATION FOR PUBLIC HEALTH REASONS

Public health activities are an exception to the stringent HIPAA, NYS, and NYC confidentiality requirements.

In enacting HIPAA, Congress was very clear that the act not impede public health practices [42 USCA § 1320-d-7(b)]. Under HIPAA, covered entities are permitted to disclose PHI without patient consent, and without giving the patient an opportunity to agree or object to the disclosure, to a public health authority authorized by law to receive such information, such as the Health Department, "for the purpose of preventing or controlling disease, injury, or disability, including, but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions" [45 CFR § 164.512(b)(1)(i)]. HIPAA also allows disclosure of PHI by a covered entity to patient contacts or individuals "who may otherwise be at risk of contracting or spreading a disease or condition" if the covered entity or public health authority is authorized by law to do so in the course of a public health intervention or investigation [45 CFR § 164.512(b)(1)(iv)]. Thus, HIPAA permits disclosure of PHI, as necessary, to TB patient contacts.

The NYS Sanitary Code narrowly allows disclosure without patient consent under certain circumstances, including for public health reasons. Specifically, 10 NYCRR §2.17 permits NYS Department of Health and NYC Health Department personnel authorized to receive TB-related medical reports to "disclose information contained in such reports when in his judgment it will serve the best interest of the patient or his family, or contribute to the protection of the public health," including releasing information to entities involved in TB control, such as in connection with contact investigations. NYC Health Code §§ 3.25(b) and 11.11(c) also permit disclosure by authorized Health Department personnel to a treating provider or agency involved

in TB prevention, treatment, or the provision of social services, or "to any person when necessary for the protection of public health."

Disclosure by the Health Department or HIPAA entities of confidential health information/PHI must be limited to the minimum information necessary for the intended purpose [NYC Health Code § 11.11(c); 45 CFR §§ 164.502(b)(1), 164.514(d)(3)(iii)(A)]. To help preserve confidentiality, the receiving individual or entity should be informed of the obligation to maintain confidentiality except if further disclosure is necessary for patient treatment or for the protection of the health of others [NYC Health Code §§ 3.25(b), 11.11(c)].

HIPAA carves out limited exceptions to the "minimum necessary" requirement, including when the PHI is disclosed to treat a patient, when the patient requests the information or authorizes its disclosure, or when the records are required pursuant to certain laws [45 CFR § 164.502(b)(2)]. NYS law allows TB records to be subpoenaed, produced, and placed into evidence if the court deems them relevant in an action for a violation of the NYS Public Health Law, NYC Health Code, or other local TB control law [10 NYCRR § 2.18].

In accordance with confidentiality laws, and consistent with its goal of maintaining public trust and confidence in its processes, the Health Department attaches the highest level of confidentiality to PHI it receives from patients, healthcare providers, and other sources. PHI is only released as necessary for the Health Department to carry out its public health mandate.

SUMMARY OF THE LEGAL FRAMEWORK FOR CONFIDENTIALITY AND DISCLOSURE OF PATIENT INFORMATION:

- **State and local law require the Health Department and all healthcare providers to treat patient information with the highest level of confidentiality.**
- **Healthcare providers (including Health Department clinics), as well as insurance companies and entities that assist in billing, must also abide by HIPAA's confidentiality and disclosure requirements.**
- **All healthcare providers must provide confidential patient information to the Health Department upon request pursuant to NYC and NYS law; HIPAA, State, and local law all have a "public health" exception enabling such disclosure.**

CONFIDENTIALITY AND DISCLOSURE OF IMMIGRATION STATUS

In NYC, TB evaluation and treatment is provided regardless of immigration status; the law strictly limits Health Department employees from asking about or sharing an individual's immigration status.

Pursuant to mayoral Executive Order No. 41, Health Department and other city agency officers and employees cannot inquire into an individual's immigration status in performing TB investigations, providing treatment, or for any other purpose unless:

- Such information is necessary for the determination of a program, service, or benefit eligibility; or
- The officer or employee is required by law to inquire about such person's immigration status.

Further, immigration status is considered confidential information, and can only be disclosed by the Health Department:

- Upon the individual's written consent;
- If required by law;
- To another NYC officer or employee as necessary in carrying out the Health Department's or other NYC agency's mission;
- Where the individual is suspected of illegal activity other than mere status as an undocumented immigrant, or such information is necessary to apprehend another person suspected of illegal activity other than mere status as an undocumented immigrant; or
- Where disclosure is necessary in furtherance of an investigation of potential terrorist activity.

Limiting questions regarding immigration status, maintaining confidentiality when immigration status becomes known, and informing individuals regarding these confidentiality requirements gains patients' trust and increases the likelihood that immigrants will seek evaluation and treatment for TB, respond to Health Department investigations, and accept and abide by treatment protocols.

For specific questions about confidentiality and disclosure of personal health or other information:

- **Health Department personnel should contact their supervisors; supervisors who cannot answer staff questions should contact the Health Department Office of the General Counsel or a Health Department Privacy Officer**
- **Non-Health Department healthcare providers should call 311**

HUMAN IMMUNODEFICIENCY VIRUS TESTING REQUIREMENTS, INFORMED CONSENT, AND CONFIDENTIALITY AND DISCLOSURE OF HUMAN IMMUNODEFICIENCY VIRUS/ACQUIRED IMMUNODEFICIENCY SYNDROME INFORMATION

NYS law exclusively regulates reporting and confidentiality of information related to human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS), which are not defined or treated as "communicable diseases" in NYS. There are no applicable NYC Health Code provisions or any other local laws or regulations elsewhere in NYS relating to HIV information.

Providers offer all TB patients and their contacts HIV testing due to the implication for the diagnosis and treatment of TB, as well as the NYS requirement that HIV testing be offered as part of patient care. HIV-related patient information is subject to more stringent confidentiality and disclosure requirements than TB and most other patient information. NYS Public Health Law Article 21 Title 3 and Article 27-F, and 10 NYCRR Part 63, regulate HIV testing, confidentiality, and disclosure. In recent years, NYS HIV law has changed to improve HIV testing uptake and ease the sharing of HIV-related patient information to improve patient outcomes.

Effective March 28, 2017, providers are no longer required to obtain informed consent prior to ordering

an HIV-related test, including elimination of written consent for HIV testing in New York State correctional facilities. However, providers performing an HIV test as part of routine medical care, at a minimum, must advise that an HIV-related test is being performed prior to ordering an HIV-related test [§ 2786 and § 2139].

When a patient is told that an HIV test is being performed, a note must be placed in the patient's record that the patient was so notified [§ 2781(2)]. The provider must tell the patient each time an HIV test is being performed and document it in the patient's record [§ 2781(2)].

There are specific requirements regarding confidentiality and disclosure of HIV-related patient information. All persons who obtain HIV-related patient information in the course of providing healthcare or social services to a patient are required to maintain confidentiality [§ 2782(1)], except that disclosure is permitted to:

- The patient and any person the patient authorizes pursuant to a release of confidential HIV information [§§ 2134, 2782(1)(a)-(b)]
- A healthcare provider or facility in connection with treatment of the patient, the patient's child, or a contact of the patient; and any agent or employee of the provider or facility in connection with treatment or reimbursement [§§ 2782(1)(c)-(d)]
- A patient contact, but without revealing the identity of the protected individual or other contacts [§ 2134]
- A healthcare facility or provider in connection with organ and human body part and matter procurement for transplant, therapy, research, or education [§ 2782(1)(e)]
- A person authorized to make medical decisions for the patient, as necessary for treatment [§ 2782(4)(e)]
- A healthcare facility and authorized staff or government organization in connection with accreditation or oversight [§ 2782(1)(f)]
- A federal, State, or local health officer when disclosure is mandated by law (such as a physician's obligation to disclose an HIV diagnosis to the NYS Commissioner of Health (§ 2130)) [§ 2134, 2782(1)(g)]
- An authorized agency in connection with foster care or adoption of a child [§ 2782(1)(h)]
- Insurance companies and billing entities, with appropriate authorization if necessary [§§ 2782(1)(i)-(j)]
- Any person to whom disclosure is ordered by a court pursuant to NYS Public Health Law § 2785 (provides for court ordered disclosure in limited circumstances including where there is a "clear and imminent danger" to an individual or the public health) [§ 2782(1)(k)]; confidential HIV information cannot be released pursuant to a general subpoena [10 NYCRR § 63.6(k)]
- Authorized corrections agency and facility personnel [§§ 2782(1)(l)-(o)]
- An attorney appointed to represent a minor pursuant to social services law or the family court act [§ 2782(1)(p)]

- An executive or administrator of an estate if necessary to fulfill their obligations [§ 2782(1)(q)]

Documentation of HIV-related information must be made in the patient's medical record so that it is readily accessible for care and treatment [10 NYCRR § 63.7(a)]. In addition, a State or local health officer, such as authorized Health Department personnel, may disclose confidential HIV-related information:

- To the patient and any person the patient authorizes pursuant to a release of confidential HIV information [§§ 2134, 2782(2)(b)]
- To the patient's contact(s) but without revealing the identity of the protected individual or other contacts (the Health Department is required to notify any known contacts of an HIV case if the treating healthcare provider has not done so) [§§ 2133(3), 2134, 2782(2)(c)]
- To any person to whom disclosure is ordered by a court pursuant to NYS Public Health Law § 2785 (provides for court-ordered disclosure in limited circumstances including where there is a "clear and imminent danger" to an individual or the public health) [§ 2782(2)(d)]; confidential HIV information cannot be released pursuant to a general subpoena [10 NYCRR § 63.6(k)]
- When used in the aggregate as part of agency programs to improve HIV quality of care (but without patient-identifying information) [§ 2135]
- When used to assess comorbidity or completeness of reporting and to direct program needs (provided patient-identifying information is not released outside the department) [§ 2135]
- For public health purposes, information may be shared with other health departments or the patient's current treating provider
- As otherwise authorized or required by federal or State law [§§ 2135, 2782(2)(a)]

Persons in receipt of confidential HIV-related information pursuant to the above exceptions are obligated to maintain confidentiality [§2782(3)]. Oral or written disclosure of confidential HIV information must be accompanied by a statement prohibiting re-disclosure except where disclosure is made pursuant to the patient's written consent, for treatment of the patient or the patient's child, or to third-party payers [10 NYCRR §§ 63.5]; under most circumstances, disclosure must be documented in the patient's medical record [10 NYCRR § 63.7(b)].

The law regarding HIV testing, confidentiality, and disclosure is ever-changing; BTBC staff should check with the Office of the General Counsel or a Health Department privacy officer whenever they have an issue related to disclosure. Additional information regarding HIV testing, consent, reporting test results, and other HIV resources are available at https://www1.nyc.gov/site/doh/providers/health-topics/infectious-diseases.page#hiv.

REPORTING REQUIREMENTS

Prompt reporting enables BTBC to evaluate a patient's treatment plan and reinforces to providers the importance of adherence to prescribed treatment. Physicians, laboratories, healthcare facilities, and other providers must report suspected or confirmed cases of active TB disease, for persons alive or deceased, within 24 hours of diagnosis [10 NYCRR §§ 2.10, 2.11; NYC Health Code §§ 11.03(a), 11.03(b)(2), 13.03(a)], and must continue to report on various aspects of patient treatment [NYC Health Code § 11.21(a)]. Animal care providers and facilities are also required to report confirmed cases of TB disease in animals to the Health Department [NYC Health Code §11.25(a)(2)]. Further, if no physician or other clinician is in attendance, heads of private households or of any institution, including child care services, schools, camps, hotels, shelters, or correctional facilities, have a duty to report an individual likely to have active TB disease [10 NYCRR § 2.12; NYC Health Code §§ 11.05(c), 43.19(e), and 47.27(e)].

Healthcare providers must provide access to necessary paper and electronic medical records to authorized Health Department staff as requested [NYC Health Code § 11.03(e)].

REPORTING SUSPECTED OR CONFIRMED CASES OF TUBERCULOSIS DISEASE BY PHYSICIANS AND MEDICAL FACILITIES

Medical providers are required by NYS and NYC law to report all patients, alive or deceased, with suspected or confirmed TB disease to the Health Department within 24 hours [10 NYCRR §§ 2.10, 2.11; NYC Health Code §§ 11.03(a), (b)(2)]. Providers are encouraged to call the Health Department immediately if they have questions about screening, treating, or reporting a suspected or confirmed TB case. (See *Chapter 9: Tuberculosis Reporting and Surveillance*.)

NYC Health Code § 11.03(a) requires providers to report patients who meet at least one of the following criteria:

- Clinical suspicion of pulmonary or extrapulmonary TB such that the physician or other healthcare provider has initiated or intends to initiate isolation or treatment for TB disease
- Acid-fast bacilli (AFB)-positive smears (from any anatomic site)
- Nucleic acid amplification (NAA) test (e.g., Roche's COBRAS®AMPLICOR, the Gen-Probe® Amplified™ Mycobacterium Tuberculosis Direct [MTD] Test) positive for *Mycobacterium tuberculosis* (*M. tuberculosis*) complex (including *M. tuberculosis*, *M. africanum*, *M. bovis*-bacille Calmette-Guérin [BCG], *M. caprae*, *M. canettii*, *M. microti*, *M. pinnipedii*, *M. bovis*)
- Culture-positive for *M. tuberculosis* complex
- Biopsy, pathology, or autopsy findings consistent with active TB disease, including caseating granulomas in biopsy of lung, lymph nodes, or other specimens

Providers must report a suspected or confirmed case of TB disease within 24 hours of diagnosis by telephone or in writing submitted electronically or by fax using the Health Department Universal Reporting

Form (URF). (See *Appendix Q: New York City Health Department Universal Reporting Form*.) Information reported must be as complete as possible and include the following:

- Information needed to identify and locate the individual (name, telephone number, address, and date of birth)
- Provider information (physician's name, email, telephone number, and reporting facility)
- Results of AFB smear culture (including date specimen obtained and accession number, if available)
- Results of any chest radiographs (CXR)

To obtain free copies of the URF, call toll free 866-NYC-DOH1 (866-392-3641) or access the form at nyc.gov/health and search for "URF." Providers have 4 options for submitting the URF:

1. **ELECTRONICALLY (preferred method): Complete the URF electronically using the Reporting Central online via NYCMED within 24 hours at nyc.gov/health and search for "NYCMED"**
   - ›› **A NYCMED account must be set up to access and submit the form. Assistance is available if needed by calling 888-NYC-MED9 or 347-396-2400, or by email at nycmed@health.nyc.gov**
2. **TELEPHONE: Call the TB HOTLINE at 844-713-0559 within 24 hours. Mail a completed URF within 48 hours to the address below.**
3. **FACSIMILE: Fax the URF to BTBC at 844-713-0557 within 24 hours. Mail a completed URF within 48 hours to the address below.**
4. **MAIL: Express or overnight mail the URF, ensuring it will arrive within 24 hours to:**
   New York City Department of Health & Mental Hygiene
   49-02 28th Street, CN#72, Long Island City, NY 11101

REPORTING OF CHILDREN YOUNGER THAN FIVE YEARS OF AGE WITH A POSITIVE TEST FOR TUBERCULOSIS INFECTION

Medical providers are required to report any child younger than five years of age (up to the day of their fifth birthday) who has a positive tuberculin skin test (TST) or a positive blood-based interferon gamma release assay (IGRA) test for TB infection, regardless of whether the child has received BCG vaccination [NYC Health Code §11.03(a) and §11.21].

For any child younger than five years of age (up to the day of their fifth birthday) with a positive TB test, providers must also report qualitative and quantitative TB test results (including induration [in millimeters (mm)] for TST), radiography results (CXR, computed tomography [CT], and magnetic resonance imaging [MRI]), and any prophylactic medication initiated for latent TB infection (LTBI).

In addition, laboratories are required to report positive results for TB infection obtained from a blood based test (e.g., IGRA) or other laboratory test when performed on children younger than five years of age [NYC Health Code §13.03(b)(1)].

REPORTING PATIENT TREATMENT PLANS AND PATIENT STATUS

Medical providers or heads of treatment facilities who treat active TB patients are required to do the following [NYC Health Code § 11.21(a)(1-3)]:

- Submit a treatment plan to the patient's case manager for all newly diagnosed cases within one month of treatment initiation. This plan must include at least:
  - The name of the healthcare provider who has assumed responsibility for TB treatment
  - Names and duration of prescribed anti-TB drugs
  - Anticipated date of treatment completion
  - A plan for promoting treatment adherence
- Submit to BTBC monthly clinical status reports for active TB disease patients, which must include at least:
  - The name, address, and telephone number(s) of the patient
  - Whether treatment is still ongoing
  - The stage, clinical status, and treatment being provided
  - Dates and results of sputum and CXR exams
- Provide any other information required by the Health Department.
- Report to BTBC when treatment ceases and the reason for the cessation.

To facilitate the submission of mandatory monthly patient status reports, the Health Department has created the REPORT OF PATIENT SERVICES FORM (TB 65), available at nyc.gov/health and search for "TB provider resources." This form, or other report containing the same information, must be submitted to the patient's case manager. (See *Appendix R: Report of Patient Services Form*.)

REPORTING HOSPITAL DISCHARGE OF AN INFECTIOUS TUBERCULOSIS PATIENT

Medical providers are required to obtain discharge approval from the Health Department prior to discharging an infectious TB patient from inpatient care. The Health Department will respond to discharge approval requests within one business day and will either approve the discharge or request additional information or actions [NYC Health Code § 11.21(a)(4)]. (See *Chapter 9: Tuberculosis Reporting and Surveillance*.)

All requests for inpatient discharge approval must be made using the HOSPITAL DISCHARGE APPROVAL REQUEST FORM (TB 354). All forms must be submitted at least 72 hours prior to planned discharge. To submit by fax, send to 844-713-0557.

To assist in discharge planning, providers should use the HOSPITAL DISCHARGE PLANNING CHECKLIST for TB Patients. Both forms are available at nyc.gov/health; search for "TB provider resources." (See *Appendix S: Hospital Discharge Approval Form*.)

If there is a concern that an infectious patient who does not meet discharge criteria may leave the hospital without authorization, healthcare providers should contact the Health Department immediately, 24 hours a day, seven days a week at:

- BTBC **TB HOTLINE** at **844-713-0559** (regular business hours)
- Poison Control Center at **212-POISONS** (212-764-7667) (after hours/weekends/holidays)

REPORTING OUTBREAKS AND UNUSUAL MANIFESTATIONS OF DISEASE

Healthcare providers must immediately report by telephone a suspected TB outbreak among three or more persons or animals, and any unusual manifestation of disease in an individual [NYC Health Code §§ 11.03(c)(1), 11.25(a)(4), 13.03(a); 10 NYCRR § 2.10]. An outbreak may be detected based on clinical, laboratory, or epidemiologic evidence. Telephone reports must be followed up in writing within 24 hours [NYC Health Code §§ 11.03(c)(1), 11.25(a)(4), 13.03(a)]. The Health Department has a duty to immediately report any outbreak to the NYS Department of Health (NYS DOH) [10 NYCRR §§ 2.1(b)-(c), 2.16].

Reports of suspected TB outbreaks or unusual manifestations of TB disease must be made immediately by calling the following numbers and asking to speak to the Health Department doctor on-call:

- **Business Hours (Monday through Friday 9 AM to 5 PM): Call the TB HOTLINE at 844-713-0557**
- **Non-Business Hours (nights, weekends, and holidays): Call the Poison Control Center at 212-POISONS (212-764-7667)**

A written report must be submitted in addition to telephone notification unless the Health Department explicitly instructs otherwise. The report must be submitted within 24 hours by fax, electronically, or by mail [NYC Health Code §§ 11.03(c)(1), 13.03(a)].

REPORTING CONTACTS

If a healthcare provider examines any contacts to a patient with infectious TB disease, the results of the examination must be reported when requested by the Health Department [NYC Health Code § 11.21(b)]. Suspected or confirmed cases of active TB disease among contacts must be reported in the same manner as with the initial case. There is no requirement to report all persons who test positive for TB infection (as opposed to active TB disease), except when the person is younger than five years of age, the Health Department is investigating outbreaks, or otherwise requests such information.

MICROBIOLOGY AND PATHOLOGY LABORATORIES: TESTING AND REPORTING

NYC Health Code §§ 13.03(a) and (b)(1) require laboratories testing specimens submitted for NYC resident patients to report the following to the Health Department, whether confirmed or presumptive, for patients alive or deceased, within 24 hours of obtaining test results (see *Chapter 9: Tuberculosis Reporting and Surveillance*):

- AFB-positive smears (from any anatomic site)
- Cultures positive for *M. tuberculosis* complex (including *M. tuberculosis*, *M. africanum*, *M. bovis-BCG*, *M. caprae*, *M. canettii*, *M. microti*, *M. pinnipedii*, *M. bovis*)
- NAA test results that identify *M. tuberculosis* complex (e.g., Roche's COBRAS®AMPLICOR, the Gen-Probe® Amplified™ MTD Test, Xpert MTB/RIF assay)
- Results of drug-susceptibility tests (DSTs) performed on *M. tuberculosis* complex cultures on a drug-specific basis
- Biopsy, pathology, and autopsy findings consistent with TB, including the presence of AFB or granulomas
- Any culture result associated with an AFB-positive smear, including negatives and species identification, even if negative for *M. tuberculosis* complex
- All subsequent laboratory TB tests (negative or positive) on samples collected within one year from patients with a prior AFB-positive smear or positive test for *M. tuberculosis* complex [also § 13.05(b)(8)]
- All results including negative and indeterminate results of blood-based or other later-developed laboratory tests for tuberculosis infection

All reports by laboratories to the Health Department must contain all of the information required by the reporting form including:

- The full name, date of birth, and address of the patient, as well as the patient's email, mobile phone number, race, ethnicity, and sex if known
- The specimen source and the collection date
- The medical record number if known, and any other assigned patient identifiers
- The name, address, and telephone number of the physician, facility, and/or laboratory that submitted the specimen, as well as the submitting provider's email, fax number, mobile phone number, and National Provider Identification (NPI) number (and facility NPI) if known
- The name and address of the laboratory
- The date the test results were first available
- The name(s) of the tests performed [NYC Health Code § 13.03(a)]

In addition to the above reporting requirements, the NYC Health Code requires laboratories to:

- Adhere to the following testing schedule (or, if unable to do so, send specimens to another laboratory within 24 hours after receipt of the specimen [§ 13.05(b)(5)]):
  - Examine smears performed to detect AFB within 24 hours of receipt [§ 13.05(b)(1)].
  - Initiate conventional cultures of clinical specimens within 24 hours of receipt, and examine for growth at least once each week after inoculation and, upon observing adequate suspicious growth, perform acid fast smear examination [§ 13.05(b)(2)].
  - Complete cultures of clinical specimens within 15 working days after growth is first indicated [§ 13.05(b)(3)].
  - Identify the presence or absence of *M. tuberculosis* complex within four working days after adequate suspicious growth is first detected [§§ 13.05(b)(2), (3)].
  - If direct DST is performed, initiate test within 24 hours of the next scheduled work day after obtaining the smear-positive for AFB; if indirect DST of pure cultures is performed, initiate as soon as growth typical of *M. tuberculosis* is observed [§ 13.05(b)(4)].
  - For other laboratory techniques, adhere to the methodologies and examination schedules recommended by the manufacturer [§ 13.05(b)(6)].
- Perform NAA testing on all positive AFB smears from patients not previously diagnosed with TB disease, or send such specimens to the Health Department for testing if the facility lacks NAA testing capabilities [§ 13.05(b)(1)].
- Submit, within 24 hours of observing growth of a culture or subculture of *M. tuberculosis* complex, a portion of the initial culture from any specimen to the Health Department for deoxyribonucleic acid (DNA) or other molecular analysis (a specimen submitted to Health Department for DST meets this requirement unless Health Department notifies otherwise) [§ 13.05(a)].
- Report any results of TB-related tests to the physician or other person authorized to order such tests within 24 hours of test results or findings, whether positive or negative [§§ 13.05(b)(1) and (b)(7)].

Laboratories must report the above listed findings via the ELECTRONIC CLINICAL LABORATORY REPORTING SYSTEM (ECLRS), the mandatory method of laboratory reporting in NYC [NYC Health Code §§ 13.03(c)]. Access to ECLRS is available through the NYS Health Commerce System (formerly the Health Provider Network) at https://commerce.health.state.ny.us/public/hcs_login.html

Laboratories must submit positive *M. tuberculosis* cultures for DNA analysis to the Health Department Public Health Laboratory within 24 hours of observing growth:

New York City Health Department Public Health Laboratory
455 First Avenue, Room 136
New York, NY 10016

VETERINARIAN AND ANIMAL CARE INSTITUTIONS: REPORTING ANIMALS INFECTED WITH TUBERCULOSIS

A confirmed diagnosis of TB disease in an animal must be reported to the Health Department by veterinarians, veterinary technicians, persons who work at an animal hospital or other facility providing or responsible for animal care or treatment (e.g., animal shelters, zoos), and veterinary diagnostic laboratories [NYC Health Code §§ 11.25(a) (2), (b)(1)].

Diseases in animals raised as food sources must be reported to the NYS Department of Agriculture and Markets via fax, mail, or in an electronic transmission acceptable to the Health Department.

Reports must be made within 24 hours of laboratory diagnosis by telephone or in writing by submission of an "Animal Disease Case Report" form via fax, mail, or in an electronic transmission acceptable to the Health Department. This form can be found at nyc.gov/health; search for "Animal Disease Case Report" [NYC Health Code §§ 11.25(a) (2), (b)(1)]. Reports must contain all information available concerning the disease and the infected animal and its owner, including the species and location of the animal, and the name, telephone number, and address of the owner [NYC Health Code § 11.25(b)(3)].

See "Reporting Outbreaks and Unusual Manifestations of Disease" subsection for information regarding reporting suspected or confirmed outbreaks or unusual manifestation of disease in animals.

Laboratory confirmed cases of TB disease in animals must be reported to Health Department Bureau of Communicable Disease within 24 hours by telephone or in writing:

TELEPHONE: Business Hours (Monday through Friday 9 AM to 5 PM): Call the Bureau of Communicable Disease at 347-396-2600; Non-Business Hours (nights, weekends, and holidays): Call the Poison Control Center at 212-POISONS (212-764-7667)

MAIL: New York City Health Department Bureau of Communicable Disease; 42-09 28th Street, CN22A, Long Island City, New York 11101

TABLE 17.1: Summary of mandatory tuberculosis reporting requirements[1]

REPORTER(S)	REQUIREMENT [APPLICABLE NYC HEALTH CODE CITATION]
Non-laboratory healthcare providers (e.g., treating physician, hospital, or clinic)	• Report cases of suspected or confirmed TB disease for patients alive or deceased to the Health Department within 24 hours [§§ 11.03(a), (b)(2); 10 NYCRR §§ 2.10, 2.11]. • Report any child younger than 5 years of age who has a positive test result for TB infection, regardless of whether the child had a BCG vaccination, to the Health Department within 24 hours [§ 11.03(a)]. • Use the URF for reporting suspected or confirmed cases of TB to the Health Department [§ 11.05(b)]. • Submit an initial treatment plan [§ 11.21(a)(2)]. • Obtain consent from the Health Department at least 72 hours before discharging a patient with infectious TB via the "Hospital Discharge Approval Request" Form (TB 354) [§ 11.21(a)(4)]. • Report patient treatment plans and outcomes monthly via the "Report of Patient Services" Form (TB 65) or other means [§§ 11.21(a)(1)-(3)]. • Evaluate contacts to a TB patient, or refer such contacts to the Health Department for examination [§ 11.21(b)]; suspected or confirmed TB cases among contacts must be reported in the same manner as the initial case. • Report results of contact investigations to the Health Department as requested [§ 11.21(b)]. • Immediately report suspected TB outbreaks (3 or more cases) and unusual manifestations of disease to Health Department by phone, followed by written notification within 24 hours [§ 11.03(c)(1); 10 NYCRR § 2.10].
Laboratories	• Report the following to the Health Department within 24 hours of a confirmed or presumptive finding: AFB-positive smears; cultures or NAA test positive for *M. tuberculosis* complex; DST results; and any other biopsy, pathology, or autopsy finding consistent with TB [§§ 13.03(a), (b)(1)]. • Report TB test results (positive or negative) for a patient testing positive for TB within the last year to the Health Department within 24 hours [§§ 13.03, 13.05(b)(8)]. • Include in reports to the Health Department specific, detailed information regarding the patient, provider(s), and specimen [§ 13.03(a)]. • Use the NYS ECLRS for all TB-related reporting to the Health Department [§§ 13.05(a), (c)]. • Report results of TB-related tests to the patient's provider within 24 hours [§§ 13.05(b)(1), (7)]. • Perform NAA testing on all AFB-positive smears from patients not previously diagnosed with TB [§ 13.05(b)(1)]. • Adhere to a specific testing schedule, and send specimens to another laboratory if unable to do so [§ 13.05(b)]. • Submit positive *M. tuberculosis* cultures for DNA analysis to the Health Department Public Health Laboratory within 24 hours of observing growth [§ 13.05(a)]. • Immediately report suspected TB outbreaks (3 or more cases) and unusual manifestations of disease to the Health Department by phone, followed by written notification within 24 hours [§ 13.03(a); 10 NYCRR § 2.10]. • Report positive results for TB infection obtained from a blood based test (e.g., IGRA) or other laboratory test when performed on children younger than 5 years of age [NYC Health Code §13.03(b)(1)].

TABLE 17.1: Summary of mandatory tuberculosis reporting requirements (*continued*)[1]

REPORTER(S)	REQUIREMENT [APPLICABLE NYC HEALTH CODE CITATION]
Veterinary and animal care facilities	• Report all animals infected with TB, alive or deceased, to the Health Department within 24 hours of diagnosis by telephone or in writing [§ 11.25(a)(2)]. • Include in report specific, detailed information regarding the animal, its owner, and test results [§ 11.25(b)(3)]. • When making a written report to the Health Department, use the "Animal Disease Case Report" form [§ 11.25(a)(2)]. • Immediately report suspected TB outbreaks (3 or more animals) and unusual manifestations of disease to Health Department by phone, followed by written notification within 24 hours [§ 11.25(a)(3)]. • Report diseases in animals used as food sources to NYS Department of Agriculture and Markets.
Persons in charge of other institutions (e.g., schools, child day care centers, camps, hotels, shelters, correctional facilities)	• If no healthcare provider is in attendance, report an individual likely to be infected with TB [§ 11.05(c); 10 NYCRR § 2.12].

[1]All citations are to the NYC Health Code unless otherwise indicated

Abbreviations Used: AFB=acid-fast bacilli; BCG=bacille Calmette-Guérin; BTBC=Bureau of Tuberculosis Control; DNA=deoxyribonucleic acid; DST=drug-susceptibility test; ECLRS=Electronic Clinical Laboratory Reporting System; IGRA=interferon gamma release assay; *M. tuberculosis*=*Mycobacterium tuberculosis*; NAA=nucleic acid amplification; NYC=New York City; NYCRR=New York Compilation of Codes, Rules and Regulations; NYS=New York State; TB=tuberculosis; URF=universal reporting form

INVESTIGATION, ISOLATION, EXCLUSION REQUIREMENTS, AND ENFORCEMENT MECHANISMS FOR NON-ADHERENT PATIENTS

Healthcare providers who come in contact with a suspected or confirmed case of TB disease are required to minimize the risk of transmission to others, including advising contacts on their risk and need for evaluation, isolating infectious patients, and providing information to infectious patients and their contacts regarding TB transmission and prevention. Every effort should be made to secure voluntary compliance with these measures, and to identify and remove any barriers to testing, isolation, and treatment.

The Health Department can require examination of suspected cases and isolation of infectious patients until they are no longer infectious when the patient's presence in the community constitutes a danger to any person or the public's health. Patients who are non-adherent with TB evaluation or treatment and who may pose a danger to public health must be evaluated for appropriate regulatory action if voluntary compliance or other less restrictive measures of securing compliance have been unsuccessful or were considered and rejected. (See *Chapter 10: Case Management for Patients with Tuberculosis*.)

DUTY TO INVESTIGATE CONTACTS AND OTHER SUSPECTED TUBERCULOSIS CASES

The Health Department must investigate all reported suspected or confirmed TB cases to verify diagnosis (including collecting laboratory specimens for testing), ascertain the source of infection, and discover contacts and unreported cases [10 NYCRR §§ 2.6(a), 2.6(b), 2.7(a), 43-1.2]. If a patient with suspected TB disease is being treated by a private physician, the Health Department must ascertain whether the physician is maintaining proper sanitary supervision [10 NYCRR § 2.7(b)]. The Health Department is required to maintain supervision of every suspected and confirmed case of TB in a NYC resident until the patient has completed treatment and is no longer a public health risk.

Healthcare providers must examine all household contacts, or refer contacts to the Health Department for examination, and report results to the Health Department if requested [NYC Health Code § 11.21(b)]. The Health Department may require any contact to be examined, and re-examined as necessary, referring patients with suspected or confirmed TB disease for further examination or treatment [NYC Health Code § 11.21(b)]. Such examination must include any necessary tests for TB [NYC Health Code § 11.21(b); 10 NYCRR § 2.5]; suspected or confirmed TB cases among contacts must be reported pursuant to regular reporting requirements (see *Summary of Reporting Requirements*).

DUTY TO ISOLATE, EXCLUDE, AND INFORM SUSPECTED AND CONFIRMED TUBERCULOSIS PATIENTS AND THEIR CONTACTS

Physicians and persons in charge of medical facilities and nursing homes have a duty to isolate any patient with suspected or confirmed TB disease using recognized infection control principles until the Health Department can evaluate the patient's risk to public health [NYC Health Code § 11.17(a), 10 NYCRR §§ 2.27, 2.29]. Facilities that cannot implement appropriate isolation precautions, such as schools, day care facilities, camps, homeless shelters, correctional facilities, or other congregate residential settings, must provide the patient with a mask to wear as necessary, and separate them from others until transfer to an appropriate medical facility [NYC Health Code § 11.17(c)].

An individual with infectious TB disease must be excluded from attending work, school, or any location where TB transmission can occur (as determined by the Health Department) [NYC Health Code § 11.21(c)] (see *Schools, Childcare Services, and Other Children's Facilities* for requirements specific to these institutions).

Physicians who attend a patient with suspected or confirmed TB disease must inform the patient and any contacts regarding applicable isolation, exclusion, quarantine, screening, and treatment requirements [NYC Health Code § 11.13]. Physicians, or the Health Department if no physician is attending the patient, must also advise members of the patient's household regarding the risks of personal contact with the patient and specific precautions to be taken to prevent the spread of TB [10 NYCRR §§ 2.7(b), 2.27; Public Health Law § 2222(1); NYC Health Code § 11.13]. All patient and contact education should be documented.

Every effort should be made by healthcare providers and the Health Department to identify, address, and remove barriers to outpatient TB treatment and to document such efforts before considering imposing compulsory measures. It is also necessary to document evaluations showing that in some rare cases it is necessary to impose compulsory measures without undertaking less restrictive alternatives.

NYC Health Code § 11.21(d) authorizes the Commissioner of Health to exercise a range of enforcement options (i.e., to issue "any orders he or she deems necessary to protect the public health or the health of any other person") to control TB in patients who are non-adherent with evaluation or treatment and whose presence in the community constitutes a danger to an individual's or the public's health. These enforcement options may be issued without obtaining judicial review, and include an order:

- **Authorizing the removal to or detention in a hospital or other treatment facility of a person with confirmed or suspected active TB disease for examination [§11.21(d)(1)];**
- **Requiring a person with active TB disease to complete prescribed treatment and follow required infection control precautions [§ 11.21(d)(2)];**
- **Requiring a person with active TB disease who is unwilling or unable to complete an appropriate treatment course to follow directly observed therapy (DOT) [§ 11.21(d)(3)];**
- **Authorizing the removal to or detention in a hospital or other treatment facility of a person who has, or is substantially likely to have, active TB disease that is infectious, where there is a substantial likelihood of TB transmission because of the patient's inadequate separation from others [§ 11.21(d)(4)];**
- **Authorizing the removal to or detention in a hospital or other treatment facility of a person who has active TB disease, or who has been reported to the Health Department as having active TB disease with no report to the Health Department of treatment completion, where such person cannot be relied upon to participate in or complete treatment or follow infection control precautions as evidenced by past or present non-adherent behavior [§ 11.21(d)(5)].**

NOTICE OF OBLIGATION TO ISOLATE

Sometimes an infectious TB patient will not or cannot adhere to hospital isolation procedures or threatens to leave the hospital without a suitable discharge plan. When a provider believes that a patient with suspected or confirmed TB disease will leave the hospital against medical advice, BTBC must be contacted immediately. When this happens a Notice of Obligation to Isolate (NOI) will be faxed to the provider to remind them of their obligation to isolate a patient until BTBC evaluates the patient's risk to public health and makes a determination regarding detention.

Upon receiving the NOI, the hospital or other healthcare provider must continue to take all necessary measures to prevent the patient from leaving the hospital including placing security staff outside the patient's room if necessary. If, after evaluation of the circumstances, the Health Department agrees that detention is necessary, a Commissioner's Order for Detention will be faxed to the hospital within 24 business hours of the issuance of the NOI [Involuntary Isolation and Detention (New York City Health Code § 11.21(d)(1), (4), and (5) Orders)].

REGULATORY ORDERS

The Health Department may order removal and/or detention in a medical facility and outpatient examination and treatment of non-adherent patients [NYC Health Code §§ 11.17(d), 11.21(d)]. Detention orders may require infectious patients to remain in hospital isolation, or be admitted to a hospital for examination or treatment of TB [NYC Health Code § 11.21(d)]. Involuntary detention should only be sought where voluntary detention is not possible.

The Commissioner of Health does not have authority to order forcible administration of medication; a court order must be obtained by the hospital in order to do so [NYC Health Code § 11.21(i)].

Constitutional due process safeguards for detained patients are required by NYC Health Code §§ 11.21(e), (f), and (g). The patient ordered detained is personally served with the detention order by the Health Department or hospital staff.

Each order includes:

- The legal authority for the order
- An individualized assessment of the patient's circumstances and/or behavior constituting the basis for the order
- The less restrictive means that were attempted but unsuccessful, or that were considered and rejected with the reason for rejection
- The purpose of the detention
- How to request release from detention
- How to obtain judicial review
- The right to be represented by counsel
- The right to notify family and friends regarding the detention

The law provides for mandatory judicial review of detention orders when the patient requests release or will be detained for more than 60 days:

- When a patient requests release, the application for a court order must be filed within three business days (or within one business day following a Saturday, Sunday, or legal holiday accompanied by a request for an expedited hearing) and the detention will not continue for more than five business days after the request if there is no court order issued.
- If the patient will be detained for more than 60 days, further court review is required; additional court review is required every 90 days thereafter [NYC Health Code § 11.21(e)].

If a hearing is required, the detainee has a right to be represented by counsel; counsel must be provided free of charge upon request [NYC Health Code § 11.21(e)]. At any hearing, the hospital or the Health Department will provide the necessary infection control measures to protect the health of all participants in attendance. Evidence will be presented by representatives of the Health Department and by the patient

and their lawyer. The burden of proof rests with the Health Department, which must provide "clear and convincing evidence" supporting the detention [NYC Health Code § 11.21(e)]. The judge then determines whether the patient will be released or remain in detention based on the evidence.

Detention must end when:

- An individual detained pursuant to § 11.21(d)(1) has been examined and a determination made regarding whether the patient has active TB disease or is infectious; further detention requires issuance of another Commissioner's Order for Detention [NYC Health Code § 11.21(g)(1)].
- An individual detained pursuant to § 11.21(d)(4) can be adequately isolated from others in a location of preference while still infectiousness [NYC Health Code § 11.21(g)(2)].
- An individual detained pursuant to § 11.21(d)(5) has completed an appropriate prescribed course of medication [NYC Health Code § 11.21(g)(3)].

Inquiries regarding requests for Notices of Obligation to Isolate and Commissioner's Orders for individual patients including requests for detention may be made to the Health Department at:

Business Hours (Monday through Friday 9 AM to 5 PM): Call the TB HOTLINE at (844) 713-0559.

At all other times (nights, weekends, or holidays): Call the Poison Control Center at 212-POISONS (212-764-7667).

SCHOOLS, CHILDCARE SERVICES, AND OTHER CHILDREN'S FACILITIES*

**All citations in this section are to the NYC Health Code*

The NYC Health Code regulates schools, childcare services, and other children's facilities. Article 45 includes general health provisions for all elementary schools, junior high schools (including kindergartens that are part of an elementary school operated by the Board of Education), children's institutions, and some regulations for high schools (only §45.09 (b) through (d) apply to high schools). Other NYC Health Code articles provide additional requirements specific to school-based programs for children ages three through five years (Article 43); elementary and junior high schools, as well as kindergartens attached to elementary schools operated by the Department of Education (Article 49); and high schools (Article 49, § 49.15(d)). Article 47 regulates all childcare facilities for children under six years of age except those programs provided by schools for children aged three to five years, which are regulated by Article 43. Camps are regulated under Article 48.

TUBERCULOSIS TESTING OF CHILDREN AND STAFF

There is no longer any NYC requirement that all children and staff be tested for TB infection prior to entering a school or other children's facility. The Health Department has broad authority, however, to test any person for TB in public or private elementary and junior high schools as necessary for "epidemiological or other public health purposes" [§ 49.06]. Likewise, the Health Department may require TB testing of

any person (child or staff) in a school-based program for children ages three to five years [§ 43.11(d)]; elementary, junior high, and high schools; children's institutions [§ 45.09(c)]; and child care facilities [§ 47.33(d)] for "epidemiological investigation" as necessary. Staff of summer camps, however, must undergo TB testing at intervals prescribed by the Health Department [§§ 48.17(g)]. This is because camps are also regulated by the State Sanitary Code, which mandates testing in this setting.

While TB testing is no longer specifically mandated for school entry, requirements for staff employment and student medical examination help identify medical issues, including TB.

EXCLUSION AND ISOLATION OF TUBERCULOSIS-INFECTED PERSONS FROM SCHOOLS AND OTHER CHILDREN'S FACILITIES

NYC Health Code § 11.21(c) requires that persons with infectious TB disease (both staff and students) be excluded from schools and other places where they can transmit TB infection. This requirement is reinforced elsewhere in the NYC Health Code, which prescribes exclusion requirements for children and staff at schools, children's institutions, camps, and other childcare facilities [§§ 43.11(a), 43.19(f), 45.09(b), 47.27(f), 47.33(a), 49.15(d)].

Additionally, persons in charge of elementary schools, junior high schools, and children's institutions must isolate cases and carriers of communicable diseases (both children and staff), including active TB disease, and provide facilities for their isolation pursuant to NYC Health Code § 11.57 [§ 45.17(b)]. There is also a duty to isolate any child or staff member suspected of having a communicable disease, including TB disease, in summer and overnight camps [§ 48.17(k)].

Staff or students returning to a public or private elementary, junior high, or high school, and staff returning to a children's institution after being infectious with TB disease must obtain a certificate of recovery from the Health Department before being permitted to return [§§ 45.09(b)(1), 49.15(d)(1)]. Staff or students returning to a school or non-school-based childcare program for children five years and under after being infectious with TB disease must obtain a written statement of recovery from a healthcare provider before being permitted to return [§§ 43.11(a), 43.19(f), 47.27(f), 47.33(a)]. In the case of returning children, the statement of recovery must state that the child is no longer infectious and that the period of isolation or exclusion pursuant to Article 11 has ended [§§ 43.19(f), 47.27(f)].

SPECIAL RULES FOR FACILITIES WITH CHILDREN FIVE YEARS OF AGE AND YOUNGER

Rules for reporting and monitoring TB in schools and childcare facilities are more stringent for facilities where children five years of age and younger are in attendance.

All teachers and assistant teachers employed by childcare facilities for children under three years of age (school and non-school based), and non-school based facilities for children three to five years of age, must receive training in infection control and reporting infectious diseases [§§ 47.37(b), (d)(1)].

Further, absences due to TB must be reported by parents to facilities serving children aged five and under within 24 hours, and facilities are responsible for reminding parents of this requirement at the beginning of each school year [§§ 43.19(d), 47.27(d)]. Once notified, the person in charge of the facility must report the case to the Health Department by telephone within 24 hours [§§ 43.19(e), 47.27(e)].

Additionally, childcare facilities for children under three years of age (school and non-school based), and non-school-based facilities for children three to five years of age can be asked to immediately remove a worker or close a facility, suspending its permit, if a worker with infectious TB disease has remained at work [§§ 47.01(k)(14), 47.77(a)]. Any facility so cited must submit a corrective action plan to the Health Department within five business days for review and approval [§ 47.21(a)]. The plan must include an assessment of the risk to children and must "clearly and convincingly" demonstrate that there is no danger to any child or any other person [§§ 47.21(b)]. School-based facilities for children three to five years of age must similarly submit a corrective action plan if a worker with infectious TB disease was allowed to remain at work [§§ 43.15(a)(3),(b)].

PAYMENT FOR TUBERCULOSIS SERVICES

Public Health Law (PHL) section 2202(1) (e) prohibits patients from being charged for TB healthcare services received in a licensed Article 28 facility or from a Certified Home Health Agency. Consistent with PHL section 2202(1) (e), NYS DOH regulations (10 NYCRR Section 43-1.10) prohibit providers from requesting or requiring a patient or their responsible relative to pay for TB services provided in these settings. Therefore, no provider can request or require payment from a patient or their legally responsible relative for TB care provided in or by a facility listed above, which includes co-payments and deductibles.

- Medical providers are eligible for payment by a patient's health insurance carrier or other third-party payer with no out-of-pocket payment(s) from the patient
- If the patient does not have health insurance, a provider claim can be submitted to the NYC Health Department for reimbursement at the Medicaid rate
- A provider can submit a claim to the NYC Health Department if the payment received from the patient's insurer or other third-party payer was below the Medicaid rate
- If TB healthcare services are provided in a facility other than an Article 28 facility or Certified Home Health Agency, providers may bill the patient's health insurance carrier or other third-party payer as well as the patient.

KEY SOURCES

INQUIRIES AND FORMS TO REPORT SUSPECTED OR CONFIRMED TUBERCULOSIS CASES AND FOR TUBERCULOSIS CASE MANAGEMENT:

To inquire about reporting procedures, please call the TB Hotline at 844-713-0559.

The ECLRS can be accessed at https://commerce.health.state.ny.us/public/hcs_login.html (providers need to create a username and password). Additional information regarding ECLRS can be found at https://www.health.ny.gov/professionals/reportable_diseases/eclrs/

The URF can be obtained by calling 866-NYC-DOH1 (866-392-3641) or at nyc.gov/health; search for "URF"

NYCMED Reporting Central for electronic submission of the URF can be accessed at nyc.gov/health; search for "NYCMED"

The Report of Patient Services Form (TB 65) can be obtained by calling 844-713-0559 or at nyc.gov/health; search for "TB provider resources"

The Hospital Discharge Approval Request Form (TB 354) can be obtained by calling 844-713-0559 or at nyc.gov/health; search for "TB provider resources"

The Hospital Discharge Planning Checklist can be found at nyc.gov/health; search for "TB provider resources"

The Animal Disease Case Report form can be obtained by calling 347-396-2600 or at nyc.gov/health; search for "Animal Disease Case Report"

FEDERAL LAW:

A free text version of HIPAA can be found at: https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/administrative/combined/hipaa-simplification-201303.pdf or http://www.ecfr.gov/cgi-bin/ECFR?page=browse.

Additional information regarding HIPAA can be found at: http://www.hhs.gov/ocr/privacy/

NEW YORK LAW:

The NYS Public Health Law can be found at http://public.leginfo.state.ny.us/LAWSSEAFcgi?QUERYTYPE=LAWS+&QUERYDATA=@LLPBH+&LIST=LAW+&BROWSER=BROWSER+&TOKEN=17718570+&TARGET=VIEW

The NYS Codes, Rules and Regulations can be found at http://government.westlaw.com/linkedslice/default.asp?SP=nycrr-1000, and also at http://w3.health.state.ny.us/dbspace/NYCRR10.nsf/Full+Directory?OpenView

The NYC Health Code can be found at nyc.gov/health; search for "NYC Health Code"

***NOTE:** The laws and regulations in these links might not be the current law and should be used as a starting point only. If you have any questions about the application of any of these laws, speak to a supervisor, who can contact the NYC Health Department Office of the General Counsel.

APPENDICES

APPENDIX A: INTERNATIONAL CLASSIFICATION OF TUBERCULOSIS[1]

CLASS	TYPE	DESCRIPTION	FOLLOW-UP ACTION
0	No history of TB exposure; Not infected	• Negative result on IGRA or TST • No history of TB exposure • No evidence of LTBI or disease	None
I	TB exposure; No evidence of TB infection or disease	• History of exposure to person with *M. tuberculosis* • Negative result on IGRA or TST (given at least 8 to 10 weeks after exposure [post-window period])	None
II	TB infection; No disease	• Positive results on IGRA or TST • No clinical or radiographic evidence of active TB disease • Calcified granuloma on CXR • Negative bacteriological studies (smears and cultures) for TB if performed	Classify as contact, medical, population, or administrative risk Treat for LTBI, if indicated
III	Current TB disease	• Positive culture for *M. tuberculosis* and/or • Clinical, bacteriological, or radiographic evidence of current active TB • With or without a positive result on IGRA or TST	Treat for TB disease
IV	Previous TB disease	• Positive result on IGRA or TST • History of active TB in past or abnormal but stable or fibrotic radiographic findings • Negative bacteriologic studies (if done) • No clinical or radiographic evidence of current active TB disease	Conduct patient evaluation and consider re-treatment, as indicated
V (high)[2]	Current TB disease suspected	• Current TB symptoms[3] • Diagnosis pending • Expected to be Class III	Conduct patient evaluation and reclassify patient within two months
V (low)[2]	Previous TB disease suspected	• Diagnosis pending • Expected to be Class IV or abnormality unrelated to TB	Conduct patient evaluation and reclassify patient within two months

Adapted from: *Centers for Disease Control and Prevention. (2013). Core curriculum on tuberculosis: what the clinician should know. Atlanta, Georgia: United States Department of Health and Human Services; Centers for Disease Control and Prevention; National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention; Division of Tuberculosis Elimination. Retrieved from https://www.cdc.gov/tb/education/corecurr/pdf/corecurr_all.pdf.*

1. The International Classification of TB has been modified for use by BTBC. 2. The division of Class V into "high" or "low" categories is intended to improve case management and is specific to the BTBC; it is not part of the International Classification of TB. 3. Current TB symptoms or CXR findings consistent with active TB.

Abbreviations Used: BTBC=Bureau of Tuberculosis Control; CXR=chest radiograph; IGRA=interferon gamma release assay; LTBI=latent tuberculosis infection; *M. tuberculosis*=*Mycobacterium tuberculosis*; NYC=New York City; TB=tuberculosis; TST=tuberculin skin test

APPENDIX B: TUBERCULOSIS RISK ASSESSMENT TOOL

This tool helps you identify asymptomatic adults and children at risk for latent tuberculosis infection (LTBI).

- Do not repeat testing unless there are new risk factors since the last test for TB infection.
- Do not treat for LTBI until active TB disease has been excluded.[1]

Testing for TB infection[2] is recommended if your patient meets ANY of the below criteria:

○ **HAVE THEY LIVED WITH OR SPENT TIME WITH ANYONE WHO HAD OR MAY HAVE HAD TB?**

Notify the New York City Department of Health and Mental Hygiene (NYC Health Department) if your patient has had close contact with anyone with TB disease. Call the **TB HOTLINE** at **(844) 713-0559**, available 24 hours a day, seven days a week.

○ **DO THEY HAVE HIV/AIDS, CANCER, OR AN IMMUNE DISORDER?**

Immunosuppression[3] includes the following: HIV infection, cancer, prolonged corticosteroid use (equivalent to 15 milligrams/day or more of prednisone for one month or more), other immunosuppressive treatments (for example, TNF- α antagonists, JAK Inhibitors, IL-1 receptor antagonists, chemotherapy, organ transplant medications).

○ **WERE THEY BORN OUTSIDE OF THE U.S. IN A HIGH TB INCIDENCE AREA, SUCH AS AFRICA, ASIA, MEXICO, CENTRAL OR SOUTH AMERICA, THE CARIBBEAN, OR EASTERN EUROPE, OR HAVE THEY TRAVELED TO OR LIVED IN A HIGH TB INCIDENCE AREA FOR MORE THAN ONE MONTH?**

If your patient was born outside of the U.S. in a high TB incidence area —or—traveled or lived outside the U.S. for one consecutive month or more in a high TB incidence area, they may be at greater risk of infection.

If the TB test result is positive and TB disease is ruled out,[1] treatment for LTBI is recommended.

1. Evaluate, by medical history and physical examination, all people with TB symptoms, positive TB test results or abnormal chest radiographs (CXRs) consistent with TB disease. Following NYC Health Code Article 11, report all people with potential or confirmed TB disease and children younger than 5 years of age diagnosed with LTBI to the NYC Health Department. For more information, visit: www.nyc.gov/health/tb.
2. Interferon Gamma Release Assays (IGRAs) are preferred for people age 2 years and older, particularly those who have previously received the Bacille Calmette-Guérin (BCG) vaccine since IGRAs do not cross-react with BCG; some experts recommend using IGRAs for people of all ages.
3. IGRA results may be indeterminate and may need to be repeated. IGRA results may be negative and unless indicated by clinical judgment (for example, clinical suspicion of TB disease, immunosuppression), no further evaluation is needed.

APPENDIX C: ADMINISTERING THE TUBERCULIN SKIN TEST

FIRST STEPS:

1. Gather your equipment
   - Gloves
   - Alcohol pads or alternative skin cleanser
   - Disposable 26-gauge syringe needle
   - Tuberculin syringe (do not pre-draw tuberculin into syringes prior to test)
   - Purified protein derivative (PPD)
   - Sharps container
2. Check PPD vial's expiration/opening date
3. Explain to patient why test is being done and how it will be performed

PREPARATION:

1. Wash hands and put on gloves
2. Place patient's arm on a flat surface, exposing the volar (inside) surface of the forearm
3. Locate site for the injection (two to four inches below elbow, where no scars, bumps or veins are located)
4. Clean the injection site with an alcohol swab
5. Wipe the top of the PPD vial with a second alcohol swab and place the vial on a flat surface
6. Prepare the syringe by inserting it into the vial. Inject 0.1 milliliters (ml) of air into the airspace in the vial. Do not inject air into the PPD solution. Invert the vial, keeping the needle tip below fluid level. Pull back on the plunger of the syringe and draw slightly more than 0.1 ml of PPD solution. Remove the syringe from the vial and tap the syringe lightly to dispel air bubbles. Hold the syringe point up and expel air and/or excess fluid, leaving exactly 0.1 ml of PPD solution in the syringe
7. Return the PPD vial to the refrigerator when not in use and place on a cooling pad when in use

INJECTION:

1. Stretch the skin of the injection site with the thumb of the non-dominant hand (e.g., left hand for right-handed persons)
2. Hold the syringe between the thumb and forefinger of the dominant hand (e.g., right hand for right-handed persons) with the bevel of the needle pointing upward
3. Insert the needle intradermally (just under the top layer of skin) at a 5°-15° angle
4. Inject the PPD solution slowly. A firm resistance should be felt as the tuberculin solution enters the skin. Ensure that the entire needle bevel lies just under the skin
5. Release the stretched skin and remove the needle from the injection site (DO NOT RECAP). Discard the syringe immediately in a sharps container

6. Ensure that a discrete skin elevation (wheal), six to 10 mm in diameter, has been formed (measure wheal using a tuberculin skin test [TST] ruler). If the injection angle was too deep, no wheal will appear. If the angle was too shallow, fluid may leak. Be sure to check for leakage at the insertion site.
7. Repeat injection two inches (five cm) from site, or on opposite arm, if wheal is smaller than six mm or if less than 0.1 ml was injected (both tests need to be documented; [see below]). If, after a second injection, the wheal is still less than six mm or not enough fluid is injected, clinic staff should speak with a supervisor

POST-INJECTION:

1. Educate the patient on the possible reactions to the TST (e.g., mild itching, swelling, irritation)
2. Instruct patient not to rub, scratch, or put an adhesive bandage or lotion on the test site. The area may be washed and patted dry
3. Document the test in the patient's chart (including second test if done)
4. Schedule reading date and explain the importance of the patient returning for reading in 48 to 72 hours

READING THE TUBERCULIN SKIN TEST REACTION:

The test result should be read only by a trained healthcare worker. Patients should never be allowed to read their own reaction.

1. Read the result 48 to 72 hours after administering the test. A test result that has a palpable induration can still be read up to 96 hours
2. Inspect the injection site for raised areas. Palpate the arm for a hard, dense, and raised area known as an induration. Feel the edges of the induration with the index finger
3. Mark the two edges of the induration with a dot, using a black, watermark pen, if available
4. Measure the induration (not redness) at its widest point transversely, from one marked edge to the other, using a flexible TST ruler. If the reading is between two points, the lower value should be used. Swollen areas, if they feel hard (but not red areas), should be palpated and included in the measurement
5. Record the size in mm and not simply as "positive" or "negative." If there is no induration, record the result as "00 mm"
6. Interpret the reaction as positive or negative based on both the size of the induration and the individual's risk factors. (See *Table 2.4: Criteria for Determination of a Positive Tuberculin Skin Test Result.*)
7. Explain the meaning of a positive or negative reaction to the individual and refer for follow-up evaluation, if needed. Provide appropriate literature
8. Document results in the patient's chart

APPENDIX D: THE USE OF BACILLE CALMETTE-GUÉRIN VACCINE

Bacille Calmette-Guérin (BCG) vaccine[1] is a live, attenuated strain of *Mycobacterium bovis* (*M. bovis*). In most parts of the world, BCG vaccine is used routinely to prevent serious complications of tuberculosis (TB), such as miliary TB and central nervous system (CNS) TB, in infants and children and in healthcare workers with frequent exposure to individuals with infectious TB disease.

Although the evidence is conflicting, a large body of research indicates that BCG vaccination does not completely prevent TB infection or pulmonary TB disease. Some studies suggest that BCG vaccination lessens the likelihood of disseminated TB and TB meningitis, especially in infants.

In the United States, BCG vaccination is not recommended routinely for children or used as a control strategy against TB. Specifically, it is not recommended as a general preventive strategy for healthcare workers because it complicates the interpretation of tuberculin skin test (TST) reactions and because it has not been proven effective in preventing TB infection.

BCG is not recommended for children or adults with human immunodeficiency virus (HIV) infection; HIV testing must be performed before BCG is administered. Similarly, active TB disease must be ruled out before BCG can be given. Nonetheless, BCG vaccine may be considered in very specific circumstances. These circumstances include instances in which infants and children are close household contacts of an individual with persistently untreated or ineffectively treated smear-positive TB disease, especially MDR-TB.

As of January 2018, TICE BCG (Manufacturer: MERCK) is available through Cardinal Health as a special order item. All requests for BCG must be discussed with the Bureau of Tuberculosis Control (BTBC); BTBC can be contacted via the TB Hotline at 844-713-0559.

1. INDICATIONS AND CONTRAINDICATIONS FOR BACILLE CALMETTE-GUÉRIN VACCINE

Before deciding to give BCG vaccine to a contact of an individual with persistently untreated or ineffectively treated smear-positive TB disease, every effort should be made to (1) ensure that the inadequately treated individual with infectious TB disease is treated properly, and (2) separate the individual with TB and the exposed contact(s).

If this is not possible, giving BCG vaccine may be considered if the contact meets **ALL** of the following criteria:

- The contact has a negative test for TB infection
- The contact is repeatedly exposed to an individual with persistently untreated or ineffectively treated smear-positive multidrug resistant TB (MDR-TB)
- The contact does not have HIV infection (in some situations, however, BCG vaccine may be given to infants who have a positive HIV antibody as below)

BCG vaccine should **NOT** be given to the following individuals:

- Persons with a documented history of a positive reaction to a test for TB infection
- Persons with HIV infection or persons who are otherwise immunosuppressed

There have been no reports of harmful effects of BCG vaccine on the fetus. Nevertheless, giving BCG vaccine should be avoided in pregnant patients, unless there is an unusual risk of unavoidable exposure to infectious MDR-TB.

2. SPECIAL CONSIDERATIONS FOR INFANTS

At least two other factors must be weighed before a decision is made to give BCG vaccination to a newborn or infant younger than nine months old:

- Because an infant may not be able to mount a cellular immune response to infection with *Mycobacterium tuberculosis* (*M. tuberculosis*), a TST may not be a reliable indicator of infection. Thus, there may be instances where an infant with a negative TST may receive BCG vaccine even though they may be infected with *M. tuberculosis.*
- The blood of some infants born to mothers with HIV infection may show the presence of HIV antibodies for a number of months after birth, even if the infant is not infected with HIV. Because HIV infection cannot be excluded in this situation, BCG vaccine could be considered only if the infant is otherwise healthy, especially if the evaluation of other close contacts reveals a high rate of documented TST conversions and if all other efforts to prevent transmission have failed. Such an infant needs to be followed by a specialist until HIV infection is ruled out based on the most current recommendations.

3. EVALUATION AND FOLLOW-UP

- An individual who is being considered for BCG vaccination who cannot document a history of a previous positive TST reaction should have a TST, using five tuberculin units of purified protein derivative (PPD). A blood-based test is not recommended.
- An individual who is being considered for BCG vaccination should be offered HIV counseling and testing if they have risk factor(s) for HIV infection.
- If the individual being considered for BCG vaccination is an infant or child, the parent or legal guardian must be interviewed and must agree. This must be documented in the chart.
- Eight weeks after the administration of BCG vaccine, the individual should have a repeat TST performed to document any reaction. If the contact's TST is less than five millimeters (mm), the BCG vaccination should be repeated.
- There is no evidence that revaccination with BCG later in life affords any additional protection and therefore revaccination is not recommended.

NOTE: Product names are provided for identification purposes only; their use does not imply endorsement by the New York City Health Department.

APPENDIX E: INSTRUCTIONS FOR PERFORMING SPUTUM INDUCTION

Sputum induction is the procedure for obtaining sputum from patients who have difficulty producing it spontaneously. In this procedure, patients inhale a mist of nebulized, sterile water (many facilities use hypertonic saline), which irritates their airways, causing them to cough and produce respiratory secretions.

EQUIPMENT

In order to appropriately and safely conduct sputum induction, the following equipment is required:

- A room, booth, or enclosed area that meets environmental control standards for high-risk procedures, including:
  - Negative air pressure relative to other areas (air flow must be from the corridor into the sputum induction room or booth; from there it should be exhausted to the outside or appropriately filtered and safely discharged by a mechanical ventilation system)
  - 12 or more complete air changes per hour
  - For rooms, ultraviolet germicidal irradiation (UVGI) must be used

All Bureau of Tuberculosis Control (BTBC) sputum induction rooms are fully equipped with the following:

- Nebulizer and table to support nebulizer
- Disposable tubing with cup and lid
- Sterile sputum collection jar, properly labeled
- Mycobacteriology forms
- Clear plastic biohazard specimen bag and paper bag
- Paper tissues and bag for disposal of tissues
- Sterile water
- Distilled water
- Solution of 10% bleach, 90% water
- Disposable gloves
- Disposable drinking cups

PREPARING EQUIPMENT AND THE SPUTUM INDUCTION ROOM

Once all equipment has been collected, BTBC staff prepare the room and supplies as follows:

- Assemble and organize the following equipment in quantities sufficient for the anticipated number of patients to be seen that day:
  - Sputum jars
  - Plastic biohazard bags and brown paper bags
  - Disposable plastic nebulizer tubing with cup and lid
  - Sterile water
  - Distilled water
  - 10% bleach solution, mixed at the start of the shift in an amount sufficient for that shift only
  - Disposable drinking cups

- Check that the ultraviolet light and exhaust fan are on and functional
- Prepare the nebulizer:
  - Inspect it for cleanliness
  - If necessary, wipe the nebulizer surfaces with 10% bleach solution
  - Place distilled water in the nebulizer chamber to the level marked on the chamber
  - Place a small amount of sterile water in the cup portion of the disposable nebulizer tubing
  - Insert the cup into the nebulizer
  - Test to make sure the nebulizer is functional by turning it on and checking to see whether it produces a mist
- Before beginning sputum induction:
  - Label the sputum jar in pencil with the patient's name and address, and the date
  - Place the completed Mycobacteriology form in the lab slip pocket of a biohazard bag with the patient's name facing out
- Include the TB Registry number of patients with confirmed TB disease or signs and symptoms consistent with TB disease on the mycobacteriology form

PREPARING THE PATIENT

The attending BTBC staff member prepares the patient for sputum induction:

- Explain the purpose of the procedure
- Orient the patient to the nebulizer and demonstrating how it functions
- Show patient the sputum jar and instruct them not to open the jar until ready to expectorate into it and to close the jar tightly as soon as the specimen is collected
- Provide sterile or bottled water and ask the patient to rinse their mouth prior to the procedure
- Explain not to begin the sputum induction procedure until the staff member has left the room and the door is firmly closed
- Telling the patient to:
  - Inhale the aerosol by taking three or four deep, slow breaths through the mouth without placing their mouth on the tubing (the patient is not to demonstrate deep breathing during the instruction)
  - Cough vigorously if they do not cough spontaneously in response to the mist
- Ask the patient to cover their mouth with a tissue when coughing unless expectorating into the sputum jar
  - Continue trying to cough and to expectorate after inhaling the mist
  - Expectorate all sputum into the sputum jar, without spilling it outside the jar
  - Cover the jar tightly after 5-10 milliliters (ml) of sputum from deep in the lung are in the jar

- Place sputum specimens in the biohazard bag, then the brown paper bag, and give the plastic to the TB clinic staff
- Stay in the sputum induction room, remaining in the anteroom until coughing has completely stopped
- Shut the door after leaving the sputum induction room

ROLE OF TUBERCULOSIS CLINIC STAFF DURING THE INDUCTION PROCEDURE

BTBC staff remain near, but not inside, the sputum induction room during the procedure in order to be available to assist patients if necessary and to ensure that patients remain in the sputum induction room until coughing has stopped. If a staff member must enter the sputum induction room during the procedure, a properly fitted, National Institute for Occupational Health and Safety (NIOSH)-approved respirator (e.g., respirator type N95) is worn.

HANDLING OF SPECIMENS

While in the sputum induction room or booth, patients place the sputum jar in the Ziploc section of the biohazard bag and put the biohazard bag in a brown paper bag. The patient gives the brown paper bag to clinic staff, who place the bag in the refrigerator until it is delivered to the laboratory.

- BTBC staff put on a properly fitted, NIOSH-approved N95 particulate respirator and disposable gloves before entering the sputum induction room
  - The respirator is not removed until after leaving the room
  - The door is closed after entering the sputum induction room
- BTBC staff remove nebulizer tubing with cup and lid and discard it into the disposal bag for biohazardous waste
- BTBC staff wipe the nebulizer and table surfaces clean with a 10% bleach solution and discard any litter in the treatment area
- Staff remove gloves, wash hands, and prepare the equipment for the next patient

SPUTUM INDUCTION ROOM CLEARANCE TIMES

Each sputum induction room has an individually calculated clearance time that is determined by the size of the room, the air changes per hour (ACH), and the air mixing factor. NYC Health Department TB clinic sputum induction rooms' clearance times are as follows:

- **Corona TB Clinic:** 15 minutes
- **Fort Greene TB Clinic:** 10 minutes
- **Morrisania TB Clinic:** 15 minutes
- **Washington Heights TB Clinic (3rd Floor):** 13 minutes
- **Washington Heights TB Clinic (2nd Floor):** 15 minutes

Clearance times are determined by qualified Bureau staff and calculated as follows:

- Determine the cubic volume of the room: **Cubic volume = length x width x height**
- Calculate ACH: **ACH = (cubic feet per minute x 60) / cubic volume**
- Determine air mixing factor: Isol-Aide sputum induction booths/rooms have an effective mixing factor of 1.81 as determined by the manufacturer.
- Extrapolate clearance time from Centers for Disease Control and Prevention's "Guidelines for Preventing the Transmission of *Mycobacterium Tuberculosis* in Health-Care Facilities, 2005," available at **www.cdc.gov**

CARE OF ROOM AND NEBULIZER AT THE END OF THE DAY

At the end of the day, staff restore the nebulizer and the sputum induction room as follows:

- Before entering the sputum induction room, wait at least 10 minutes after the last patient leaves
- Put on disposable gloves and a properly fitted, NIOSH-approved particulate respirator prior to entering
- Close the door after entering
- Remove and discard the nebulizer tubing with cup and lid
- Empty the nebulizer chamber
- Clean the nebulizer chamber and all exposed surfaces with a 10% bleach solution and wipe the chamber dry
- Discard the bleach solution
- Remove and discard the disposable gloves and wash hands
- Leave the ultraviolet light and the fan on
- Remove the personal N95 particulate respirator after leaving the room

APPENDIX F: POTENTIAL DRUG INTERACTIONS WITH ISONIAZID AND RIFAMYCIN MEDICATIONS

DRUG INTERACTIONS WITH RIFAMYCIN MEDICATIONS[1]

DRUG INTERACTION	EFFECTS
Angiotensin Converting Enzyme Inhibitors	Decreases angiotensin converting enzyme levels
Angiotensin Receptor Blockers	Decreases angiotensin receptor blocker levels
Antianxieties	Decreases antianxiety effect
Anticoagulants	Decreases anticoagulants effect
Antidepressants (TCA)	Decreases antidepressant effect
Antiplatelet Agents	Increases antiplatelet effect
Antipsychotics	Decreases level of antipsychotic and may increase clearance of some
Azole Antifungals	Decreases azole antifungal effect
Beta-Blockers	Decreases beta blockade; RIF has more of an effect than RBT
Barbiturates	Decrease barbiturate effect
Benzodiazepines	Decreases benzodiazepines effect that undergo oxidative oxidation
Calcium Channel Blockers	Decreases calcium channel blocker effect
Chloramphenicol	Decreases chloramphenicol effect
Contraceptives	Decreases contraceptive effect
Corticosteroids	Marked decrease in steroid effect
Cyclosporine	Decreases cyclosporine effect, increases RIF effect
Delavirdine	Marked decrease in delavirdine effect
Digoxin	Decreases digoxin effect; decreases RIF level
Dilantin	Decreases dilantin effect
Dipeptidyl Peptidase IV Inhibitors	Decreases dipeptidyl peptidase IV inhibitor effect
Efavirenz	Slight decrease in efavirenz effect
Glipizide and Metformin	Decreases glipizide effect, no effect on metformin
Glyburide and Metformin	Decreases glyburide effect, no effect on metformin
Haloperidol	Decreases haloperidol effect
HMC CoA Inhibitors (Statins)	Decreases statin levels
Macrolide antibiotics	Decreases macrolide effect; increases RBT toxicity
Meglitinide Analogue	Decreases meglitinide analogue
Methadone	Decreases methadone effect
Protease Inhibitors	Marked decrease in activity of protease inhibitors, increases RIF effect
Sitagliptin and Metformin	May decrease sitagliptin levels, no effect on metformin
Sulfonylurea	Decreases sulfonylurea effect

DRUG INTERACTIONS WITH ISONIAZID

DRUG INTERACTION	EFFECTS
Acetaminophen	Increases hepatotoxicity
Alcohol	Increase incidence of hepatitis; possible decreased INH effect
Anticoagulants	Increases anticoagulant effect
Benzodiazepine	Increases benzodiazepine toxicity
Carbamazepines	Increases toxicity of both carbamazepines and INH
Disulfiram (Antabuse)	Potential for psychotic episodes
Halpendol	Increases halpendol toxicity
Hypoglycemics	Monitor glucose, decreases effect (may cause hyperglycemia)
Ketoconazole	Decreases ketoconazole effect
Phenytoin	Increases phenytoin toxicity
Theophylline	Increases theophylline toxicity

Adapted from: Heartland National TB Center. Tuberculosis Medication Drug and Food Interactions. Retrieved from www.heartlandntbc.org/assets/products/tuberculosis_medication_drug_and_food_interactions.pdf.

1. Rifabutin is a weaker inducer of the cytochrome P450 system, potentially interacting with some of the same medications as RIF

Abbreviations Used: CNS=central nervous system; RBT=rifabutin; RIF=rifampin; TB=tuberculosis

APPENDIX G: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR FIRST-LINE MEDICATIONS USED TO TREAT TUBERCULOSIS*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	THREE TIMES PER WEEK DOSE [MAX]	TWO TIMES PER WEEK DOSE [MAX]*	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
INH *Oral/ Intramuscular* Bactericidal	Children: 10-15 mg/kg Adults: 5 mg/kg [300 mg]	Children: 20-30 mg/kg Adults: 15 mg/kg [900mg]	Children: 20-30 mg/kg Adults: 15 mg/kg [900mg]	Hepatic enzyme elevations, hepatitis, rash, peripheral neuropathy, CNS effects, increased phenytoin levels, possible interaction with disulfiram (Antabuse®)	• Monthly clinical evaluation • LFTs[1]	• Vitamin B6 (pyridoxine) 25 mg/day may decrease peripheral neuritis and CNS effects and should be used in patients who are abusing alcohol, pregnant, breastfeeding infants on INH, malnourished, or who have HIV infection, cancer, chronic renal or liver disease, diabetes, or pre-existing peripheral neuropathy • Aluminum-containing antacids reduce absorption • Drug interactions with several agents
RIF *Oral/Intravenous* Bactericidal	Children: 10-20 mg/kg Adults: 600 mg (range: 8-12 mg/kg) [600 mg]	Children: 10-20 mg/kg Adults: 600 mg (range: 8-12 mg/kg) [600 mg]	Children: 10-20 mg/kg Adults: 600 mg (range: 8-12 mg/kg) [600 mg]	Hepatic enzyme elevations, hepatitis, rash, fever, thrombocytopenia, influenza-like syndrome, reduced levels of many drugs, including methadone, warfarin, hormonal forms of contraception, oral hypoglycemic agents, theophylline, dapsone, ketoconazole, PIs and NNRTIs	• Monthly clinical evaluation • CBC including platelets and LFTs as indicated[1]	• Orange discoloration may occur in contact lenses and body secretions such as tears and urine • Patients receiving methadone will need their methadone dosage increased, by an average of 50%, to avoid opioid withdrawal • Interaction with many drugs leads to decreased levels of the co-administered drug • May make glucose control more difficult in people with diabetes • Contraindicated for patients taking most PIs and NNRTIs • Patients should be advised to use barrier contraception
RBT[2] *Oral* Bactericidal	Children: 5 mg/kg Adults: 5 mg/kg [300 mg]			Rash, hepatitis, fever, neutropenia, thrombocytopenia, reduced levels of many drugs, including PIs, NNRTIs, dapsone, ketoconazole and hormonal forms of contraception	• Monthly clinical evaluation • CBC including platelets and LFTs as indicated[1]	• Orange discoloration may occur in contact lenses and body secretions, such as urine and tears • If taken concurrently with PIs or NNRTIs, adjust dose of RBT and monitor for decreased ART activity and for RBT toxicity • Contraindicated for patients taking single PI, ritonavir/saquinavir, or delaviridine based ART regimens • Methadone dosage generally does not need to be increased • Patients should be advised to use barrier contraception

APPENDIX G: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR FIRST-LINE MEDICATIONS USED TO TREAT TUBERCULOSIS (CONTINUED)*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	THREE TIMES PER WEEK DOSE [MAX]	TWO TIMES PER WEEK DOSE [MAX]*	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
PZA *Oral* Bacteriostatic	Children: 35 mg/kg (range: 30-40 mg/kg) Adults: 25 mg/kg (range: 20-30 mg/kg) [2000 mg for children and adults]	Children: 50 mg/kg (range: 40-60 mg/kg) Adults: 35 mg/kg (range: 30-40 mg/kg [3000 mg for children and adults]	Children: 50 mg/kg (range 40-60 mg/kg) Adults: 50 mg/kg (range 40-60 mg/kg) [3500 mg for children and adults]	GI upset, hepatotoxicity, hyperuricemia, gout (rarely), arthralgias, rash	• Monthly clinical evaluation • LFTs as indicated[1]	• Hyperuricemia can be used as indicator of adherence • Treat increased uric acid only if symptomatic • May complicate management of diabetes mellitus • Allopurinol increases level of PZA by inhibiting xanthine oxidase resulting in failure of allopurinol to lower serum uric acid
EMB *Oral* Bacteriostatic	Children: 20 mg/kg (range: 15-25 mg/kg) [1500 mg] Adults: 15-25 mg/kg [2000 mg]	Children: 50 mg/kg [2500 mg] Adults: 30 mg/kg (range: 25-35 mg/kg) [2800 mg]	Children: 50 mg/kg [2500mg] Adults: 45 mg/kg (range: 40-50 mg/kg) [3600 mg]	Decreased red-green color discrimination, decreased visual acuity, skin rash	• Monthly clinical evaluation • Check color vision and visual acuity monthly	• Optic neuritis may be unilateral; check each eye separately. If possible, avoid in children too young to undergo vision testing • If patient develops visual complaints, refer for prompt ophthalmologic evaluation. May need to discontinue EMB while awaiting evaluation
SM *Intramuscular/ Intravenous* Bactericidal	Children: 15-20 mg/kg Adults: 15 mg/kg [1000 mg]	Children: 25-30 mg/kg Adults: 15 mg/kg [1000 mg]	Children: 25-30 mg/kg Adults: 15 mg/kg [1000 mg]	Auditory toxicity, renal toxicity, hypokalemia, hypomagnesemia	• Monthly clinical evaluation • Audiometry, renal function, electrolytes, including magnesium	• Ultrasound and warm compresses to injection site • Patients with decreased renal function may require the 15 mg/kg dose to be given only 3 times per week to allow for drug clearance

Source: Nahid P, Dorman SE, Alipanah N, et al. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America clinical practice guidelines: treatment of drug-susceptible tuberculosis. Clin Infect Dis. 2016 Oct 1;63(7):e147-e195.

* All toxicities are not listed here. Full prescribing information should be checked in the package insert or pharmacology texts. Use of brand names is for informational purposes only and does not imply endorsement by the New York City Health Department.

♦ Daily or three times per week therapy are the preferred treatment regimens compared to twice weekly therapy.

1. LFTs are indicated if baseline is abnormal or patient has risk factors for toxicity.

2. Not FDA-approved for the treatment of TB.

Abbreviations Used: ART=antiretroviral therapy; ATS=American Thoracic Society; CBC=complete blood count; CDC=Centers for Disease Control and Prevention; CNS=central nervous system; DOT=directly observed therapy; EMB=ethambutol; FDA=Food and Drug Administration; GI=gastrointestinal; HIV=human immunodeficiency virus; IDSA=Infectious Disease Society of America; INH=isoniazid; IUATLD=International Union against Tuberculosis and Lung Disease; kg=kilograms; LFT=liver function test; mg=milligrams; NNRTI=non-nucleoside reverse transcriptase inhibitors; PI=protease inhibitors; PZA=pyrazinamide; RBT=rifabutin; RIF=rifampin; SM=streptomycin; TB=tuberculosis; WHO=World Health Organization

APPENDIX H: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR ADDITIONAL MEDICATIONS USED TO TREAT TUBERCULOSIS*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
AK *Intramuscular/ Intravenous* Bactericidal	Children: 15–30 mg/kg Adults: 15 mg/kg [1000 mg]	Auditory toxicity, renal toxicity, vestibular toxicity (rare), hypokalemia, hypomagnesemia	• Monthly clinical evaluation • Audiometry, renal function, electrolytes, including magnesium	• Ultrasound and warm compresses to injection site may reduce pain and induration • PICC line may need to be used • AK levels are commercially available and should be followed • Patients with decreased renal function may require 15 mg/kg dose to be given only 2-3 times per week to allow for drug clearance
BDQ *Oral* Bactericidal	Children: 5 years of age and older weighing 15-29 kg: 200 mg x 2 wks, then 100 mg 3x/wk x 22 wks Children weighing > 30 kg: Dose same as adults Adults: 400 mg x 2 wks, then 200 mg 3x/wk x 22 wks	QT prolongation, hepatotoxicity, nausea, loss of appetite, abdominal pain, arthralgia, hemoptysis, rash	• Monthly clinical evaluation • Complete blood count, chemistry including K^{+}, Ca^{+2}, Mg^{+2}, and LFTs • FDA requires monitoring EKG at baseline then at 2 wks, 12 wks, and 24 wks	• Approved for pulmonary MDR-TB • Part of combination regimen for MDR-TB • Duration is 24 wks total; longer duration could be considered on a case-by-case basis especially when there are limited treatment options • BDQ's half-life is 4-5 months; consider discontinuing BDQ 4–5 months prior to discontinuing other drugs in the treatment regimen to reduce or avoid an extended period of exposure to low levels of BDQ • Should not be used with CYP3A4 inducers, i.e., rifampin and efavirenz • There may be cross resistance between BDQ and CFZ • Can be taken with food • Must be given under DOT • For children who cannot swallow, disperse tablets in water and mix with beverage or soft food or crush the tablet and mix with soft food
CFZ *Oral* Bactericidal	Children: Limited data, but doses of 2-5 mg/kg/day have been given Adults: 100 mg	Pink or red discoloration of skin and body fluids discoloration; gastrointestinal intolerance; hepatotoxicity; photosensitivity; rash, pruritus, dry skin, ichthyosis; retinopathy; severe abdominal symptoms, bowel obstruction, gastrointestinal bleeding	• Monthly clinical evaluation • Baseline and monthly EKGs to assess QT interval • Monitor complete blood count, chemistry including K^{+}, Ca^{+2}, Mg^{+2}, and LFTs	• Needs an IND from the FDA and coordination with Novartis • Skin discoloration is reversible but may take a long time • Can prolong the QT interval especially if given with BDQ and other QT prolonging agents • Each dose should be taken with food and on DOT • There may be cross resistance between BDQ and CFZ
CM *Intramuscular/ Intravenous* Bactericidal	Children: 15–20 mg/kg Adults: 15 mg/kg [1,000 mg]	Auditory, vestibular, and renal toxicity; eosinophilia, hypokalemia, hypomagnesemia	• Monthly clinical evaluation • Audiometry, renal function, electrolytes, including magnesium	• Ultrasound and warm compresses to injection site may reduce pain and induration • Patients with decreased renal function may require 15 mg/kg dose to be given only 2-3 times per week to allow for drug clearance

APPENDIX H: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR ADDITIONAL MEDICATIONS USED TO TREAT TUBERCULOSIS (CONTINUED)*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
CS *Oral* Bacteriostatic	Children: 15–20 mg/kg Adults: 500–1000 mg, divided doses [1000 mg]	Psychosis, seizures, headache, depression, suicide, other CNS effects, rash, increased phenytoin levels	• Monthly clinical evaluation • Assess and monitor mental status	• Increase gradually, checking serum levels • Pyridoxine hydrochloride (vitamin B6) may decrease CNS effects (use 50 mg for each 250 mg of CS)
ETA *Oral* Bacteriostatic	Children: 15–20 mg/kg Adults: 500–1000 mg, divided doses [1000 mg]	Nausea, vomiting, diarrhea, abdominal pain, bloating, hepatotoxicity, hypothyroidism (especially when administered with PAS), metallic taste	• Monthly clinical evaluation • LFTs (if baseline abnormal) • Thyroid function periodically, especially if also on PAS	• Antacids/anti-emetics and lying supine for 20 minutes after dose may help tolerance • Start with 250 mg daily and increase as tolerated
LFX[1] *Oral/Intravenous* Bactericidal	Children: 6 months to under 5 years of age: 10 mg/kg two times per day 5 years and older: 10 mg/kg once per day Adults: 500–1000 mg in one dose	Nausea, vomiting, diarrhea, abdominal pain, tremulousness, insomnia, headache, dizziness, lightheadedness, photosensitivity, tendonitis, tendon rupture, possible hypo- and hyperglycemia hypersensitivity	• Monthly clinical evaluation • Monitor blood sugar	• Our clinical experience shows safety with long-term use • Dose should be adjusted to 3 times per week in renal failure
LZD *Oral/intravenous* Bacteriostatic[2]	Children: Under 12 years of age: 10-15 mg/kg per day, based on weight 12 years of age and older: 10 mg/kg [600 mg/day] Adults: 600 mg	Myelosuppression, hemolytic anemia, peripheral and optic neuropathy, nausea, vomiting, diarrhea, LFT elevations, tongue discoloration	• Monthly clinical evaluation, BP, screening for optic and peripheral neuropathy • Complete blood count initially 1-2 wks, then monthly, chemistry, and LFTs	• Available in an oral suspension 100mg/5ml • Drug-drug interactions with tyramine containing foods (e.g., cured meats), SSRIs, and MAOIs • Risk of serotonin syndrome • Can cause lactic acidosis
MFX[1] *Oral/Intravenous* Bactericidal	Children: 10-15 mg/kg Adults: 400 mg[3]	Similar to LFX	• Monthly clinical evaluation • Monitor blood sugar	• More active than LFX against *M. tuberculosis*. • Avoid in patients with prolonged QTc interval and those receiving class Ia or III antiarrhythmic agents

APPENDIX H: DOSAGES, ADVERSE REACTIONS, AND MONITORING FOR ADDITIONAL MEDICATIONS USED TO TREAT TUBERCULOSIS (CONTINUED)*

DRUG *ROUTE OF ADMINISTRATION* MODE OF ACTION	DAILY DOSE [MAX]	MAJOR ADVERSE REACTIONS	RECOMMENDED REGULAR MONITORING	COMMENTS
PAS *Oral* Bacteriostatic	Children: 200-300 mg/kg total (usually divided 100 mg/kg given two times per day) Adults: 4000 mg two times per day [12,000 mg]	Nausea, vomiting, diarrhea, abdominal pain, hypersensitivity, hepatoxicity, hypothyroidism (especially when administered with ETA), decreased digoxin levels, increased phenytoin levels, PAS levels decreased by diphenhydramine	• Monthly clinical evaluation • Thyroid function periodically especially if also on ETA	• Begin gradually and increase dosage as tolerated • May cause hemolytic anemia in patients with glucose 6-phosphate dehydrogenase deficiency
Pretomanid *Oral* Bactericidal	Children: Not established Adults: 200 mg per day for 26 wks	Optic and peripheral neuropathy, myelosuppression, hepatotoxicity[4]	• Monthly clinical evaluation • Baseline and monthly EKGs to assess QT interval[5] • Monitor complete blood counts, chemistry including K^{+}, Ca^{+2}, Mg^{+2}, and LFTs • Monitor for visual changes and neuropathy	• Pretomanid must be used in combination with BDQ and LZD for treatment of pulmonary XDR-TB and treatment intolerant or nonresponsive MDR-TB (BPaL regimen); regimen must be given as specified[6] • Pretomanid is contraindicated in patients for whom BDQ and/or LZD are contraindicated • Most of the adverse reactions observed in the BPaL regimen were noted when pretomanid was given with BDQ and LZD and may be attributed to those drugs • Tablets should be taken whole and can be given with food • Should not be used with CYP3A4 inducers, i.e., rifampin and efavirenz • Avoid organ anion transport substrates (OAT3) • Testicular atrophy and male infertility in animal studies

Source: Nahid P, Mase SR, Migliori GB, et al. Treatment of drug-resistant tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. Am J Respir Crit Care Med. 2019;200(10):e93-e142.

* All toxicities are not listed here. Full prescribing information should be checked in the package insert or pharmacology texts. Use of brand names is for informational purposes only and does not imply endorsement by the New York City Health Department.

1. Although FQNs are not approved for use in children in most countries, the benefit of treating children with MDR-TB with a FQN may outweigh the risk in many instances. 2. May be bactericidal when combined with other agents in the treatment of MDR-TB. 3. Higher MFX doses have been used safely when the isolate is resistant to ofloxacin and the minimum inhibitory concentration for LFX or MFX suggests higher doses may overcome resistance. Higher doses also are used in cases of malabsorption. 4. List of adverse reactions when pretomanid is used combined with LZD and BDQ. 5. When used in combination with BDQ and LZD, the BDQ package insert recommends EKGs at baseline, and then at 2, 12, 24 wks after starting medications. Some experts recommend monthly EKG monitoring. 6. BPAL regimen: pretomanid 200 mg orally x 26 wks, BDQ 400 mg orally x 2 wks, then 200 mg 3x/wk for 24 wks, and LZD 1200 mg orally for 26 wks, with dose adjustments after the first month.

Abbreviations Used: AK=amikacin; BDQ=bedaquiline; BTBC=Bureau of Tuberculosis Control; CFZ=clofazimine; CM=capreomycin; CNS=central nervous system; CS=cycloserine; ETA=ethionamide; FQN=fluoroquinolone; kg=kilograms; LFX=levofloxacin; LZD=linezolid; MAOI=monamine oxidase inhibitors; *M. tuberculosis*=*Mycobacterium tuberculosis*; MDR-TB=multidrug-resistant tuberculosis; MFX=moxifloxacin; mg=milligrams; PAS=para-aminosalicylic acid; PICC=peripherally inserted central catheter; SSRI=selective serotonin reuptake inhibitors; TB=tuberculosis; wk=week; XDR-TB=extensively drug-resistant tuberculosis

APPENDIX I: THE USE OF ANTI-TUBERCULOSIS DRUGS AND PREGNANCY, BREASTFEEDING, TUBERCULOSIS MENINGITIS, AND RENAL AND HEPATIC FAILURE[1]

DRUG	SAFETY IN PREGNANCY[2]	SAFETY IN BREASTFEEDING	CNS PENETRATION[3]	DOSAGE IN RENAL INSUFFICIENCY[4]	DOSAGE IN HEPATIC INSUFFICIENCY
Isoniazid	Has been used safely[3]	Safe	Good (20-100%)	No change[5]	No change, but use with caution
Rifampin	Has been used safely (isolated reports of malformations)	Safe	Fair (inflamed meninges) (10-20%)	No change	No change, but use with caution
Rifapentine	Safety not established	No data	Not established	Not established; Use with caution	No change, but use with caution
Rifabutin	Use with caution (limited data on safety)	No data	Good (30-70%)	No change	No change, but use with caution
Pyrazinamide	Recommended by WHO (not FDA)	Moderately safe	Good (75-100%); Use with caution	Decrease dosage; Increase interval; Use with caution	No change, but use with caution
Ethambutol	Has been used safely	Safe	Inflamed meninges only (20-30%)	Decrease dosage; Increase interval[4]	No change
Aminoglycosides (streptomycin, kanamycin, amikacin)	Avoid[6] (associated with ototoxicity in fetus)	Safe	Poor[7] (10-20%)	Decrease dosage; Increase interval[4,8]	No change
Capreomycin	Avoid[6] (limited data on safety)	No data	Poor (10-20%)	Decrease dosage; Increase interval[4,8]	No change
Levofloxacin	Use if benefit outweighs risk	Moderately safe	Good (70-80%)	Increase interval	No change, but use with caution
Moxifloxacin	Use if benefit outweighs risk	Moderately safe	Good (70-80%)	No change, but use with caution	No change, but use with caution, esp-ecially with severe hepatic insufficiency
Cycloserine	Use with caution (limited data on safety)	Moderately safe	Good (50-100%)	Decrease dosage; Increase interval[4,5]	No change
Ethionamide	Do not use (premature labor, congenital malformation)	No data	Good (100%)	No change, but use with caution	No change, but use with caution

APPENDIX I: THE USE OF ANTI-TUBERCULOSIS DRUGS AND PREGNANCY, BREASTFEEDING, TUBERCULOSIS MENINGITIS, AND RENAL AND HEPATIC FAILURE (CONTINUED)[1]

DRUG	SAFETY IN PREGNANCY[2]	SAFETY IN BREASTFEEDING	CNS PENETRATION[3]	DOSAGE IN RENAL INSUFFICIENCY[4]	DOSAGE IN HEPATIC INSUFFICIENCY
Para-aminosalicylic acid	Has been used safely	Moderately safe	Inflamed meninges only	No change, but use with caution	No change, but use with caution
Linezolid	Use only if the potential benefit justifies the risk	Limited data	Good (30-70%)	No change, but use with caution[4]	No change, but use with caution
Bedaquiline	Use only if the potential benefit justifies the risk	Limited data; if needed, monitor infants for signs of BDQ toxicity	Limited data	No change, but use with caution	No change, but use with caution
Clofazimine	Use only if the potential benefit justifies the risk	Should not be used unless clearly indicated	Limited data	Limited data	Limited data
Pretomanid[9]	No data	No data	No data	No data	No data

1. This table presents a consensus of published data and recommendations.

2. As with all medications given during pregnancy, anti-TB medications should be used with extreme caution. The risk of TB to the fetus far outweighs the risk of most medications. Data are limited on the safety of anti-TB medications during pregnancy.

3. Steroid treatment appears to improve outcome in TB meningitis, particularly in patients with altered mental status.

4. If possible, monitor serum drug levels of patients with renal insufficiency.

5. Supplement with pyridoxine hydrochloride (vitamin B6), 25 mg per day for INH, 50 mg per day for each 250 mg per day of cycloserine.

6. If an injectable medication must be used during pregnancy, streptomycin is the preferred agent if the organism is susceptible.

7. Has been used intrathecally: efficacy not documented.

8. If possible, avoid injectable agents in patients with reversible renal damage.

9. Pretomanid is used as part of a regimen that includes linezolid and bedaquiline.

Abbreviations Used: CNS=central nervous system; FDA=Food and Drug Administration; mg=milligrams; TB=tuberculosis; WHO=World Health Organization

APPENDIX J: RECOMMENDATIONS FOR PATIENTS TO ASSIST WITH TAKING TUBERCULOSIS MEDICATIONS

DRUG	RECOMMENDATION
Isoniazid	• Avoid alcohol and acetaminophen-containing medications • Take 1 hour before or 2 hours after meals • May take with small snack if needed • Take 1 hour before or 2 hours after antacids • Supplement Vitamin B6 as needed (25-50 mg) • Avoid food and drinks that contain tyramine including hard cheeses, smoked or cured meats, and soy products
Rifampin	• Avoid alcohol • Take 1 hour before or 2 hours after meal • May take with small snack if needed • Take 1 hour before antacids
Ethambutol	• May be taken with food
Moxifloxacin and Levofloxacin	• Take 2 hours before or after aluminum-, magnesium-, or calcium-containing antacids; iron; vitamins; sucralfate; milk-containing products; and food supplements
Pyrazinamide	• May be taken with food
Ethionamide	• Avoid alcohol • Take with or after meals
Amikacin	• Increase fluid intake, if allowed
Streptomycin	• Increase fluid intake, if allowed • May affect the taste of food
Capreomycin	• May need to increase intake of foods high in potassium, if instructed • Increase fluid intake, if allowed
Para-aminosalicylic acid	• Take with or immediately following meals • Increase fluid intake • Take with yogurt, applesauce, or acidic foods
Cycloserine	• Avoid alcohol • Supplement vitamin B6 as directed
Linezolid	• May be taken with food • Avoid food and drinks that contain tyramine including hard cheeses, smoked or cured meats, and soy products • Do not use with pseudoephedrine, selective serotonin reuptake inhibitors, and other antidepressants

Adapted from: *Heartland National TB Center. Tuberculosis Medication Drug and Food Interactions.* Retrieved from www.heartlandntbc.org/assets/products/tuberculosis_medication_drug_and_food_interactions.pdf.

APPENDIX K: PROCEDURES FOR THERAPEUTIC DRUG MONITORING

Therapeutic drug monitoring (TDM) should be done when there is a clear indication for it. Routine monitoring of antituberculosis drug levels is not recommended in clinical practice. The significance of low serum levels of antituberculosis drugs in relation to clinical response has not been demonstrated. Studies have shown that as many as 60% of tuberculosis (TB) patients had low serum levels of isoniazid or rifampin. However, the clinical response to TB therapy did not differ in those with low drug levels when compared to those with normal levels.

Nonetheless, some patients will fail to respond to antituberculosis treatment despite documented adherence to the medications and absence of drug resistance. Some of these patients may have malabsorption syndromes that prevent them from achieving therapeutic levels of these drugs. Diseases such as human immunodeficiency virus (HIIV) infection, cystic fibrosis, diabetes, and sprue have been implicated in malabsorption of antituberculosis drugs.

A select number of patients with drug susceptible TB will therefore require drug level testing at some point during their treatment for tuberculosis. Patients with drug-resistant TB are more likely to require drug level testing.

In order to optimize the treatment of patients with TB while maintaining the highest levels of sound medical practice, the Bureau of Tuberculosis Control (BTBC) recommends that TDM be used in the following circumstances:

- Lack of clinical response (i.e., culture conversion) while on appropriate drugs and doses, on directly observed therapy (DOT) for at least two months and in the absence of drug resistance
- Lack of clinical response from second-line drugs with a narrow therapeutic window, such as cycloserine, when alternative drugs are limited, and when plans are in place to increase the dose of the drug should levels be low
- Patients with few effective drugs in their regimen, in order to optimize the effect of available drugs
- Lack of clinical response (i.e., lack of culture conversion at two months) in a patient with known or suspected malabsorption syndrome
- Patients with renal insufficiency and who have multidrug-resistant tuberculosis (MDR-TB) or are on certain drugs such as ethambutol
- Patients who relapse with active TB despite appropriate therapy

If drugs levels are low and doses are increased, clinical monitoring should be used to judge the response; repeat TDM should only be done when there is no clinical response after a reasonable amount of time.

Patients with pansensitive, cavitary, or otherwise very extensive disease tend to have a delayed clinical response to treatment even when adherence is documented (under DOT). In most cases these patients will respond if given enough time, usually in the third month of therapy. All patients with a delayed response (i.e., lack of culture conversion at two months) should be treated for nine months instead of six months.

In order to obtain accurate TDM results, BTBC staff must adhere strictly to the guidelines on specimen procurement and handling. Failure to do so will lead to inaccurate results, which may ultimately harm the patient. The following sections delineate procedures for obtaining and handling specimens for TDM.

PHYSICIANS

1. Request New York State (NYS) Clinical Laboratory Evaluation Program (CLEP) pre-approval for TDM through the Office of Medical Affairs, who will fax the NYS non-permitted lab test request to NYS CLEP. Approval is usually received within 1-2 days of submission of the request at the BTBC and the Bureau of Public Health Lab (PHL).
2. Schedule blood drawing on Monday or Tuesday to ensure delivery of the specimen to the Advanced Diagnostic Laboratories National Jewish Health (ADx-NJH) by Thursday. Since the serum must be frozen immediately after centrifugation, arrange immediate delivery of the serum on dry ice to the PHL if a freezer is unavailable at the chest center.
3. Order blood drawing for approximately 2 hours after an observed dose of antituberculosis medications for most medications. When testing levels for linezolid, blood should be drawn just before ingestion of the scheduled dose to obtain the trough level. After the observed ingested dose, blood should be drawn again in 2 hours to obtain the peak level. Additional information on the number of hours after administration of the drug/s dose to collect peak concentration is available on the ADx-NJH Pharmacokinetics Laboratory Requisition (https://www.nationaljewish.org/NJH/media/ADX/Requisitions/ADx700-Pharmacokinetics_Req_10-2018.pdf).
4. For most drug assays, continue all other antituberculosis medication as usually given. For streptomycin, inquire if patient is taking ampicillin and record this on ADX-NJH Pharmacokinetic Laboratory requisition.

PHLEBOTOMISTS

1. Communicate with PHL at (212) 447-6745 to inform them about the scheduled blood draw for TDM at the clinic and to arrange dry ice for specimen delivery back to the PHL.
2. Complete ADX-NJH pharmacokinetic laboratory requisition and PHL requisition to accompany the serum sample to the PHL.
3. Draw blood 2 hours or as applicable after an observed dose of anti-tuberculosis medication(s). Use two 5mL serum separator tubes (SST) or Northwell Lab gold top tubes to draw 5 mL of blood in each tube for one drug assay. Allow blood to clot for 30 minutes before centrifuging specimen to separate serum from cells. Label the cryovial to be used for aliquoting serum with the patient's name, DOB, the date and time of the blood draw, and the name of the drug(s) to be assayed.
4. Centrifuge blood tubes and aliquot serum from each 5mL tube into a separate 2 mL labeled cryovial. ADx-NJH requires at least 2mL of serum per test. Allow room for expansion of the serum inside the tube.

5. Freeze serum in the cryovial immediately and contact PHL to have the frozen serum picked up and transported to them on dry ice.

BUREAU OF PUBLIC HEALTH LABORATORY

1. At PHL, the sample will be frozen overnight at −70° C; the next day it will be packed in dry ice and labeled as specified in full compliance with the shipper and guidelines on handling of dry ice and potentially infectious materials. The ADx-NJH Pharmacokinetic Laboratory requisition sent with the specimen will be included in the shipping package.
2. PHL staff will call the shipper to pick up and deliver the samples.

ADVANCED DIAGNOSTIC LABORATORIES NATIONAL JEWISH HEALTH

1. TDM reports will be delivered from ADx-NJH to the BTBC Office of Medical Affairs. Assays may require up to seven business days for completion.
2. ADx-NJH will bill the BTBC and the bill will go directly to Internal Accounting.
3. The Office of Medical Affairs will notify the staff taking care of the patient of the results. The results will be attached in the surveillance system and the electronic medical record.

APPENDIX L: INITIAL PATIENT INTERVIEW TOPICS

1. Educate the patient about tuberculosis (TB), debunking any misconceptions about the disease. The case manager should determine the most appropriate educational intervention and provide appropriate literature. The educational content should include information about:
   - TB transmission and pathogenesis
   - Preventing TB
   - Distinguishing infection from disease
   - How drug resistance develops
   - Length of treatment needed for sensitive vs. drug-resistant TB (DR-TB)
   - Standard TB medications, including names, dosages, actions, and side effects
   - Directly observed therapy (DOT) program and free New York City (NYC) Health Department services for TB
2. Establish long-term plans for treatment (including DOT).
3. Determine whether the patient will stay in NYC during TB treatment.
4. Inquire about contacts and emphasize to the patient why it is important that contacts be identified and evaluated as soon as possible.
5. Establish a trusting relationship, as this determines how well the patient views the role of the case manager and the healthcare establishment.
6. Obtain and document locating information and agree with the patient on a mode of communication (e.g., cell phone, home/work number, significant other). Identify who will always know where to find the patient.
7. Educate family and identified contacts about TB and the importance of getting evaluated.
8. Assess social needs such as access to social services to resolve issues with child care, housing, employment, substance abuse, and (if appropriate) legal or immigration issues (tell the patient that all services are provided irrespective of immigration status) and refer patient to social worker.
9. If the patient is diagnosed with TB while in a hospital, plans for follow-up care upon discharge must be initiated at the onset of hospitalization and not on the day before discharge. These plans must address issues that will ensure adherence with the treatment regimen.

APPENDIX M: DIRECTLY OBSERVED THERAPY AGREEMENT FORM

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

BUREAU OF TUBERCULOSIS CONTROL (BTBC)
DIRECTLY OBSERVED THERAPY (DOT) AGREEMENT FORM

For Office Use Only:

Patient Name:_____

EMR ID (DOHMH): _____ TB Registry ID: _____

Patient's telephone number: ( ) _____ VDOT telephone number: ( ) _____

This is an agreement between the Bureau of Tuberculosis Control and _____to enroll into the Directly Observed Therapy program for: [ ] myself or [ ] _____ of who I am the legal guardian.

It has been explained to me that the most effective way to treat and prevent tuberculosis (TB) is by taking prescribed anti-TB medication and having a trained health care worker observe the ingestion of all oral medication doses. This observation can be done face to face or virtually by the use of a video-enabled device also known as video DOT (VDOT).

PATIENT/GUARDIAN AGREEMENT

I am enrolling [ ] myself [ ] my ward (e.g. minor child) in:

(1) Face to Face DOT: (a) _____ clinic (b) _____community

(2) Video DOT: (a) _____live video (LVDOT) (b) _____Recorded video (RVDOT)

Therefore, I, _____, agree to the following:
Name of patient /guardian

- I will take or ensure that _____(ward) takes his/her medication under direct observation either face to face in the clinic or the community or by video-enabled device, e.g., phone, tablet, or computer, in my home or secure location of my choice.
- I will or ensure that _____(ward) attends <u>all</u> clinic appointments until the doctor tells me that treatment is completed or is removed from the DOT program.
- If I or _____(ward) cannot make an appointment, I will call to reschedule it as soon as I know I cannot make it:
  - For VDOT appointments, I will call: _____ at _____
    Name of VDOT supervisor Telephone Number
  - For Chest Center appointments, I will call: _____ at _____
    Name of Clinic Nurse Telephone Number
  - For home/community provider appointments, I will call: _____ at _____
    Name of DOT case manager Telephone Number
- I understand that I may transfer between DOT options at any time during the course of the treatment.

APPENDIX M: DIRECTLY OBSERVED THERAPY AGREEMENT FORM (CONTINUED)

- If I or _____ (ward) attends a DOHMH clinic and enrolled in VDOT and decides to withdraw for any reason, I will immediately return unused medication to the clinic so that a new treatment plan can be made by my doctor. I will not give (ward) medication on my own without permission from the treating physician or designee.

Participants who selected VDOT, please initial beside each statement below to indicate that you understand and agree:

- If using my own equipment:
  _____ I understand that standard rates apply. I understand that the DOHMH is not responsible for any data, wireless, or other charges that may occur due to the use of the free VDOT software.

- If I am loaned a DOHMH videophone equipment:
  _____ I understand that the videophone equipment is the property of the DOHMH, and I am responsible for its care, maintenance, and return to the DOHMH upon completion or discontinuation of the VDOT program.

  _____ I will only use the equipment for VDOT and for communication directly related to my TB care.

BUREAU OF TUBERCULOSIS CONTROL (BTBC) AGREEMENT

I have explained the importance of TB treatment and DOT to the patient/guardian. Therefore,

I, _____, as a representative of the BTBC, agree to the following:
Name/title of Nurse/Case Manager/DOT Observer

- BTBC staff will meet _____ at _____AM/PM in person or by video conferencing.
  Name of Patient/ward

- BTBC staff will notify the patient and or guardian as quickly as possible if there is a scheduling conflict by phone at:
  _____ or _____.
  Home Number Mobile Number

- BTBC staff will assist the patient in maintaining his/her DOT and clinic appointments.

- BTBC staff will respond to all questions, concerns, and needs raised by the patient or guardian to the best of his/her capacity, including referrals for social services.

By signing below, we agree to be responsible for the above statements:

_____ Date____/____/____
Signature of Patient/Guardian

_____ Date____/____/____
Signature of Case Manager/DOT Observer/Nurse

If you have any questions, concerns, suggestions or complaints about any aspect your care, please contact:

_____ at _____
Name/Title Telephone Number

Last updated: March 2019

APPENDIX N: HOME ISOLATION AGREEMENT

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

HOME ISOLATION PATIENT AGREEMENT

I _____ acknowledge that I have active infectious tuberculosis,
(Patient's full name)
and that I must separate myself from others in order to prevent other from being exposed to my tuberculosis disease.
I have discussed this agreement with _____
(Full name of DOHMH employee)
a _____ at the Department of Health and Mental Hygiene
(Job title)
(DOHMH), who has answered my questions about home isolation fully to my satisfaction. I further acknowledge that if I am unable or unwilling to observe any of the conditions of this agreement, while my tuberculosis remains infectious, I represent a danger to the health of others and I am subject to removal to a hospital for respiratory isolation either voluntarily or by order of the Commissioner of Health.

In return for being allowed to remain in my home while my tuberculosis is infectious, I agree to all of the following conditions.

- I will take all my prescribed anti-tuberculosis medications in a program of daily directly observed therapy (DOT) as directed by my physician or the Commissioner of Health.
- I will entertain no visitors in my home and will not visit other persons' home.
- I will cover my mouth and nose whenever I cough, sneeze, or hack while indoors or outdoors in the presence of other people.
- I will not use any public (bus, train, taxi, subway, airplane) or private (automobile) transportation unless absolutely necessary to obtain medical attention, and then only using the mask which my physician has prescribed for me.
- I will not visit enclosed public spaces such as theaters, shopping malls, department, supermarket or other stores; but I may spend time in open spaces such as parks, backyards or public streets which are not crowded.
- I will not care for or spend time with children of any age or work outside my home without permission from my physician and the DOHMH.
- I will not leave New York City for any reason without the DOHMH and my physician's permission and under such conditions as are prescribed.
- I have received a copy of the instructions entitled "Instructions for Patients with Potentially Infectious TB"
- Any additional conditions:

_____
_____
_____

If I have any further questions about how to comply with this agreement, I will telephone
_____ at _____
(Full name and title of contact person at DOHMH) (Telephone number with area code)

Date: _____ _____
(Patient's signature)

Date: _____ _____
(Staff signature)

Revised: July 2006

APPENDIX O: INSTRUCTIONS FOR PATIENTS WITH POTENTIALLY INFECTIOUS TB

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

Instructions for patients with potentially infectious TB

You are being discharged from the hospital although your sputum tests indicate that you may still infect other people with TB or you are advised to be evaluated as an outpatient while you may have infectious TB.

You are being discharged because you said that either you live alone or will be going back to a living arrangement where the other people living there are healthy and wish to have you home. We are required by law to notify them that they have been exposed to TB and to evaluate them.

You may have been placed on medication to treat TB already or are waiting to start medications after you have been evaluated as an outpatient.

The following instructions will help reduce the spread of TB germs to other people and you should follow them carefully:

- If you return to a home that has other people, you should always:
  - Limit the time spent in common household areas (such as bathroom or kitchen) and keep your bedroom door closed
  - Wear a surgical mask when spending time in a space that is also used by others to reduce the number of TB germs that you put in the air when you cough or talk.
- You should always cover your mouth when coughing or sneezing
- You should not be around infants, young children or, to the best of your knowledge, persons who have weakened immunity such as people with HIV/AIDS. (If there are young children at home, you may still be discharged to the home if the children have been evaluated for latent TB infection and are on "preventive" medication, as determined by their physician)
- You should participate in a program of directly observed therapy (DOT), about which you have been educated by an employee of the NYC health department
- You should avoid going to public places or return to work or school until your doctor, working with the health department, says it is OK for you to do so
- You should keep your doctor's or clinic appointments to ensure that treatment for TB is not interrupted
- Some of these restrictions will be removed once your physician, along with the health department, determines that you are no longer infectious
- Your TB treatment and DOT will continue even after these restrictions are removed.

Following these instructions will help in limiting the spread of TB germs to your family and others. If you have questions about your treatment please call your physician or health department at 311.

You can also find more information about TB on our website at nyc.gov/health/tb.

APPENDIX P: INFORMATION FOR PERSONS WHO LIVE WITH PATIENTS WITH TB

NEW YORK CITY DEPARTMENT OF
HEALTH AND MENTAL HYGIENE
Dave A. Chokshi, MD MSc
Commissioner

Information for persons who live with patients with TB

A family member or someone in your household was recently diagnosed with or is suspected of having active TB. TB is a preventable and treatable disease. TB is transmitted through the air when a patient with the disease coughs or sneezes without covering his or her mouth. People with the active form of the disease must take their medication and must follow certain rules to prevent the spread of TB germs to people they live or work with. ***We are required by state law to inform you of this information.***

If there are children in your home they should be evaluated by their doctor and they should be placed on "preventive" therapy if appropriate. They can also be evaluated and treated at the health department's chest centers.

If a family member or someone in your household has been diagnosed with TB:

- You should get tested to see if you have already been infected with the germs that cause TB
- If you have been infected with the germs that cause TB, you should have a medical evaluation and a chest x-ray to make sure that you have not progressed to active TB
- If you have TB infection, you should take medicine to prevent the development of active TB.
- **The member of your household with TB should stay at home until his or her physician and the health department says he/she can go out.**
- He/she should not go to work or school during this time period and should avoid going to any public areas during this time period.
- Please assist the TB patient by doing their errands, such as grocery shopping.
- Your household member with TB should cover his/her mouth with a tissue whenever he/she coughs or sneezes; he/she should put the used tissue in the regular garbage.
- When around other people, the patient should wear a surgical mask that covers the nose and mouth.
- While at home, limit your contact with the TB patient as much as possible; the patient should sleep in a separate room until advised by their physician.
- It is OK to share eating utensils (spoons, forks, cups or glasses) and other household items.

Following these instructions will help in limiting the spread of TB germs to your family and others.
If you have questions about your treatment please call your physician or health department at 311.
You can also find more information about TB on our website at nyc.gov/health/tb.

APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM

NYC Health

New York City Department of Health and Mental Hygiene

Universal Reporting Form

To report an **immediately notifiable** disease or condition, an outbreak among three or more persons or an unusual manifestation of any disease or condition, or any newly apparent or emerging disease or syndrome, call the Provider Access Line at **866-692-3641**.

Diseases and conditions in green and marked with * are **immediately notifiable**; those marked with † are immediately notifiable if case meets the risk group criteria on page 2. Report by calling **866-692-3641**.

For all other diseases and conditions, report using Reporting Central online via NYCMED at **www.nyc.gov/health/nycmed**, mail this form to the NYC Department of Health and Mental Hygiene, 42-09 28th Street, CN-22, Long Island City, NY 11101, or call **866-692-3641** for the appropriate fax number.

Go to **www.nyc.gov/health/diseasereporting** for more information.

Patient Information

Patient Last Name	First Name	Middle Name	DATE OF REPORT
Patient AKA: Last Name	AKA: First Name	AKA: Middle Name	_____/_____/_____
Age / Date of Birth _____/_____/_____	Country of Birth	Social Security Number	DATE OF DIAGNOSIS
If patient is a child, Guardian Last Name	Guardian First Name	Guardian Middle Name	_____/_____/_____
Medical Record Number	Medicaid Number		DATE OF ILLNESS ONSET
Patient Home Address	City / State / Zip Code		_____/_____/_____
Country	Borough: ☐ Manhattan ☐ Bronx ☐ Brooklyn ☐ Queens ☐ Staten Island ☐ Unknown ☐ Not NYC		
Email Address	Mobile Phone	Home Phone	☐ Homeless

Sex: ☐ Male ☐ Female ☐ Transgender MTF ☐ Transgender FTM ☐ Unknown

Race: ☐ Black ☐ White ☐ American Indian/Alaska Native ☐ Native Hawaiian/Pacific Islander ☐ Asian ☐ Other: _____ ☐ Unknown

Ethnicity: ☐ Hispanic ☐ Non-Hispanic ☐ Unknown

Is patient alive? ☐ Yes ☐ No ☐ Unknown
If no, date of death: _____/_____/_____

Is patient pregnant? ☐ Yes ☐ No ☐ Unknown
If yes, due date: _____/_____/_____

Is case suspected to be due to healthcare associated transmission? ☐ Yes ☐ No ☐ Unknown

Was patient admitted to hospital? ☐ Yes ☐ No ☐ Unknown
Admission date: _____/_____/_____
Discharge date: _____/_____/_____

Is patient a newborn infant? ☐ Yes ☐ No ☐ Unknown
If yes, name of hospital where infant was born _____
Name of facility where infant's mother obtained prenatal care _____

Foreign travel

Countries _____ **Date returned to U.S.** _____/_____/_____

Other Information

REPORTER	Name of Person Reporting Disease	Email address	Phone	
	Name of Facility of Person Reporting Disease	National Provider Identifier (NPI) Code	Permanent Facility Identifier (PFI) Code	
	Facility Street Address	City	State	Zip Code
FACILITY	Name of Hospital/Healthcare Facility Providing Care for Patient	Facility National Provider Identifier (NPI) Code	Permanent Facility Identifier (PFI) Code	
	Facility Street Address	City	State	Zip Code
LAB	Name of Testing Laboratory	Phone	CLIA Number	
	Laboratory Street Address	City	State	Zip Code
PROVIDER	Name of Provider Caring for Patient	National Provider Identifier (NPI) Code	Fax	
	Email address	Phone	Mobile	
	Provider Street Address	City	State	Zip Code

Form PD-16 (Rev. 3/2017)

-1-

APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM (CONTINUED)

Patient Last Name	First Name	Medical Record Number

Diseases and conditions in green and marked with * are immediately notifiable; those marked with † are immediately notifiable if case meets the risk group criteria at the bottom of the page. Report by calling **866-692-3641**.

For all other diseases and conditions, report using Reporting Central online via NYCMED at **www.nyc.gov/health/nycmed**, mail this form to the NYC Department of Health and Mental Hygiene, 42-09 28th Street, CN-22, Long Island City, NY 11101, or call **866-692-3641** for the appropriate fax number.

Go to **www.nyc.gov/health/diseasereporting** for more information.

- ☐ **Amebiasis†**
- ☐ **Anaplasmosis** (Human granulocytic anaplasmosis)

  Animal bite – see Environmental Conditions section on page 3. See rabies if potential for exposure.
- ☐ **Anthrax***
- ☐ **Arboviral infections,** acute*

  Specify which virus: _____
  If Chikungunya, Dengue, West Nile, Yellow Fever or Zika report as such.
  Attach copies of diagnostic laboratory results if available.
- ☐ **Babesiosis**
- ☐ **Botulism***
  ○ Foodborne ○ Infant ○ Wound
- ☐ **Brucellosis***
- ☐ **Campylobacteriosis†**

  Carbon Monoxide poisoning* – see Poisonings section on page 3

  Chancroid – see STD section on page 4
- ☐ **Chikungunya**

  Chlamydia – see STD section on page 4
- ☐ **Cholera***

  Creutzfeldt-Jakob disease – see Transmissable spongiform encephalopathy
- ☐ **Cryptosporidiosis†**
- ☐ **Cyclosporiasis†**
- ☐ **Dengue**
  Attach copies of dengue diagnostic laboratory results if available.
- ☐ **Diphtheria***

  Drownings – see Environmental Conditions section on page 3
- ☐ **Ehrlichiosis** (Human monocytic ehrlichiosis)
  If human granulocytic anaplasmosis report as anaplasmosis.
- ☐ **Encephalitis**
  If Jul.1–Oct. 31 consider and test for West Nile virus. If due to another reportable disease (e.g. Lyme, West Nile, arbovirus), report under the other disease.
- ☐ **Escherichia coli** O157:H7 infection†

  Falls from windows – see Environmental Conditions section on page 3
- ☐ **Food poisoning** in a group of 2 or more individuals*
- ☐ **Giardiasis†**
- ☐ **Glanders***

  Gonorrhea – see STD section on page 4

  Granuloma inguinale – see STD section on page 4
- ☐ **Haemophilus influenzae** (invasive disease)†

  Test type:
  ○ Culture ○ Antigen
  ○ PCR ○ Gram stain
  ○ Other _____

  Specimen Source:
  ○ Blood ○ CSF ○ Unknown
  ○ Other _____

  Specify Serotype:
  ○ Type B ○ Not typeable
  ○ Not tested ○ Unknown
  ○ Other _____
- ☐ **Hantavirus disease***
- ☐ **Hemolytic uremic syndrome**

FOR ALL HEPATITIS REPORTS

Jaundice ○ Yes ○ No ○ Unknown
ALT (SGPT) value:_____ ○ Unknown
Lab reference range:_____ ○ Unknown

- ☐ **Hepatitis A†**
  Total Ab to Hepatitis A is NOT reportable.
  IgM anti-HAV: ○ Pos ○ Neg ○ Unknown
- ☐ **Hepatitis B†**
  Report at least one positive hepatitis B test result. Total Ab to Hepatitis B is not reportable.
  IgM anti-HBc: ○ Pos ○ Neg ○ Unknown
  HBsAg: ○ Pos ○ Neg ○ Unknown
  HBeAg: ○ Pos ○ Neg ○ Unknown
  HBV Nucleic Acid: ○ Pos ○ Neg ○ Unknown

  If IgM is positive, describe symptoms and risk in comments box on last page.

  Hepatitis B in pregnancy
  Report cases in Reporting Central or fax IMM-5 form to 347-396-2558. For more information, call 347-396-2403.
- ☐ **Hepatitis C†**
  Check all that apply:
  ○ EIA pos
  ○ HCV Nucleic Acid (e.g.PCR) pos

  Is this an acute infection?
  ○ Yes
  ○ No
  ○ Unknown

Herpes, neonatal – see STD section on page 4

HIV/AIDS
Report using the New York State Provider Report Form (PRF). Call 518-474-4284 for forms or 212-442-3388 for more information.

Influenza
- ☐ Suspected novel viral strain with pandemic potential (e.g., avian H5N1 or H7N9)*
- ☐ Death in a child aged 18 or younger

Lead poisoning – see Poisonings section on page 3

- ☐ **Legionellosis†**

  Specify positive test:
  ○ Culture ○ Urine antigen
  ○ DFA ○ Serology
  ○ NAAT or PCR
- ☐ **Leprosy** (Hansen's disease)
- ☐ **Leptospirosis**
- ☐ **Listeriosis†**
- ☐ **Lyme disease**

  Erythema migrans present?
  ○ Yes ○ No ○ Unknown
- ☐ **Lymphocytic choriomeningitis virus**

  Lymphogranuloma venereum – see STD section on page 4
- ☐ **Malaria†**

  Select at least one of the following:
  ○ falciparum ○ vivax ○ malariae
  ○ ovale ○ undetermined

  Complete Foreign Travel section on page 1.
- ☐ **Measles** (rubeola)*
- ☐ **Melioidosis***
- ☐ **Meningitis,** bacterial

  Specify bacteria identified _____
- ☐ **Meningococcal disease,** invasive (including meningitis) *

  Test type/Specimen source:
  ○ Blood culture ○ CSF culture
  ○ Antigen test from CSF ○ Gram stain
  ○ PCR ○ Other _____
- ☐ **Monkeypox***
- ☐ **Mumps†**
- ☐ **Paratyphoid fever†**
- ☐ **Pertussis** (whooping cough)†
- ☐ **Pesticide poisoning** - see Poisonings section on page 3
- ☐ **Plague***

  Poisoning – see Poisonings section on page 3
- ☐ **Poliomyelitis***
- ☐ **Psittacosis**
- ☐ **Q Fever***
- ☐ **Rabies** and **exposure to rabies*** – see animal bites in Environmental Conditions section on page 3
- ☐ **Ricin poisoning***
- ☐ **Rickettsialpox**
- ☐ **Rocky Mountain spotted fever**
- ☐ **Rubella** (German measles)*
- ☐ **Rubella syndrome,** congenital
- ☐ **Salmonellosis†**

  Serogroup: _____
  If due to Salmonella typhi or paratyphi, select Typhoid or Paratyphoid Fever.
- ☐ **Severe or novel coronavirus** (e.g., SARS or MERS-CoV)*
- ☐ **Shiga-toxin** producing Escherichia coli (STEC) infection†
- ☐ **Shigellosis†**
- ☐ **Smallpox** (variola)*
- ☐ **Staphylococcal enterotoxin B poisoning***
- ☐ **Staphylococcus aureus,** vancomycin intermediate (VISA) and resistant (VRSA)*

  Source: _____
  MIC (µg/ml): _____
- ☐ **Streptococcus** (Group A and B) invasive†

  Specify Source: ○ Blood ○ CSF ○ Unknown
  ○ Other, Specify:_____

  Syphilis, including congenital – see STD section on page 4
- ☐ **Tetanus**
- ☐ **Toxic shock syndrome**
- ☐ **Trachoma**
- ☐ **Transmissible spongiform encephalopathy** (Creutzfeldt-Jakob disease and variants)

  Testing done: _____
  (e.g. 14-3-3 on CSF, brain biopsy, autopsy, EEG/MRI)
- ☐ **Trichinosis**

  Tuberculosis – see Tuberculosis section on page 3
- ☐ **Tularemia***
- ☐ **Typhoid fever†**
- ☐ **Vaccinia disease** (adverse events associated with smallpox vaccination)*
- ☐ **Vibrio species,** non-cholera

  Specify species:_____
- ☐ **Viral hemorrhagic fever***
- ☐ **West Nile** fever and viral neuroinvasive disease (e.g., meningitis and encephalitis)

  Attach copies of diagnostic laboratory results if available.
- ☐ **Yellow fever***

  Attach copies of diagnostic laboratory results if available.
- ☐ **Yersiniosis,** non-plague†
- ☐ **Zika**

*Report suspected and confirmed cases immediately to 1-866-692-3641 †If case meets any of the risk group criteria below, report immediately to 1-866-692-3641

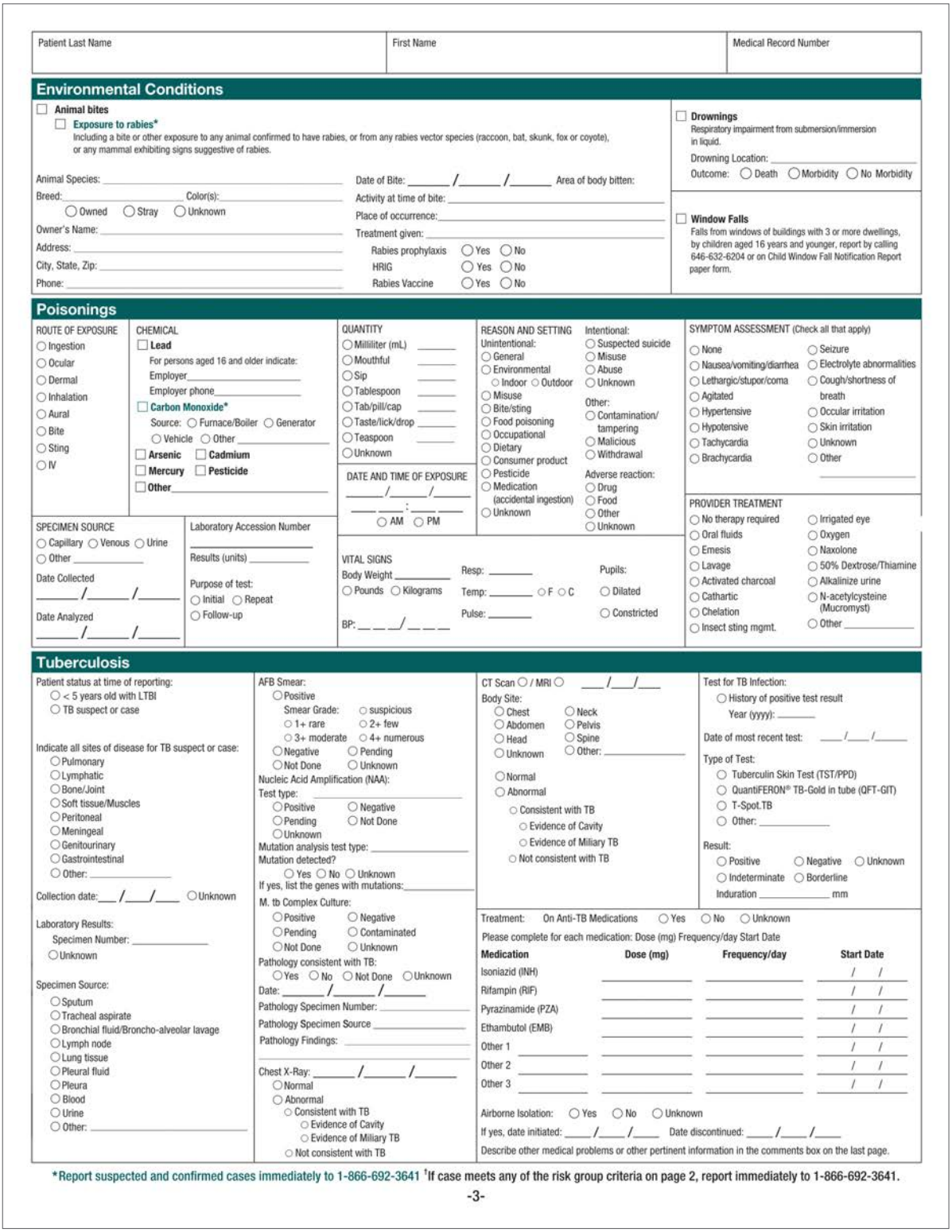
Risk Groups for Disease Exposure/Transmission Complete this section for diseases marked with † and if case meets any criteria, report it immediately to 1-866-692-3641.

Patient works in:
☐ Childcare ☐ Health care facility ☐ Long-term care facility/Nursing home ☐ Clinical/Research laboratory
☐ Unknown ☐ Food service ☐ Correctional facility ☐ Position with routine animal contact ☐ Other _____

Patient attends/resides in:
☐ Assisted living facility ☐ School ☐ Dormitory ☐ Long-term care facility/nursing home
☐ Unknown ☐ Correctional facility ☐ Shelter ☐ Day care/group baby-sit ☐ Other congregate living facility (specify: _____)

-2-

APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM (CONTINUED)



Patient Last Name | First Name | Medical Record Number

Environmental Conditions

☐ **Animal bites**

☐ **Exposure to rabies***
Including a bite or other exposure to any animal confirmed to have rabies, or from any rabies vector species (raccoon, bat, skunk, fox or coyote), or any mammal exhibiting signs suggestive of rabies.

Animal Species: _____
Breed: _____ Color(s): _____
○ Owned ○ Stray ○ Unknown
Owner's Name: _____
Address: _____
City, State, Zip: _____
Phone: _____

Date of Bite: ____/____/____ Area of body bitten:
Activity at time of bite: _____
Place of occurrence: _____
Treatment given: _____
Rabies prophylaxis ○ Yes ○ No
HRIG ○ Yes ○ No
Rabies Vaccine ○ Yes ○ No

☐ **Drownings**
Respiratory impairment from submersion/immersion in liquid.
Drowning Location: _____
Outcome: ○ Death ○ Morbidity ○ No Morbidity

☐ **Window Falls**
Falls from windows of buildings with 3 or more dwellings, by children aged 16 years and younger, report by calling 646-632-6204 or on Child Window Fall Notification Report paper form.

Poisonings

ROUTE OF EXPOSURE
○ Ingestion ○ Ocular ○ Dermal ○ Inhalation ○ Aural ○ Bite ○ Sting ○ IV

CHEMICAL
☐ **Lead**
For persons aged 16 and older indicate:
Employer_____
Employer phone_____
☐ **Carbon Monoxide***
Source: ○ Furnace/Boiler ○ Generator ○ Vehicle ○ Other _____
☐ **Arsenic** ☐ **Cadmium** ☐ **Mercury** ☐ **Pesticide** ☐ **Other**_____

QUANTITY
○ Milliliter (mL) _____ ○ Mouthful _____ ○ Sip _____ ○ Tablespoon _____ ○ Tab/pill/cap _____ ○ Taste/lick/drop _____ ○ Teaspoon _____ ○ Unknown

DATE AND TIME OF EXPOSURE
____/____/____
____ : ____
○ AM ○ PM

REASON AND SETTING
Unintentional:
○ General ○ Environmental ○ Indoor ○ Outdoor ○ Misuse ○ Bite/sting ○ Food poisoning ○ Occupational ○ Dietary ○ Consumer product ○ Pesticide ○ Medication (accidental ingestion) ○ Unknown
Intentional:
○ Suspected suicide ○ Misuse ○ Abuse ○ Unknown
Other:
○ Contamination/tampering ○ Malicious ○ Withdrawal
Adverse reaction:
○ Drug ○ Food ○ Other ○ Unknown

SYMPTOM ASSESSMENT (Check all that apply)
○ None ○ Nausea/vomiting/diarrhea ○ Lethargic/stupor/coma ○ Agitated ○ Hypertensive ○ Hypotensive ○ Tachycardia ○ Brachycardia ○ Seizure ○ Electrolyte abnormalities ○ Cough/shortness of breath ○ Occular irritation ○ Skin irritation ○ Unknown ○ Other _____

PROVIDER TREATMENT
○ No therapy required ○ Oral fluids ○ Emesis ○ Lavage ○ Activated charcoal ○ Cathartic ○ Chelation ○ Insect sting mgmt. ○ Irrigated eye ○ Oxygen ○ Naxolone ○ 50% Dextrose/Thiamine ○ Alkalinize urine ○ N-acetylcysteine (Mucromyst) ○ Other _____

SPECIMEN SOURCE
○ Capillary ○ Venous ○ Urine ○ Other _____
Date Collected ____/____/____
Date Analyzed ____/____/____

Laboratory Accession Number _____
Results (units) _____
Purpose of test:
○ Initial ○ Repeat ○ Follow-up

VITAL SIGNS
Body Weight _____ ○ Pounds ○ Kilograms
BP: ___ ___/___ ___
Resp: _____
Temp: _____ ○ F ○ C
Pulse: _____
Pupils:
○ Dilated ○ Constricted

Tuberculosis

Patient status at time of reporting:
○ < 5 years old with LTBI ○ TB suspect or case

Indicate all sites of disease for TB suspect or case:
○ Pulmonary ○ Lymphatic ○ Bone/Joint ○ Soft tissue/Muscles ○ Peritoneal ○ Meningeal ○ Genitourinary ○ Gastrointestinal ○ Other: _____
Collection date: ___/___/___ ○ Unknown

Laboratory Results:
Specimen Number: _____
○ Unknown

Specimen Source:
○ Sputum ○ Tracheal aspirate ○ Bronchial fluid/Broncho-alveolar lavage ○ Lymph node ○ Lung tissue ○ Pleural fluid ○ Pleura ○ Blood ○ Urine ○ Other: _____

AFB Smear:
○ Positive
Smear Grade: ○ suspicious ○ 1+ rare ○ 2+ few ○ 3+ moderate ○ 4+ numerous
○ Negative ○ Pending ○ Not Done ○ Unknown
Nucleic Acid Amplification (NAA):
Test type: _____
○ Positive ○ Negative ○ Pending ○ Not Done ○ Unknown
Mutation analysis test type: _____
Mutation detected?
○ Yes ○ No ○ Unknown
If yes, list the genes with mutations: _____
M. tb Complex Culture:
○ Positive ○ Negative ○ Pending ○ Contaminated ○ Not Done ○ Unknown
Pathology consistent with TB:
○ Yes ○ No ○ Not Done ○ Unknown
Date: ____/____/____
Pathology Specimen Number: _____
Pathology Specimen Source _____
Pathology Findings: _____

Chest X-Ray: ____/____/____
○ Normal
○ Abnormal
○ Consistent with TB
○ Evidence of Cavity
○ Evidence of Miliary TB
○ Not consistent with TB

CT Scan ○ / MRI ○ ___/___/___
Body Site:
○ Chest ○ Abdomen ○ Head ○ Unknown ○ Neck ○ Pelvis ○ Spine ○ Other: _____
○ Normal
○ Abnormal
○ Consistent with TB
○ Evidence of Cavity
○ Evidence of Miliary TB
○ Not consistent with TB

Test for TB Infection:
○ History of positive test result
Year (yyyy): _____
Date of most recent test: ___/___/___
Type of Test:
○ Tuberculin Skin Test (TST/PPD)
○ QuantiFERON® TB-Gold in tube (QFT-GIT)
○ T-Spot.TB
○ Other: _____
Result:
○ Positive ○ Negative ○ Unknown
○ Indeterminate ○ Borderline
Induration _____ mm

Treatment: On Anti-TB Medications ○ Yes ○ No ○ Unknown
Please complete for each medication: Dose (mg) Frequency/day Start Date

Medication	Dose (mg)	Frequency/day	Start Date
Isoniazid (INH)			/ /
Rifampin (RIF)			/ /
Pyrazinamide (PZA)			/ /
Ethambutol (EMB)			/ /
Other 1			/ /
Other 2			/ /
Other 3			/ /

Airborne Isolation: ○ Yes ○ No ○ Unknown
If yes, date initiated: ___/___/___ Date discontinued: ___/___/___
Describe other medical problems or other pertinent information in the comments box on the last page.

*Report suspected and confirmed cases immediately to 1-866-692-3641 †If case meets any of the risk group criteria on page 2, report immediately to 1-866-692-3641.

-3-

APPENDIX Q: NEW YORK CITY HEALTH DEPARTMENT UNIVERSAL REPORTING FORM (CONTINUED)

Patient Last Name	First Name	Medical Record Number

Sexually Transmitted Diseases

For All STD Reports

As of the date of this report,

Were any of this patient's sex partners notified of possible exposure to an STD? (Check all that apply)
- ◯ Yes, our office notified the partner(s)
- ◯ Yes, the patient was asked to notify partner(s)
- ◯ No
- ◯ Unknown

Did you provide treatment for any of this patient's partners? (Check all that apply)
- ◯ Yes, I saw the sex partner(s) in my office
- ◯ Yes, I gave extra medication for ___(#) partner(s)
- ◯ Yes, I wrote a prescription for ___(#) partner(s)
- ◯ Yes, some other way (specify):_____
- ◯ No
- ◯ Unknown

Is the patient on pre-exposure prophylaxis (PrEP) to prevent HIV infection?
- ◯ Yes, started PrEP at time of current STD diagnosis
- ◯ Yes, already on PrEP at time of current STD diagnosis
- ◯ No
- ◯ Unknown

Please indicate gender of sexual partners in the past year: (Check all that apply)
- ◯ Males
- ◯ Females
- ◯ Transgender Male to Female
- ◯ Transgender Female to Male
- ◯ Unknown

☐ **Chancroid**
Specify type of specimen:
◯ Penile ◯ Vaginal ◯ Endocervical ◯ Anorectal ◯ Oropharyngeal ◯ Other: _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

☐ **Granuloma inguinale**
Specify type of specimen:
◯ Penile ◯ Vaginal ◯ Endocervical ◯ Anorectal ◯ Oropharyngeal ◯ Other _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

☐ **Lymphogranuloma venereum**
Clinical Presentation (Check all that apply)
◯ Proctitis ◯ Lymphadenopathy ◯ Buboe ◯ Skin lesion ◯ Other: _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

Syphilis Test Types: (Check all that apply)

1. Serologic tests for syphilis

A. Non-treponemal Test
◯ RPR ◯ Reactive ◯ Non-reactive
Titer _____
◯ VDRL ◯ Reactive ◯ Non-reactive
Titer _____
Specimen collection date: ____/____/____

B. Treponemal Test
◯ TP-PA/MHA-TP ◯ Reactive ◯ Non-reactive
◯ FTA ◯ Reactive ◯ Non-reactive
◯ Treponemal IgG ◯ Reactive ◯ Non-reactive
Specimen collection date: ____/____/____

2. Cerebrospinal fluid tests
◯ CSF VDRL ◯ Reactive ◯ Non-reactive
◯ CSF FTA ◯ Reactive ◯ Non-reactive
◯ Other Test: _____ Result _____
Specimen collection date: ____/____/____
◯ Elevated CSF protein ◯ Yes ◯ No
◯ Elevated CSF leukocytes ◯ Yes ◯ No
Specimen collection date: ____/____/____

3. Organism visualization
◯ Darkfield ◯ Positive ◯ Negative
◯ Other Test: _____ Result _____
Specimen collection date: ____/____/____

☐ **Chlamydia** (CT)
Specify type of specimen:
◯ Endocervical ◯ Urethral ◯ Anorectal ◯ Oropharyngeal ◯ Urine ◯ Other: _____
Specify test type:
◯ Culture ◯ Nucleic acid amplification ◯ Nucleic acid hybridization ◯ EIA ◯ DFA ◯ Other: _____
Specimen collection date: ____/____/____
Treatment: _____
Treatment date: ____/____/____ ◯ Unknown

☐ **Herpes, neonatal**
Herpes simplex virus infection in infants aged 60 days and younger.
◯ Clinical diagnosis
◯ Lab confirmed diagnosis
◯ Culture ◯ PCR ◯ Other _____
Herpes type: ◯ Type 1 ◯ Type 2 ◯ Not typed
Clinical Syndrome (Check all that apply)
◯ Skin, eye, mucous membrane infection
◯ CNS involvement
◯ Disseminated disease
Herpes lesions present?
◯ Yes, anatomic site _____
◯ No
◯ Unknown
Specimen collection date: ____/____/____
Treatment for infant: _____
Treatment date: ____/____/____ ◯ Unknown
Mother's Name: _____
Mother's DOB: ____/____/____
Birth Hospital _____
Mother's Labor and Delivery Medical Record No: _____

☐ **Syphilis****
Stage:
◯ Congenital
◯ Primary, chancre present (Check all that apply)
◯ Penile ◯ Vaginal ◯ Endocervical ◯ Anorectal ◯ Oropharyngeal ◯ Other: _____
◯ Secondary (Check all that apply)
◯ Alopecia ◯ Condylomata ◯ Mucous patches ◯ Rash
◯ Early Latent
no symptoms, infection ≤ 1 year duration
◯ Late Latent
no symptoms, infection of > 1 year duration
◯ Tertiary, gumma or cardiovascular
Neurologic symptoms present?
◯ Yes ◯ No ◯ Unknown
Ocular symptoms present?
◯ Yes ◯ No ◯ Unknown
Otic symptoms present?
◯ Yes ◯ No ◯ Unknown
Treatment – list medication and dosage below:
_____
_____
_____
Treatment date: ____/____/____ ◯ Unknown
Continue to next column

☐ **Gonorrhea*** (GC)
Specify type of specimen:
◯ Endocervical ◯ Urethral ◯ Anorectal ◯ Oropharyngeal ◯ Urine ◯ Other: _____
Specify test type:
◯ Culture ◯ Nucleic acid amplification ◯ Nucleic acid hybridization ◯ Other: _____
Specimen collection date: ____/____/____
Treatment 1*: _____ mg/gram
Treatment 2*: _____ mg/gram
Treatment date: ____/____/____ ◯ Unknown

* For uncomplicated gonococcal infections of the cervix, urethra, anorectum or pharynx, CDC recommends dual therapy (irrespective of concurrent chlamydial infection) using BOTH Ceftriaxone 250mg IM AND Azithromycin 1g PO.

** Licensed health care providers can access current and historical syphilis test results and treatment information in the New York City Syphilis Registry to inform the diagnosis and management of syphilis in their patients. For more information, see the Syphilis Registry check at: http://www1.nyc.gov/assets/doh/downloads/pdf/std/hcp-syphilis-registry-check.pdf, or call 347-396-7201

Comments:

APPENDIX R: REPORT OF PATIENT SERVICES FORM

NYC Health

Bureau of Tuberculosis Control
42-09 28th Street, Box 72
Long Island City, N.Y. 11101
844-713-0559/ FAX: 844-713-0557

REPORT OF PATIENT SERVICES

Please print firmly and legibly

By law this form must be submitted for every monthly visit of patients with active tuberculosis.

TB Registry Number _____ Social Security Number ___ ___ _____ Chart Number _____

Patient Name: _____ (Last) _____ (First) _____ (M.I.)

Address _____ Apt. # _____ Zip Code _____

Daytime Phone ( ) ___ _____ Evening Phone ( ) ___ _____ Date of Birth ____ (Month) / ____ (Day) / ____ (Year)

❑ If patient missed appointment, check here and go to box at bottom of page. (Date of missed appointment ____ (Month) / ____ (Day) / ____ (Year))

TB Site of Disease (check all that apply):

- ❑ Pulmonary
- ❑ Other (Specify)
- ❑ Pleural _____
- ❑ Lymphatic _____
- ❑ Meningeal _____

Latest chest X-ray: ____ (Month) / ____ (Day) / ____ (Year)

- ❑ Normal
- ❑ Abnormal-noncavitary (including adenopathy)
- ❑ Abnormal-cavitary

Findings: _____

If prior films available; is this film

- ❑ Stable ❑ Worsening ❑ Improving

Most recent bacteriology:

Date specimen collected: ____ (Month) / ____ (Day) / ____ (Year)

Source of Specimen: _____

Smear:	Culture:
❑ Positive	❑ Positive
❑ Negative	❑ Negative
❑ Pending	❑ Pending

If culture positive:

❑ M.tb ❑ Other _____

Was susceptibility ordered? ❑ Yes ❑ No

Medications prescribed at this visit?

❑ Yes ❑ No Reason: _____

Medication regimen changed this visit?

❑ Yes ❑ No Reason: _____

Is patient on Directly Observed Therapy?

❑ Yes ❑ No Reason: _____

Frequency of DOT:

- ❑ Daily
- ❑ 2x per week
- ❑ 3x per week
- ❑ 5x per week
- ❑ once a week

Drugs and dosages:

❑ INH ____ mg	❑ RIF ____ mg	❑ PZA ____ mg
❑ EMB ____ mg	❑ SMN ____ mg	❑ PAS ____ mg
❑ Ethio ____ mg	❑ CYC ____ mg	❑ Kana/AMI ____ mg
❑ RPT ____ mg	❑ Levo ____ mg	❑ Capreo ____ mg
❑ RBT ____ mg	❑ Other ____	❑ MOXI ____ mg

Services provided
Check all that apply:

- ❑ Doctor visit
- ❑ Nurse visit
- ❑ X-ray
- ❑ Sputum sample
- ❑ Audiometry
- ❑ Liver enzymes
- ❑ Vision testing
- ❑ Other

Date of this visit: ____ (Month) / ____ (Day) / ____ (Year) Date of next visit: ____ (Month) / ____ (Day) / ____ (Year)

Management Course/Outcome:

- ❑ Completed treatment
- ❑ Expired – was cause of death TB? ❑ Yes ❑ No
- ❑ Moved/transferred (where): _____
- ❑ Rehospitalized (where): _____
- ❑ Other _____

M.D. Name: _____ M.D. License # _____

Facility: _____ Prepared by: _____ Phone: ( ) ___ _____

TB 65 (Rev. 11/11)

COPIES: White–DOHMH; Yellow–Chart; Pink–Clinic Records

APPENDIX S: HOSPITAL DISCHARGE APPROVAL FORM

NYC Health

NEW YORK CITY DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BUREAU OF TUBERCULOSIS CONTROL

HOSPITAL DISCHARGE APPROVAL REQUEST FORM

Please complete this form in entirety and fax to 844-713-0557 (toll-free)

SECTION A: Patient Contact Information

Patient name: _____ DOB: ____/____/____ (mm/dd/yyyy)

Tel. #: (1) (____)_____–_____ (2) (____)_____–_____

Address: _____ Apt.: _____ City: _____ State: _____ Zip: _____

Emergency contact name: _____ Relationship to patient: _____ Tel. #: (____)_____–_____

SECTION B: Discharge Information

Discharging facility: _____ Discharging facility tel. #: (____)_____–_____

Address: _____ Fl.: _____ City: _____ State: _____ Zip: _____

Patient medical record #: _____ Date of admission: ____/____/____ (mm/dd/yyyy) Planned discharged date: ____/____/____ (mm/dd/yyyy)

Discharged to: ☐ Home (if not the same address as above, fill in address below)

☐ Shelter ☐ Skilled nursing facility ☐ Jail/Prison ☐ Residential facility ☐ Other facility

Name of facility: _____ Tel. #: (____)_____–_____

Address: _____ Apt./Fl.: _____ City: _____ State: _____ Zip: _____

Is patient scheduled to travel outside of NYC? ☐ Yes ☐ No If yes, specify date/destination: _____

SECTION C: Patient Follow-Up Appointment

Patient follow-up appointment date: ____/____/____ (mm/dd/yyyy)

Physician assuming care: _____ Tel. #: (____)_____–_____ Cell. #: (____)_____–_____

Address: _____ City: _____ State: _____ Zip: _____

Potential barriers to TB therapy adherence: ☐ None ☐ Adverse reactions ☐ Homelessness

☐ Physical disability (*specify*) _____ ☐ Medical condition (*specify*) _____

☐ Substance use (*specify*) _____ ☐ Mental disorder (*specify*) _____ ☐ Other _____

SECTION D: Laboratory Results

Dates of three most recent acid fast bacilli (AFB) smears	Specimen source	Acid fast bacilli (AFB) smear results
____/____/____	_____	☐ Positive Grade: _____ ☐ Negative
____/____/____	_____	☐ Positive Grade: _____ ☐ Negative
____/____/____	_____	☐ Positive Grade: _____ ☐ Negative

SECTION E: Treatment Information

Date TB therapy initiated: ____/____/____ (mm/dd/yyyy) Interruption in therapy? ☐ Yes ☐ No If yes, state the reason and duration of the interruption? _____

TB medications at discharge: ☐ INH ____ mg ☐ RIF ____ mg ☐ PZA ____ mg ☐ EMB ____ mg ☐ SM ____ mg ☐ Vitamin B_6 ____ mg

☐ Injectables (*specify*) _____ ☐ Other TB meds (*specify*) _____

Frequency: ☐ Daily ☐ 2x weekly ☐ 3x weekly ☐ Other _____

Was a central line (i.e. PICC) inserted on the patient? ☐ Yes ☐ No

Number of days of medications supplied to patient at discharge _____ Patient agreed to be on DOT? ☐ Yes ☐ No

Print name of individual filling out this form: _____ Date: ____/____/____ (mm/dd/yyyy)

Name of responsible physician at the discharging facility: _____ License #: _____

Signature of responsible physician at the discharging facility: _____ Tel. #: (____)_____–_____

COMPLETED BY THE HEALTH DEPARTMENT **BTBC NUMBER:** _____

Discharge approved: ☐ Yes ☐ No Action required before discharge: _____

Reviewed by: _____ (NAME OF HEALTH OFFICER/DESIGNEE) Date: ____/____/____ (mm/dd/yyyy)

TB 354 (11/10)

APPENDIX S: HOSPITAL DISCHARGE APPROVAL FORM (CONTINUED)

Guidelines for How to Complete and Submit the Mandatory TB Hospital Discharge Approval Request Form (TB 354)

As of June 16, 2010, Article 11 of the New York City Health Code mandates health care providers to obtain approval from the New York City Department of Health & Mental Hygiene (DOHMH) before discharging infectious TB patients from the hospital.

Discharge of an Infectious (sputum smear positive) Tuberculosis Patient

Health care providers must submit a Hospital Discharge Approval Request Form (TB 354) at least 72 hours prior to the anticipated discharge date. The DOHMH will review the form and approve or request additional information before the patient can be discharged from the health care facility.

Weekday (non-holiday) Discharge: The written discharge plan should be submitted by fax to the Bureau of TB Control between 8am-5pm. Bureau of TB Control staff will review the discharge plan and, within 24 hours, notify the provider of approval or inform the provider of any additional information/actions required for approval prior to discharge.

Weekend and Holiday Discharge: All arrangements for discharge should be made in advance when weekend or holiday discharge is anticipated.

For detailed information about hospital admission and discharge of TB patients, please refer to the New York City DOHMH Bureau of TB Control Policies and Protocols manual available online at http://www1.nyc.gov/site/doh/health/health-topics/tb-hosp-manual.page

Instructions for Completing the Hospital Discharge Approval Request Form (TB 354)

Section A Patient contact information: Provide the patient's contact information including patient's name, a verified address and telephone numbers. In addition, include a name of an emergency contact, the contact's relationship to the patient and the contact's verified phone number.

Section B Discharge information: Provide the name and phone number of the discharging facility, the medical record number of the patient at the facility, date the patient was admitted, planned discharge date, and the location to which the patient is being discharged. If the patient will be discharged to a location other than the patient's address listed in Section A, a facility name (if applicable), address and phone number must be provided. If the patient plans to travel, provide the date and destination.

Section C Patient follow-up appointment: Provide the patient's follow-up appointment date, as well as the name and contact information of the provider who is assuming patient care. Check all potential obstacles that may affect TB therapy adherence.

Section D Laboratory results: Report the results of the three most recent acid fast bacilli (AFB) smears including the date of specimen collection, specimen source, and AFB smear results and/or grade.

Section E Treatment information: Fill in the date TB treatment was initiated. If there were any treatment interruptions, indicate the reason and number of days treatment was stopped. Check the box next to each prescribed drug and state dosages for each drug. Write in drugs and dosages for drugs not specified. Specify the treatment frequency by checking one of the three boxes, or writing in a different treatment schedule. State whether the patient will have a central line inserted at the time of discharge. If TB medication will be supplied to the patient at discharge, write the number of days for which the medication will be supplied. State whether the patient agreed to be on directly observed therapy (DOT).

After Section E, the name of the person completing the form should be printed and the authorized physician at the discharging facility must print and sign their name, and provide their medical license number and telephone number.

Forms should be faxed to the DOHMH at 844-713-0557 (toll-free).

If you have questions about completing the form, please call 311 and ask to speak to a Bureau of TB Control physician.

To fulfill State requirements for communicable disease reporting, health care providers must report all suspected or confirmed TB cases to the DOHMH via Reporting Central (formerly Universal Reporting Form (URF)). Instructions for reporting a case of TB can be found at http://www1.nyc.gov/site/doh/providers/reporting-and-services/hcp-urf.page

NOTE: A discharge approval request form does not substitute required case reports.

TB 354 (11/10)