

MDSS: Suspect/Active Tuberculosis Case Reporting Guide

Michigan Department
of Community Health



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Introduction:

The Michigan Disease Surveillance System (MDSS) TB Case Report Form is designed to collect information on suspects and cases of active tuberculosis (TB) disease diagnosed in Michigan.

Beginning in January, 2008, the MDCH TB Program will collect suspect and active TB case report data through the MDSS TB Case Report Form. The data collected in this form is very similar to the data that has historically been collected on the Report of Verified Case of Tuberculosis (RVCT) which is the currently used case report form. There are some additional variables that have been added to the MDSS TB Form in anticipation of the new RVCT that is being developed by the CDC. The new MDSS form is designed to facilitate more rapid reporting by eliminating the time spent filling out paper RVCT forms by hand and mailing them to MDCH and allowing for easier transmission of data to the CDC.

Local patient identifying information, though collected by state and local health departments, is not transmitted to the CDC. The surveillance information transmitted to the CDC is used for statistical and analytic reports in which no individual can be identified, and for special investigations of the natural history and epidemiology of TB. Thus, consistency and accuracy of data collection is important so that Michigan is properly represented in the national TB picture. The following instructions are designed to explain the reporting process that will be used in the new MDSS TB Form.

The MDSS TB Suspect/Case Report Form Sections:

- 1) Report of Suspect/Verified Case of Tuberculosis Section (Pages 1-4): Investigation Information, Patient Information, Demographics, Referral Information, Clinical Information, Laboratory Information, Epidemiologic Information, and Treatment Information are collected in this four-page section.
- 2) Follow-Up Report 1 – Initial Drug Susceptibility Report Section, **State Use Only**, (Page 5): Susceptibility results from the MDCH Lab are collected in this section.
- 3) Follow-Up Report 2 – Case Completion Report Section (Pages 6-7): Treatment outcomes are collected in this section.
- 4) Contact Information Section (Page 8): General Information about contacts to active TB cases is collected on this form.
- 5) Other Information Section (Page 9): Comments or Additional Information is collected in this section.

Process for Reporting Suspect and Active Cases of Tuberculosis:

- 1) A suspect /active case of TB can be reported to the Local Health Department (LHD) by a laboratory or health care practitioner (HCP). Similar to other reports in the MDSS, lab reports from the MDCH lab will be submitted electronically into the MDSS. Also, like other reportable conditions, HCPs may enter initial information about a suspect/active case of TB into the MDSS; therefore LHD staff need to be aware of new reports of TB cases in the MDSS that require investigation.
- 2) If Non-TB or Mycobacterium other than TB (MOTT) labs are submitted electronically into the MDSS, it is the local health department's responsibility to mark them appropriately. If these cases appear, please mark the Case Status as "Not a Case" then mark the Investigation Status to "Active". MDCH TB Program will then review and change the Investigation Status to "Completed".
- 3) If entering the case manually, LHD reports a suspect/active case to MDCH TB Program by entering the case into the MDSS under the reportable condition: "Tuberculosis" as soon as a specimen has been submitted to a lab and/or the patient has been started on TB treatment. It is important at this step to leave the Investigation Status as "New".
- 4) LHD will then complete the Report of Suspect/Verified Case of Tuberculosis section, pages 1-4, the fields "Submitted By", "Date", "Health Department", "Phone Number" and "Ext." on page 9 and change the Investigation Status to "Active" to indicate the case is ready for review by MDCH TB Program. It is important at this step to leave the Investigation Status as "Active" as this is the signal for the MDCH TB Program to review the case for counting. For any data that are unknown, please mark "unknown" or "pending" as appropriate.
- 5) Following review, MDCH will mark "No" for the completion questions for Follow-Up 1 Report and Follow-Up 2 Report, indicating that these sections are not yet complete. Once all necessary information is collected to count a case, MDCH will mark the case "Completed" which triggers the MDSS to report the data to CDC.
- 6) When drug susceptibility information is available, MDCH TB Program will re-open the case to enter information into Follow-Up 1 Report, page 5, of the MDSS. The case will then be marked by MDCH as "Completed" to send updated notification to CDC.
- 7) LHD staff are responsible for case management of the TB patient. When follow-up of a case is completed and a case is closed, the LHD should re-open the case, by changing the investigation status to "Active" and enter the Case Completion Report information into the Follow-up 2 Report, pages 6-7, of the MDSS TB Form.
- 8) After the Follow-Up 2 information has been added to the MDSS, MDCH will review all of the entered information and once all necessary information is collected to close a case, MDCH will mark the case "Completed" for final notification to CDC.

General Instructions for Form Completion:

The instructions in this guide are not a substitute for guidelines about TB diagnosis, treatment, or control. Any contradictions between the implied content of these instructions and the policies and practices of local health departments or other local health providers should be discussed, according to the context, with the state TB program.

All data items on the forms should be completed according to these instructions. Please direct all questions for clarification, or assistance with unusual circumstances to the state TB Epidemiologist.

The sections and variables that are marked “State Use Only” should be left blank. All other questions should only be left blank or marked pending if the information requested is pending.

Mark the one best choice from among the values listed unless the field is marked “select all that apply”. For example, the Site of Disease field allows more than one selection. If the answer to an item is not among the choices given on the form, please note it in the Comments section of the form.

If a valid value cannot be determined for a data item, mark the field “unknown” or if there is not an “unknown” option, please write “unknown” in the text field or leave the numeric field blank. This will let the MDCH TB Program know that the person who completed the form attempted to collect this information, but was unable to do so due to unusual circumstances. All of the data collected on the TB Case Reporting forms are a standard part of suspect TB case work-up and thus “Unknown” boxes should rarely need to be used. All data items left blank or marked “unknown” without explanation will be verified with you by state TB Program staff.

Patient history, without medical documentation, should not be accepted for any of the clinical, treatment, or laboratory information requested on the Tuberculosis Case Reports. The information required by the forms can however, be obtained from any documented medical records such as those found in hospitals, clinics, directly observed therapy records, pharmacy and prescription records.

Detailed Instructions for Completing Each Section:

I. REPORT OF SUSPECT/VERIFIED CASE OF TB (RVCT) SECTION:

i. Investigation Information:

1. Investigation ID (**Automatic**) – This number is automatically generated by MDSS and cannot be changed; you do not fill this out.
2. State TB Case Number (**State Use Only**) – This number assigned by MDCH as the official identification number for the case. If there is communication needed between the state and CDC, this number is used in order to protect confidentiality of the patient.
3. Part of an outbreak (**State Use Only**) – This field designates whether a TB case is involved in a genotype cluster and will be marked as such when genotyping information is available from MDCH Lab.
4. Outbreak Name (**State Use Only**) – If the TB case is involved in a genotype cluster (indicated in the previous field), this field designates the name of the genotype cluster. This number allows for matching cases based on their genotypes.
5. Referral Date (**Automatic**) – This date is automatically generated by MDSS and cannot be changed; you do not fill this out.
6. Investigation Status – This field defaults to “New”.

New – This option indicates that a case is new and ready for investigation by the LHD.

Active – This option indicates that the TB Report Form is ready for review by MDCH TB Program.

Completed (**State Use Only**) – This option is only used by MDCH TB Program. It is important that only MDCH marks this field as “Completed” as this triggers the MDSS to transmit the data to CDC.

Superseded – This option is used to indicate a manual de-duplication (i.e., the case has been reported elsewhere)

Cancelled – This option should only be used if there was no investigation for some reason. Otherwise, if there is an investigation and a case was ruled out the “Case Status” field should be marked "not a case" and the investigation status field

should be marked "active."

7. Case Status –

Confirmed – This option indicates that a TB case meets one of the CDC TB Case Definitions (See Appendix A).

Not a Case – This option is marked if a suspect case is initially reported and it is determined to not follow one of the CDC TB Case Definitions.

Probable – This option is a standard field in MDSS for all conditions/diseases. However, due to the unique nature of the CDC TB Case Definitions a TB case is considered either suspect or confirmed. Therefore, this option should not be selected.

Suspect – This option is marked when a suspect TB case is reported to the LHD. A suspect case is one which there is clinical or laboratory evidence supporting submission of a specimen to a laboratory and/or starting the patient on TB treatment.

8. Patient Status:

Inpatient – This option indicates that the patient is hospitalized at the time of diagnosis or discovery. This can be changed if the patient goes in and out of the hospital during treatment.

Outpatient – This option indicates that the patient is not hospitalized at the time of diagnosis or discovery. This can be changed if the patient goes in and out of the hospital during treatment.

Died – This indicates that the patient is dead at the time of diagnosis or discovery. This can be changed if the patient dies during the 6 or more month treatment.

9. Patient Status Date (**Automatic**) – This date is automatically generated by MDSS and is the date at which the patient status is identified. If the patient status is changed at any time during the management of the case, this date will automatically update. This date can be manually changed by the user if needed.

10. Diagnosis Date – This is the date at which the diagnosis of TB is made by a Health Care Practitioner.

11. Onset Date – This is the date at onset of TB signs or symptoms.

ii. Patient Information:

1. Patient ID (**Automatic**) – This number is automatically generated by MDSS and cannot be changed; you do not fill this out.
2. First – This is the patient’s first or given name.
3. Last – This is the patient’s last or surname.
4. Middle – This is the patient’s middle name/initial.
5. Patient Address of Residence (**Can only be modified through address history tab**)

This should represent the home address or community which the patient considers their home, whether permanent or temporary in nature. Coordination among neighboring LHDs may be necessary to determine proper jurisdiction for a given case. For example, cases diagnosed in an acute care hospital are not recorded at the address of the hospital, but rather at the patient’s regular home address. However, those diagnosed in long term care or correctional facilities are usually recorded at the address of that facility.

Immigrants, migrants, U.S. military personnel, and other transitory individuals should be reported as residents of the community in which they reside at the time of diagnosis. Homeless persons or others without any fixed residence should also be reported in the community in which they are living at the time of diagnosis (e.g., the address of the shelter in which the patient spent the night).

Street Address – This is the patient’s street address at the time of diagnosis.

City – This is the patient’s city of residence at the time of diagnosis.

County – This is the patient’s county of residence at the time of diagnosis.

State – This is the patient’s state of residence at the time of diagnosis.

Zip – This is the patient’s zip code at time of diagnosis.

6. Home Phone – This is the patient’s current home telephone number. This number should be updated as it changes.

Ext. – This is the extension number to the patient’s current home phone number.

7. Other Phone – This is any other telephone number that is used to reach the patient.

Ext. – This is the extension number to the patient’s other phone number.

8. Parent/Guardian (required if under 18)

First – This is the parent/guardian’s first name. If patient is under 18 and the parent is unknown, enter unknown in this field.

Last – This is the parent/guardian’s last name. If patient is under 18 and the parent is unknown, enter unknown in this field.

Middle – This is the parent/guardian’s middle name/initial.

iii. Demographics:

1. Sex – Female or Male. Mark the appropriate box for the biological sex of the patient.
2. Date of Birth – Indicate the month, day, and year of the birth of the patient in the format mm/dd/yyyy. Partial dates are not acceptable.
3. Age (**Automatic**) – This number is automatically generated by MDSS and cannot be changed; you do not fill this out. This is the age at onset.
4. Age Units (**Automatic**) – This number is automatically generated by MDSS and cannot be changed; you do not fill this out. This is the age unit at onset.
5. Race – Select one based on the patient’s self identity. Indicate the race that the patient considers himself or herself to be.

Caucasian – Persons who have origins in any of the original peoples of Europe, the Middle East or North Africa.

African American – Persons who have origins in any of the black racial groups of Africa.

American Indian/Alaska Native – Persons who have origins in any of the original peoples of North and South America (including Central America), and who maintain tribal affiliation or community attachment.

Hawaiian/Pacific Islander – Persons who have origins in any of the original peoples of Hawaii or other Pacific Islands. Specify, in the space provided, the Pacific Island or ethnic group to which the person associates. These include: Carolinian, Chamorro, Chuukese, Fijian, Guamanian, Kiribati, Kosraean, Mariana Islander,

Marshallese, Melanesian, Micronesian, Native Hawaiian, New Hebrides, Palauan, Papua New Guinean, Pohnpeian, Polynesian, Saipanese, Samoan, Solomon Islander, Tahitian, Tokelauan, Tongan, and Yapese.

Asian – Persons who have origins in any of the original peoples of the Far East, Southeast Asia, or the Indian subcontinent. Specify, in the space provided, the Asian country or ethnic group to which the person associates. These include: Asian Indian, Bangladeshi, Bhutanese, Burmese, Cambodian, Chinese, Filipino, Hmong, Indonesian, Iwo Jiman, Japanese, Korean, Laotian, Madagascar, Malaysian, Maldivian, Nepalese, Okinawan, Pakistani, Singaporean, Sri Lankan, Thai, and Vietnamese.

6. Ethnicity – Select one based on the patient’s self identity. Indicate whether or not the person considers themselves to be Hispanic or Latino.

Hispanic/Latino – The patient considers himself/herself to be of Spanish, Hispanic or Latino origin. Persons who are from many of the countries of Central or South America, Mexico, Puerto Rico, Cuba, or Dominican Republic are likely to consider themselves to be Hispanic or Latino.

Non-Hispanic/Latino – The patient does not consider himself/herself to be Hispanic or Latino.

7. Worksites/School – This is the name of the workplace or school the patient attends at the time of signs or symptoms onset.
8. Occupation/Grade – This is the patient’s occupation or grade in school at the time of sign or symptom onset.

iv. Referral Information:

1. Person Providing Referral – This is the person that initially reported the case to the LHD.

First – This is the first name of the person reporting the case to the LHD.

Last – This is the last name of the person reporting the case to the LHD.

Phone – This is the telephone number for the person reporting the case to the LHD.

Ext. – This is the extension to the telephone number of the person reporting the case to the LHD.

Email – This is the email address for the person reporting the case to the LHD.

2. Primary Physician – This is the physician acting as the TB patient’s primary care giver during the duration of his or her TB treatment. If the TB treatment is being given by the physician at a LHD TB clinic, please use the name of this physician.

First – This is the first name of the primary care physician.

Last – This is the last name of the primary care physician.

Phone – This is the telephone number where the primary care physician can best be contacted.

Ext. – This is the extension to the telephone number where the primary physician can best be contacted.

Email – This is the email address where the primary physician can best be contacted.

Street Address – This is the primary physician’s office street address.

City – This is the city where the primary physician’s office is located.

County – This is the county where the primary physician’s office is located.

State – This is the state where the primary physician’s office is located.

Zip – This is the zip code where the primary physician’s office is located.

v. Clinical Information:

1. Primary Reason Evaluated for TB Disease – This is the single or primary reason why the TB patient was evaluated for TB disease (select one choice only).

TB Symptoms – This option is marked when a patient is evaluated for TB disease due to signs and symptoms consistent with TB (e.g., prolonged or persistent cough, fever, lymphadenopathy, night sweats, and weight loss).

Abnormal Chest Radiograph – This option is marked when a patient has an incidental chest radiograph consistent with TB disease. The reason for taking the chest radiograph should **not** have been to rule out TB disease. For example, if a patient had a chest radiograph as part of preoperative testing, where there was no suspicion of TB disease and an abnormal result suggesting TB was observed thus leading to TB diagnosis, the option “Abnormal Chest Radiograph” should be selected.

Contact Investigation – This option is marked when a patient is diagnosed with TB as a result of being evaluated during a contact investigation.

Immigration Medical Exam – This option is marked when a patient is diagnosed with TB as a result of a medical examination which is part of the immigration application process. An immigration medical exam may be performed overseas or in the US depending on the situation. If TB is diagnosed in either setting due to the immigration medical exam, the option “Immigration Medical Exam” should be selected.

Targeted Testing – This option should be selected when a patient is evaluated for TB because of a positive TST that was given during targeted testing, or because the patient was considered at high risk for TB (e.g., persons from areas of the world with high rates of TB). The option “Targeted Testing” should **not** be selected if another more appropriate option exists such as contact investigation or immigration medical exam.

Health Care Worker – This option should be selected when a patient is evaluated for TB disease due to a positive TST which was administered because the patient was a health care worker. Health care worker refers to all paid and unpaid persons working in healthcare settings who have the potential to be exposed to *Mycobacterium tuberculosis*.

Employment/administrative Testing – This option should be selected if the patient was evaluated for TB disease due to a routine employment physical examination, employment tuberculin skin testing requirement, or primary or secondary school program for routine tuberculin skin testing. This category reflects an administrative requirement (e.g., a tuberculin skin testing program applied to all 5th graders in a school or to all job applicants) rather than targeted testing of a select group of individuals considered at high risk. If skin testing was performed because the individual was considered to be part of a known high risk group, select “Targeted testing” or other more appropriate category such as “Health care worker.” If employment was health care related, check “Health care worker” rather than “Employment/administrative testing.”

Incidental Lab Result – This option should be selected if a specimen is collected and has an incidental result that is smear positive for acid fast bacilli (AFB) or culture positive for *Mycobacterium tuberculosis* (e.g., when the specimen was tested for AFB or cultured for TB without suspicion of TB disease or when TB disease was not considered a possible diagnosis, such as during a bronchoscopy or autopsy, organ donation, hospitalization or analysis for a disease other than *M. tuberculosis*).

2. Verification Criteria (**State Use Only**): This is an automatically generated variable that is created when MDCH counts the case.
3. Date Counted (**State Use Only**): This date is the month, day, and year that the MDCH verifies the case as TB and includes it in the official TB case count.
4. Previous Diagnosis of Tuberculosis: This field designates whether a TB case has ever been diagnosed with TB disease in the past.

Yes – Select “Yes” if the patient has had a previous diagnosis of TB disease. A previous diagnosis of latent TB infection (i.e., LTBI) should not be entered. A patient is considered to have had a previous diagnosis of TB disease if he or she had verified disease in the past, had completed therapy or was lost to supervision for more than 12 consecutive months, and now has verified disease again. Often, TB disease is confused with latent TB infection (LTBI). LTBI should not be coded as previous TB disease. Therefore, documentation of the previous episode of TB disease is important. Written documentation of the previous episode of TB diseases is ideal. However, if the TB disease episode occurred years ago, or in another location (e.g., country) obtaining written documentation can be difficult. Therefore, when written documentation is not available, reliable verbal documentation of a previous episode of TB disease is acceptable (e.g., medications taken, length of medication, sputum smear examination results).

If “Yes” is selected, please provide the year of previous TB disease diagnosis.

No – Select “No” if the patient has never been diagnosed with TB disease in the past.

5. Site of TB Disease: This field designates the *primary* location of TB disease in the patient.
6. Other Sites of TB Disease (1): This field designates a secondary location of TB disease in the patient. Select one from the dropdown menu if appropriate.
7. Other Sites of TB Disease (2): This field designates a secondary location of TB disease in the patient. Select one from the dropdown menu if appropriate.
8. Other Sites of TB Disease (3): This field designates a secondary location of TB disease in the patient. Select one from the dropdown menu if appropriate.
9. Status at Diagnosis of TB: This field designates the whether the patient is alive or dead at the time of TB disease diagnosis.

Alive – Select “Alive” if the patient was living at the time of TB disease diagnosis. Patients whose TB was suspected and who were started on at least two antituberculosis drugs prior to the day of death should be classified as alive at the time of TB diagnosis even though the TB case may not be verified and counted until after death.

Dead – Select “Dead” if the patient was deceased at the time the investigation of possible TB disease was initiated. Patients who were only on one antituberculosis drug prior to the day of death because TB disease was not suspected, and who were then diagnosed with TB disease after death are classified as dead at the time of TB diagnosis. For example, if a person who was taking isoniazid as preventive therapy for latent TB infection dies, and is found after death to have had TB disease, this person should be classified as “Dead” at TB diagnosis.

If “Dead” is selected, please indicate if TB was a cause of death: This field designates whether TB was listed as a primary or other cause of death in the patient's death certificate. If available, please send written documentation of the cause of death (i.e. copy of death certificate).

If “Dead” is selected, please provide the date of death.

vi. Laboratory Information:

1. Sputum Smear: This field indicates the result of an AFB smear of a sputum specimen. Only include smears that were done on spontaneous or induced sputum samples. *Do not* include specimens that were collected by any other means such as microscopic examination of pulmonary secretions obtained by tracheal suction, bronchoscopy procedures (e.g., bronchial washing, scrapings, biopsies), or gastric aspiration (see Smear/Pathology/Cytology of Tissue and Other Body Fluids – Question 3 below)

Positive – Select “Positive” if any of the examinations are positive for acid-fast organisms (i.e., AFB).

Negative – Select “Negative” if the results of all examinations (or the only examination) were negative.

Not Done – Select “Not Done” if it is known that no sputum smears were performed.

Sputum Smear Collection Date – If the sputum smear was “Positive” or “Negative”, indicate the date (mm/dd/yyyy) the sputum specimen was

collected. If several sputum examinations were done and one or more sputum examinations were “Positive” for acid-fast organisms, enter the date the first positive sputum examination was collected. If several sputum examinations were done and all were “Negative” for acid-fast organisms, enter the date the first negative sputum examination was collected.

2. Sputum Culture: This field indicates the result of a sputum culture. Only include smears that were done on spontaneous or induced sputum samples. *Do not* include specimens that were collected by any other means such as microscopic examination of pulmonary secretions obtained by tracheal suction, bronchoscopy procedures (e.g., bronchial washing, scrapings, biopsies), or gastric aspiration (see Culture of Tissue and Other Body Fluids – Question 7 below).

Positive – Select “Positive” if a sputum culture result was positive for *M. tuberculosis* (*Mycobacterium tuberculosis*) complex. If several sputum cultures were done, check “Positive” if any one is positive for *M. tuberculosis* complex.

Negative – Select “Negative” if the results of all sputum cultures (or the only sputum culture) were negative for *M. tuberculosis* complex.

Not Done – Select “Not Done” if it is known that no cultures were performed.

Sputum Culture Collection Date – If the sputum culture was “Positive” or “Negative”, indicate the date (mm/dd/yyyy) the sputum specimen was collected. If several sputum cultures were done and one or more sputum cultures were “Positive” for *M. tuberculosis* complex, enter the date the first positive sputum culture specimen was collected. If several sputum cultures were done and all were “Negative” for *M. tuberculosis* complex, enter the date the first negative sputum culture specimen was collected.

3. Smear/Pathology/Cytology of Tissue and Other Body Fluids: This field indicates the result of a smear, pathology examination or cytology examination of specimen of tissue or body fluids *other than sputum*.

Positive – Select “Positive” if any tissue or body fluid other than sputum (e.g., gastric or tracheal aspirate, bronchial washing, urine, bone marrow, lymph node, cerebral spinal fluid, lung, pleura) collected from procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration) was either: positive for acid-fast organisms (i.e., AFB) during a smear examination, **OR** showed granulomas, granulomatous inflammation, or other pathologic or histologic findings consistent with TB disease during a pathologic/cytologic examination (e.g., such findings would be listed on the pathology or cytology report).

Negative – Select “Negative” if the results of all examinations (or the only examination) were negative.

Not Done – Select “Not Done” if such examinations (e.g., smear, pathology/cytology) of tissue or body fluids are known not to have been done.

Smear/Pathology/Cytology Collection Date – If the smear/pathology/cytology was “Positive” or “Negative”, indicate the date (mm/dd/yyyy) the specimen was collected. If several examinations were done and one or more examinations were “Positive”, enter the date the first positive specimen was collected. If several examinations were done and all were “Negative”, enter the date the first negative specimen was collected.

If positive specimen, enter anatomic code – If the smear/pathology/cytology was “Positive” please enter the anatomic code that corresponds to the location in the body from which the specimen was collected.

Type of Exam – If Smear/Pathology/Cytology was performed, please indicate the type of exam that was done. Select “Smear” if a smear was done to examine for AFB. Select “Pathology/Cytology” if a pathologic/cytologic examination was done. This information should be found on the laboratory report.

4. Culture of Tissue and Other Body Fluids – This field indicates the result of a culture of tissue or body fluids. For the purposes of this question, tissue or body fluids do not include sputum.

Positive – Select “Positive” if any tissue or body fluid, other than sputum (e.g., gastric or tracheal aspirate, bronchial washing, urine, bone marrow, lymph node, cerebral spinal fluid, lung, pleura) collected from procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration) was positive for *M. tuberculosis* complex.

Negative – Select “Negative” if all tissue or fluid cultures, other than sputum cultures, were negative for *M. tuberculosis* complex.

Not Done – Select “Not done” if tissue or body fluid cultures are known not to have been done.

Culture of Tissue and Other Body Fluids Collection Date – If the culture of tissue and other Body Fluids was “Positive” or “Negative”, indicate the date (mm/dd/yyyy) the specimen was collected. If several cultures were done and one or more cultures were “Positive” for *M. tuberculosis* complex, enter the date the first positive culture specimen was collected. If several cultures were done and all

were “Negative” for *M. tuberculosis* complex, enter the date the first negative culture specimen was collected.

If culture is positive, enter anatomic code – If the culture of tissue and other body fluids was “Positive” please enter the anatomic code that corresponds to the location in the body from which the specimen was collected.

5. Nucleic Acid Amplification Test (NAA) Result – This field indicates the result of a nucleic acid amplification test.

Positive – Select “Positive” if the NAA test was positive for *M. tuberculosis* complex. If several NAA tests were done and one or more were “Positive”, enter the results for the first positive NAA test.

Negative – Select “Negative” if all NAA test were negative for *M. tuberculosis* complex.

Not Done – Select “Not Done” if an NAA test was not performed.

Indeterminate – Select “Indeterminate” if the NAA test yielded indeterminate results (e.g., inconclusive, inhibitory).

Nucleic Acid Amplification Test Result Collection Date – If the NAA test was “Positive” or “Negative” please enter the date on which the specimen was collected.

If nucleic acid amplification test is positive, enter anatomic code – If the NAA test was “Positive” please enter the anatomic code that corresponds to the location in the body from which the specimen was collected.

6. Initial Chest Radiograph – This field indicates the result of the initial chest radiograph taken during the diagnostic evaluation for TB.

Normal – Select “Normal” if the initial chest radiograph(s) showed no abnormalities consistent with TB and was normal.

Abnormal – Select “Abnormal” if the initial chest radiograph(s) showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB.

Not Done – Select “Not Done” if an initial chest radiograph is known not to have been done.

For Abnormal Initial Chest Radiograph: Evidence of Cavity – If the initial chest radiograph(s) was abnormal, please indicate whether one or more cavities were seen by selecting “Yes”, “No”, or “Unknown”.

For Abnormal Initial Chest Radiograph: Evidence of miliary TB – If the initial chest radiograph(s) was abnormal, please indicate whether evidence of “miliary” disease (e.g., “miliary” TB or “miliary or “bilateral micronodular” pattern) was seen by selecting “Yes”, “No”, or “Unknown”.

7. Initial Chest CT Scan or Other Chest Imaging Study – This field indicates the result of an initial chest CT scan or other chest imaging study taken during diagnostic evaluation for TB.

Normal – Select “Normal” if the initial chest CT scan or other chest imaging study showed no abnormalities consistent with TB and was normal.

Abnormal – Select “Abnormal” if the initial chest CT scan or other chest imaging study showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB.

Not done – Select “Not Done” if an initial chest CT scan or other chest imaging study is known not to have been done.

For Abnormal Chest Scan: Evidence of Cavity - If the initial chest CT scan or other chest imaging study was abnormal, please indicate whether evidence of one or more cavities was seen by selecting “Yes”, “No”, or “Unknown”.

For Abnormal Chest CT Scan: Evidence of miliary TB – If the initial chest CT scan or other chest imaging study was abnormal, please indicate whether evidence of “miliary” disease (e.g., “miliary” TB or “miliary or “bilateral micronodular” pattern) was seen by selecting “Yes”, “No”, or “Unknown”.

8. Tuberculin (Mantoux) Skin Test at Diagnosis – This field indicates the result of the Tuberculin Skin Test (TST) performed during the diagnostic TB disease evaluation.

Positive – Select “Positive” if the TST measurement meets the criteria for a positive TST as defined by current guidelines.

Negative – Select “Negative” if the TST did not meet current criteria for a positive test and was negative as defined by current guidelines.

Not Done – Select “Not Done” if the TST is known to not have been done.

TST Placement Date – If the TST was “Positive” or “Negative” please indicate the date that the initial TST was placed on the patient.

TST Read Date – If the TST was “Positive” or “Negative” please indicate the date that the TST was read (measured).

Millimeters (mm) of induration – If the TST was “Positive” or “Negative” please indicate the measurement of the induration in millimeters. If the available skin test result indicates only that the result was “Positive” or “Negative,” but does not give the millimeters of induration, code the millimeters of induration as “99”.

9. Previously Positive TST – This field indicates whether the TB patient had a positive TST result in the past.

Date of Previously Positive TST – If the TB patient has had a positive TST result in the past, please indicate the date that the prior TB test was given.

10. Interferon Gamma Release Assay for Mycobacterium tuberculosis at Diagnosis – This field indicates the result of an Interferon Gamma Release Assay (IGRA, QuantiFERON or T-Spot) that was performed during the diagnostic evaluation for TB disease.

Positive – Select “Positive” if any IGRA test result was interpreted as positive for *M. tuberculosis* infection.

Negative – Select “Negative” if all IGRA test results were interpreted as negative for *M. tuberculosis* infection.

Indeterminate – Select “Indeterminate” if the IGRA test results could not be determined to be positive or negative.

Not Done – Select “Not Done” if the IGRA test is known to not have been performed.

Interferon Gamma Release Assay: Type of Test – If any IGRA for *M. tuberculosis* was performed please indicate the type of test that was administered, “QuantiFERON-TB Test” or “T-Spot.TB Test”.

Interferon Gamma Release Assay Collection Date – If any interferon gamma release assay for *M. tuberculosis* was performed please indicate the date that the blood sample was collected. If more than one test was conducted, and one or more test results were “Positive,” enter the date the first positive IGRA blood sample was collected. If one or more IGRA tests were done and all the results were negative,

enter the date the first negative IGRA blood sample was collected. If all test results were indeterminate, enter the date the first indeterminate result was reported.

vii. Epidemiologic Information:

1. Country of Birth (if other than US) – This field designates the country of the patient’s birth if they were born outside the United States. If the patient was born in one of the 50 United States or born abroad of a U.S. citizen parent (e.g., born on a military installation), leave this field blank. U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) should be considered as distinct areas and their specific names should be entered in this field. Choose the appropriate country from the drop-down menu.

Month-Year Arrived in the US – If the patient was born outside the United States please enter the month and year in which they arrived in the US.

2. Immigration Status – This field designates the immigration status of a patient that was born outside of the United States. The criteria regarding the birthplace of the patient is slightly different in this field as compared to the previous Country of Birth field. If a TB patient was born in one of the 50 United States, born abroad of a U.S. citizen parent (e.g., born on a military installation), or born in one of the U.S. Territories, U.S. Island Areas, or U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) then a visa would not be issued and “Not Applicable/U.S.-born” should be checked. If the patient does not fit into the category “Not Applicable/U.S.-born” then one of the following options should be selected:

Immigrant Visa – Select “Immigrant Visa” for foreign-born TB patients who first entered the U.S. with permanent resident status (e.g., immigrants).

Student Visa “F”, “M”, “J” – Select “Student Visa” for foreign-born TB patients who first entered the U.S on a student visa. This is a non-immigrant visa and is obtained by an alien coming temporarily to the U.S. to pursue a full course of study in an approved institution.

Asylee or Parolee - Select “Asylee or Parolee” for foreign-born patients who first entered the U.S seeking asylum or who are parolees. An asylee is an alien in the U.S. who is unable or unwilling to return to his or her country of nationality because of persecution or a well-founded fear of persecution. An asylee must

meet the same criteria as a refugee; the only difference is the location of the person upon application – the potential asylee is in the U.S. or applying for admission at a port of entry, and the potential refugee is outside the U.S. A parolee is an alien, appearing to be inadmissible to the inspecting officer, allowed to enter the U.S. under urgent humanitarian reasons or when that alien’s entry is determined to be for significant public benefit.

Other Immigration Status – Select “Other Immigration Status” for foreign-born TB patients who first entered the U.S with other immigration status, which is not Immigrant, Refugee, Asylee, Parolee, Student, Tourist, Employment, “V” visa, or “K” visa status, and is not “Unknown.” This includes foreign-born persons who were not required to obtain a visa (e.g., foreign-born visitors from specific countries such as Canada that are part of the U.S. visa waiver program and are not required to obtain visas if visiting the U.S. for short periods of time (e.g., ≤90 days)), or those who entered the U.S. with no official immigration status at entry (e.g., “undocumented” status). If possible, please specify the reason for selecting this option.

Tourist Visa “B” - Check “Tourist Visa” for foreign-born TB patients who first entered the U.S temporarily for business or pleasure. This is a non-immigrant visa.

Employment Visa “H”, “E”, “L”, “J” – Select “Employment Visa” for foreign-born patients who first entered the U.S with a non-immigrant employment visa (an alien coming to the U.S. to work for a temporary period of time). There are many different non-immigrant employment visas depending upon type of work. (Note: Some persons entering the U.S. for work are immigrants; they should be checked as “immigrants”).

“V” Visa or “K” Visa – Select “V” Visa or “K” Visa for foreign-born TB patients who first entered the U.S with a “V” visa or “K” visa. A “V” visa is a non-immigrant category that allows a spouse or child of a U.S. lawful permanent resident to live and work in the U.S. A “K” visa is a non-immigrant category that allows a fiancé of a U.S. citizen to temporarily enter the U.S. for a specific purpose (i.e., marriage).

Refugee – Select “Refugee” for foreign-born patients who first entered the U.S as refugees. A refugee is a person who is outside his or her country of nationality who is unable or unwilling to return to that country because of persecution or a well-founded fear of persecution.

Unknown – Select “Unknown” for jurisdictions with directives or policies forbidding asking a TB patient their immigration status; foreign-born TB patients who do not

know their immigration status at first entry to the U.S; those who may have had a visa at entry to the U.S., but the type of visa is unknown; and those who refuse to respond.

3. Pediatric Patients (<15 years old) – This section is designed to better capture important information about pediatric TB patients (<15 years old), this section will request information on country of birth for primary guardian(s) of the pediatric case and whether the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months. Please fill out this section for all pediatric TB patients (<15 years old).

- A. Patient Lived outside US for >2 months – This field indicates whether the pediatric patient has lived outside of the US for an uninterrupted period of >2 months. If the pediatric patient lived outside the U.S. in more than one country for an uninterrupted period of more than 2 months complete the question for the three most recent countries. For this question, “lived” is defined as the place where a person lives or sleeps most of the time or the place the person considers to be their usual home during the stated time period. Although it may be difficult to determine the exact amount of time that a person lived outside the U.S. for an uninterrupted period, indicate “Yes” and the country code(s) if time period is believed to be ≥ 8 weeks.

Yes – Select “Yes” if the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months and enter the appropriate countries. If the patient lived in more than one country, enter the three countries in which the patient lived for more than 2 uninterrupted months most recently.

No – Select “No” if the pediatric TB patient did not live outside the U.S. for an uninterrupted period of more than 2 months.

Unknown – Select “Unknown” if it is unknown whether the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months.

If yes, enter country (1) – If the pediatric TB patient lived outside the U.S. for an uninterrupted period of more than 2 months and specify the country in the drop-down menu.

If yes, enter country (2) – If the pediatric TB patient lived outside the U.S., in more than one country, for an uninterrupted period of more than 2 months select the second most recent country from the drop-down menu.

If yes, enter country (3) – If the pediatric TB patient lived outside the U.S. in more

than one country for an uninterrupted period of more than 2 months select the third most recent country from the drop-down menu.

- B. Country of Birth for Primary Guardian(s) – Please enter the country of birth for the primary guardian(s) (e.g., mother, father, foster parent, grandparent) of the pediatric TB patient. If the guardian was born in one of the 50 United States or born abroad of a U.S. citizen parent (e.g., born on a military installation), select “United States” as the country of birth. U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands) should be considered distinct areas and their specific names should be selected.

Country of Birth for Primary Guardian1 – Please indicate the country of birth of the first primary guardian.

Country of Birth for Primary Guardian 2 - Please indicate the country of birth of the second primary guardian.

4. HIV Information - CDC recommends that **ALL** TB cases receive HIV counseling, testing, and referral at the time of TB diagnostic evaluation or TB diagnosis. Refer to the CDC public health surveillance definition for HIV infection.

HIV Status – Please indicate the HIV status of the TB patient at the time of diagnosis.

Negative – Select “Negative” if the patient has had a documented negative HIV test at the time of TB diagnostic evaluation or at TB diagnosis. Undocumented patient history that an HIV test result was negative is not acceptable. Such patients should be offered the opportunity to be tested for HIV. In addition, if a patient has had a negative test in the past, regardless of when the HIV test was performed, the patient should be offered HIV counseling and testing at the time of TB diagnostic evaluation or TB diagnosis. If the patient had received HIV counseling and testing a short period before the TB diagnostic evaluation or TB diagnosis (e.g., a few months) and the documented results were negative for HIV infection, and the patient has absolutely no risk for HIV, then these HIV test results may be used for this question. The length of time prior to TB diagnosis for which a negative HIV test result may be accepted should be based on clinical judgment of patient risk, not to exceed one year.

Positive – Select “Positive” if the patient is tested for HIV and the laboratory result is interpreted as positive according to published criteria OR the patient has a documented medical history of a previous positive HIV test, or a documented previous diagnosis of HIV infection or AIDS.

Indeterminate – Select “Indeterminate” if the patient has had a documented indeterminate HIV test at the time of TB diagnostic evaluation or TB diagnosis. Undocumented patient history is not acceptable.

Refused – Select “Refused” if the patient was offered the test at the time of the TB diagnostic evaluation or TB diagnosis, but declined to be tested.

Not Offered – Select “Not Offered” if the patient was not offered the test at the time of the TB diagnostic evaluation or TB diagnosis.

Test Done, Results Unknown – Select “Test Done, Results Unknown” if the patient had a HIV test at the time of the TB diagnostic evaluation or TB diagnosis and the results are not known to the TB program.

Unknown – Select “Unknown” if it is not known if the patient has had an HIV test, was ever offered a test, or was referred for HIV counseling and testing (e.g., anonymous testing center, private testing center).

If Positive, State HIV/AIDS Patient Number (If AIDS reported 1993 or later) – If the HIV status is positive, please enter the State HIV/AIDS patient number.

If Positive, City/County HIV/AIDS Patient Number (If AIDS reported 1993 or later) – If the HIV status is positive, please enter the State HIV/AIDS patient number.

5. Homeless Within Past Year – This field indicates whether the TB patient was homeless within the 12 months prior to the time when the TB diagnostic evaluation was performed. A homeless person may be defined as an individual who lacks a fixed, regular, and adequate nighttime residence; or an individual who has a primary nighttime residence that is a supervised publicly or privately operated shelter designed to provide temporary living accommodations, including welfare hotels, congregate shelters, and transitional housing for the mentally ill; or an institution that provides a temporary residence for individuals intended to be institutionalized; or a public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings. A homeless person may also be defined as a person who has no home (e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends). Another definition is a person who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in nonresidential buildings. Also included are residents of homeless shelters, shelters for battered women, welfare hotels, and single room occupancy (SRO) hotels. In the rural setting, where there are usually few shelters, a homeless person often will live on the street or with relatives in substandard housing. Being homeless does

not refer to a person who is imprisoned or in a correctional facility.

No – Select “No” if the patient was not homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.

Yes – Select “Yes” if the patient was homeless at any time during the 12 months prior to the time when the TB diagnostic evaluation was performed.

Unknown – Select “Unknown” if it is not known whether the patient was homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.

6. Resident of Correctional Facility at Time of Diagnosis – This question indicates whether the TB patient was an inmate in a correctional facility at the time TB diagnostic evaluation was performed.

No – Select “No” if the TB patient was not an inmate in a correctional facility at the time of the TB diagnostic evaluation.

Yes – Select “Yes” if the TB patient was an inmate in a correctional facility at the time of the TB diagnostic evaluation.

Unknown – Select “Unknown” if the TB patient it is unknown whether the patient was an inmate in a correctional facility at the time of TB diagnostic evaluation.

If yes, specify type of correctional facility at time of diagnosis – If the TB patient was an inmate in a correctional facility at the time of TB diagnostic evaluation, please indicate the type of correctional facility. If the TB patient was an inmate of more than one facility when the diagnostic evaluation was performed, select the facility where the majority of the TB diagnostic evaluation was performed.

Federal Prison – Select “Federal Prison” if the TB patient was an inmate in a confinement facility administered by a federal agency. For the purpose of this question, privately operated federal correctional facilities are included in “federal prison.”

State Prison – Select “State Prison” if the TB patient was an inmate in a confinement facility administered by a state agency. For the purpose of this question, privately operated state correctional facilities are included in “state prison.”

Local Jail – Select “Local Jail” if the TB patient was an inmate in a confinement facility usually administered by a local law enforcement agency, intended for adults but sometimes also containing juveniles, which holds persons detained

pending adjudication and/or persons committed after adjudication for sentences of usually a year or less. Temporary holding facilities, or lockups, that do not hold persons after being formally charged in court are excluded. Both city and county jails are included in this category. Federal and state prisoners who are boarded at local jails should be reported as residents of the local jail. For the purpose of this question, privately operated local correctional facilities are included in “local jail.”

Juvenile Correctional Facility – Select “Juvenile Correctional Facility” if the TB patient is a resident of a public or private residential facility, including juvenile detention centers, reception and diagnostic centers, ranches, camps, farms, boot camp, residential treatment centers, and halfway houses or group homes. The juveniles served by these facilities include those charged or adjudicated as delinquents; non-delinquent/non-criminal offender (e.g., runaways, truants, incorrigibles, curfew violators); and those committed or detained for treatment of abuse, dependency, neglect, or other reasons. Juveniles who are boarded at federal or state prisons or local jails should be reported as residents of the sites at which they are boarded.

ICE (Former INS) Detention – Select “ICE (Former INS) Detention” if the TB patient was in the custody of Immigration and Customs Enforcement (ICE) at the time of TB diagnostic evaluation. Persons in ICE custody can be housed in stand alone ICE Detention Centers or other correctional facilities (e.g., federal or state prison, local jail) when a stand-alone ICE Detention Center is not available.

Other Correctional Facility – Select “Other Correctional Facility” if the TB patient was an inmate in a correctional facility at the time of TB diagnostic evaluation that was not listed above. Example of other correctional facilities are Indian reservation facilities (e.g., tribal jails), military stockades and jails, federal Park Police facilities, police lockups (temporary-holding facilities for persons who have not been formally charged in court), or other correctional facilities that are not included in the other choices and is not “Unknown.” Please specify the type or name of the facility in space provided.

Unknown – Select “Unknown” if it is not known what type of correctional facility the TB patient was an inmate in at the time of TB diagnostic evaluation.

7. Resident of Long-Term Care Facility at Time of Diagnosis – This field indicates whether the TB patient was living in a long-term care facility at the time of TB diagnostic evaluation.

No – Select “No” if the TB patient was not living in a long-term care facility at the time of TB diagnostic evaluation.

Yes – Select “Yes” if the TB patient was living in a long term care facility at the time of diagnosis.

Unknown – Select “Unknown” if it is not known whether the TB patient was living in a long-term care facility at the time of TB diagnostic evaluation.

If yes, specify type of long-term care facility at time of diagnosis – If the TB patient was living in a long-term care facility at the time of TB diagnostic evaluation, please indicate the type of long-term care facility.

Nursing Home – Select “Nursing Home” if the TB patient was living in a facility at the time of TB diagnostic evaluation having 3 beds or more *and* is certified as a skilled nursing facility, or certified as an immediate care facility, or is licensed as a nursing home, or is identified as a nursing care unit of a retirement center, or is determined to provide nursing or medical care and/or supervision over medications that may be self-administered.

Hospital-Based Facility – Select “Hospital-Based Facility” if the TB patient was living in a nursing home at the time of TB diagnostic evaluation that is a distinct unit of hospital, with 3 or more beds, that is either physically attached or if not attached, managed by a hospital. Facilities may be certified by Medicare or Medicaid, or licensed by the State.

Residential Facility – Select “Residential Facility” if the TB patient was living in a residential facility at the time of TB diagnostic evaluation. A facility with 3 or more beds is classified as a residential facility (e.g., congregate residential setting) if it meets both of the following criteria: 1) was not classified as a nursing home or hospital-based facility as described above, and 2) provides personal care or supervision to its residents, not nursing care services, in addition to room and board (e.g., help with bathing, dressing, eating, walking, shopping). Included under residential facilities are assisted living facilities, homes for mentally retarded or developmentally disabled persons, board and care homes (e.g., residential care homes, group homes, homes for the aged, family care homes, adult foster care homes, personal care homes, adult congregate living facilities, residential community care facilities, domiciliary care homes).

Mental Health Residential Facility – Select “Mental Health Residential Facility” if the TB patient was living in a mental health residential facility at the time of TB diagnostic evaluation that provides 24-hour care in a hospital or residential treatment or supportive setting. This includes state and local mental hospitals, private psychiatric hospitals, non-federal general hospitals with separate psychiatric services, VA medical centers, multi-service mental health organizations with residential treatment programs, and residential treatment

centers for emotionally disturbed children. Excluded are other federal psychiatric facilities and Indian reservation facilities, for these select “Other Long-Term Care Facility” below instead.

Alcohol or Drug Treatment Facility – Select “Alcohol or Drug Treatment Facility” if the TB patient was living in a long-term rehabilitation/residential facility at the time of TB diagnostic evaluation that is designated for treatment of 30 days or longer. This category does not include all ambulatory or outpatient facilities, hospital inpatient detoxification units, etc.

Other Long-Term Care Facility – Select “Other Long-Term Care Facility” if the TB patient was living in a facility at the time of TB diagnostic evaluation that was not mentioned above that is designated for treatment of 30 days or longer and is not “Unknown.” Please specify the type or name of the facility in space provided.

Unknown – Select “Unknown” if it is not known whether the TB patient was living in a long-term care facility at the time of TB diagnostic evaluation.

8. **Injecting Drug Use Within Past Year** – This field indicates whether the TB patient has used injectable drugs within the past 12 months (as of the date of TB diagnosis). Injection drug use involves the use of hypodermic needles and syringes for injection of drugs not prescribed by a health care provider. Route of administration may be intravenous, subcutaneous or intramuscular. Drugs injected may include heroin, cocaine, amphetamines, PCP, LSD, barbiturates, steroids, etc. Use of injecting drugs within the past year should be sought as an indicator of recent activity (e.g. when did the patient last inject drugs). Medical documentation or other indices of a history of enrollment in a drug treatment program (e.g. methadone treatment, narcotics anonymous, etc.), medical or laboratory documentation of injecting drug use (e.g. urine toxicology), or physical evidence (e.g. needle tracks) may be useful in answering this question. Since the patient interview for injecting drug use is often negative initially, it may be necessary to inquire at multiple visits.

No – Select “No” if the TB patient has not used injectable drugs in the past 12 months.

Yes – Select “Yes” if it is known the TB patient has used injectable drugs within the last 12 months (as of the date of TB diagnosis).

Unknown – Select “Unknown” if it is unknown whether the TB patient has used injectable drugs in the past 12 months.

9. **Non-Injecting Drug Use Within Past Year** – This field indicates whether the TB

patient has used non-injection drugs within the past 12 months (as of the date of TB diagnosis). Non-injection drug use involves the use of licensed, prescription, or illegal drugs that were not injected and were not prescribed by a health care provider. The drug(s) may be ingested, inhaled or smoked. Non-injection drugs may include heroin, cocaine, amphetamines, Valium, PCP, LSD, barbiturates, marijuana, nitrates, inhalants, steroids, etc. Use of non-injection drugs within the past year should be sought as an indicator of recent activity (e.g. when did the patient last use non-injection drugs). Medical documentation or other indices of a history of enrollment in a drug treatment program (e.g. outpatient or inpatient, cocaine anonymous, etc.), and/or medical or laboratory documentation of injecting drug use (e.g. urine toxicology) may be useful in answering this question. Since the patient interview for non-injecting drug use is often negative initially, it may be necessary to inquire at multiple visits.

No – Select “No” if the TB patient has not used non-injection drugs in the past 12 months.

Yes – Select “Yes” if it is known the TB patient has used non-injection drugs within the last 12 months (as of the date of TB diagnosis).

Unknown – Select “Unknown” if it is unknown whether the TB patient has used non-injection drugs in the past 12 months.

10. Excess Alcohol Use Within Past Year – This field indicates whether the TB patient has excessively consumed alcohol within the past 12 months (as of the date of TB diagnosis). Reliable indicators of excess alcohol use include: participation in Alcoholics Anonymous or alcohol treatment programs description by the patient, the patient’s family or acquaintances, or a health care provider report of chronic, high intake of alcohol with behavior associated with alcohol abuse, repeated visits to health care facilities during which alcohol intoxication was observed, reported alcohol use coupled with the existence of organic, alcohol associated disease (e.g. cirrhosis, pancreatitis), or diagnosis of alcoholism on available medical records. Use of excess alcohol within the past year should be sought as an indicator of recent activity (e.g. when did the patient last have a drink). Since the patient interview for excess alcohol use is often negative initially, it may be necessary to inquire at multiple visits.

No – Select “No” if the TB patient has not excessively consumed alcohol within the past 12 months.

Yes – Select “Yes” if it is known the TB patient has excessively consumed alcohol within the past 12 months

Unknown – Select “Unknown” if it is unknown whether the TB patient has excessively consumed alcohol within the past 12 months.

11. Occupation Within Past 24 Months – This field designates the TB patient’s occupation within the past 2 years (as of the date of TB diagnosis).

Employed – Select “Employed” if the TB patient was working in the 24 months prior to the TB diagnosis.

Unemployed – Select “Unemployed” if the TB patient was not employed during the past 24 months prior to the diagnostic TB evaluation. This should not include persons who are ineligible for employment such as infants, children, students, housewives, retirees, and persons receiving permanent disability benefits or persons who were institutionalized - such individuals should be included in the “Other” option and indicated as such (i.e., Retired, Child, Student etc). “Unemployed” should be checked if the person was unemployed for the majority of the prior 24 month period; shorter time frames, such as 1 week of unemployment in the past 12 months such not be coded as “Unemployed.”

Unknown – Select “Unknown” if it is not known whether the patient was employed in the 24 months prior to TB diagnosis.

Other – Select “Other” if the patient had special circumstances for which they were not employed such as infants, children, students, homemakers (e.g., housewife, househusband), persons receiving permanent disability benefits or persons who were institutionalized, retirees etc. If “Other” is selected, please specify the reason in the text field.

If Employed - If the TB patient was employed within the past 24 months, please indicate the type/setting of the employment. If the TB patient performed duties in more than one of the occupations listed, mark all that apply (e.g. physician who works in both a hospital and a prison medical clinic, mark both “Health Care Worker” and “Correctional Employee”). If the patient was employed in more than one setting, select all that apply.

12. Additional TB Risk Factors – This field indicates the additional TB risk factors that the TB patient may have (*select all that apply*). Documentation of additional TB risk factors from the medical records or a reliable source (e.g., health care provider) is preferred. Undocumented (e.g. verbal reporting from the patient or non-health care provide) reporting is not acceptable. Please note that other specific TB risk factors (e.g., occupation, HIV) are collected elsewhere in the MDSS TB Form.

Contact of Infectious TB Patient – Select “Contact of Infectious TB Patient” if the TB patient being reported is a known contact of an infectious TB patient. If this infectious TB patient is known to have had multidrug resistant TB, and the TB patient being reported was not a contact of any other infectious TB patient, select the option “Contact of MDR-TB Patient” and do not check “Contact of infectious TB patient.” The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago.

Contact of MDR-TB Patient – Select “Contact of MDR-TB Patient”, if the TB patient being reported is a contact of a multidrug resistant (MDR) TB patient, regardless of whether the MDR-TB case was infectious or not. Multidrug resistant TB is defined as resistance to at least isoniazid and rifampin. If this MDR-TB patient was the only known contact for the patient being reported, check “Contact of MDR-TB patient” and do not check “Contact of infectious TB patient.” The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago. This question is being asked because clinical management of the TB patient may be affected if the TB patient is a contact of a documented MDR-TB patient.

Contact of XDR-TB Patient – Select “Contact of XDR-TB Patient”, if the TB patient being reported is a contact of a extensively drug resistant (XDR) TB patient, regardless of whether the XDR-TB case was infectious or not. Extensively drug resistant TB is defined as resistance to isoniazid and rifampin, plus resistance to any fluoroquinolone and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin). If this XDR-TB patient was the only known contact for the patient being reported, check “Contact of XDR-TB patient” and do not check “Contact of infectious TB patient.” The association between the TB patients may have been found through investigation (e.g., a formal contact investigation) or identified as an incidental finding. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago. This question is being asked because clinical management of the TB patient may be affected if the TB patient is a contact of a documented XDR-TB patient.

Missed Contact – Select “Missed Contact”, if after having been diagnosed with TB disease, the TB patient being reported was found to have been a contact of a known TB patient. For the purpose of this question, the contact should be recent and should not have occurred more than 2 years ago. DO NOT include TB patients identified as having TB disease during a contact investigation or as a result of a

contact investigation in this choice. These patients are not “missed contacts” since they were identified during a contact investigation, despite having TB disease. This “risk factor” is trying to capture those TB patients that could be identified as preventable cases of TB.

Incomplete LTBI Treatment – Select “Incomplete LTBI Treatment” if the TB patient was previously identified as having latent TB infection (LTBI) and was not treated completely for LTBI. This “risk factor” is trying to capture those TB patients that could be identified as a preventable case of TB.

Diabetes Mellitus – Select “Diabetes Mellitus” if the TB patient has diabetes mellitus (Type I or Type II) at the time of TB diagnosis. Diabetes may be controlled by medication or diet.

End-Stage Renal Disease – Select “End-Stage Renal Disease” (i.e., ESRD) if the TB patient has end-stage renal disease or chronic renal failure at the time of TB diagnosis.

Post-organ Transplantation – Select “Post-organ transplantation” if the TB patient has a history of solid organ transplantation (e.g., renal, cardiac).

TNF- α Antagonist Therapy – Select “TNF- α Antagonist Therapy” if the TB patient had recently or has been receiving tumor necrosis factor-alpha (TNF- α) antagonist therapy at the time of TB diagnosis. The Food and Drug Administration (FDA) has approved TNF- α antagonist therapy for treatment of rheumatoid arthritis and other selected autoimmune diseases. The FDA has also recently determined that TB disease is a potential adverse reaction from treatment with TNF- α antagonists. The three currently FDA approved TNF- α antagonists are infliximab (Remicade[®]), etanercept (Enbrel[®]), and adalimumab (Humira[®]).

Immunosuppression (not HIV/AIDS) – Select “Immunosuppression (not HIV/AIDS)” if the TB patient has immunosuppression due to either a medical condition or medication, such as hematological or reticuloendothelial malignancies [e.g., leukemia, Hodgkin’s lymphoma, carcinoma of the head or neck], or immunosuppressive therapy, such as prolonged use of high dose adrenocorticosteroids (e.g., prednisone). If the TB patient has diabetes mellitus or end-stage renal disease, select either “Diabetes Mellitus” and/or “End-Stage Renal Disease” for this question, and do not check “immunosuppression” unless the patient has another immunosuppressive condition. If the patient is infected with HIV, complete the “HIV Status” Question, and do not check “immunosuppression” for this question, unless the patient has another immunosuppressive condition.

Other – Select “Other” if the TB patient has a TB risk factor not included in the above choices [e.g., undernutrition (e.g., intestinal bypass surgery for obesity, gastrectomy, jejunioileal bypass, chronic malabsorption syndromes), silicosis, travel to a TB endemic country]. If “Other” is selected, please indicate specific risk factor in the test field.

Unknown – Select “Unknown” if no TB risk factors could be identified.

viii. Treatment Information:

1. Date Therapy Started – This field designates the date when the TB patient began therapy for TB or suspected TB. This may be (in order of preference) the date the patient first ingested medication, the date medication was first dispensed to patient, or the date medication was first prescribed to patient by health care provider. This date must be documented by medical or pharmacy records.
2. Directly Observed Therapy (DOT) – This field indicates whether the TB patient is receiving Directly Observed Therapy (DOT) defined as supervised therapy in which a health care provider (e.g. nurse, outreach worker, etc.) has direct visual observation of a patient’s ingestion of medication. This is the recognized standard of care for TB in the United States. Performing pill counts or dropping the filled prescription off to the patient without observing the patient ingest the medication is unacceptable and does **not** constitute DOT.

Yes – Select “Yes” if the patient is receiving DOT.

No – Select “No” if the patient is not receiving DOT.

Unknown – Select “Unknown” if it is not known whether the patient is receiving DOT.

If Yes, DOT Start Date – If the TB patient is receiving DOT, please indicate the date at which the DOT was started.

3. Initial Drug Regimen – This table designates the treatment initially prescribed for the treatment of TB disease. Mark “Yes” for each drug that is known to be part of the initial regimen and “No” for each drug known not to be part of the initial regimen. Mark “Unknown” for the rare instance it is not known whether the drug is part of the initial regimen. If “Other TB drug” is marked “Yes,” specify the name of the anti-tuberculosis drug (e.g. levofloxacin, clofazamine, etc.) Do not include pyridoxine (Vitamin B6). Please also include the dosage for each drug given (in

milligrams) to the patient and the frequency at which it is given (7x/week, 5x/week, 3x/week or 2x/week).

II. FOLLOW-UP REPORT 1: INITIAL DRUG SUSCEPTIBILITY REPORT SECTION
(STATE USE ONLY)

- i. Drug Susceptibility Report Completed:
- ii. Was Drug Susceptibility Testing Done:
- iii. If Yes, Enter Specimen Type:
- iv. If not Sputum, enter Anatomic Code:
- v. Susceptibility Results:

III. FOLLOW-UP REPORT 2: CASE COMPLETION REPORT

1. Case Completion Report Completed: (State Use Only)

2. Sputum Culture Conversion Documented: This field indicates whether a sputum specimen had culture conversion from culture positive to culture negative during the course of treatment.

No – Select “No” if the patient had an initially positive sputum culture and no subsequent negative sputum culture (e.g. no initial sputum samples were collected, all follow-up sputum cultures were positive, patient could not produce sputum after therapy started, or no follow-up sputum cultures were obtained).

Yes – Select “Yes” if the patient had an initially positive sputum culture followed by one or more consistently negative sputum cultures.

Unknown – Select “Unknown” if it is not known whether a sputum culture conversion was documented.

If Yes, Date Specimen Collected on First Consistently Negative Culture – Indicate the month, day and year the first culture positive sputum specimen was collected. This information is available on the laboratory report form. Partial dates are not acceptable.

If No, Reason for Not Documenting Sputum Culture Conversion – If no sputum culture conversion was documented, please indicate the reason.

Clinically Improved: No follow-up sputum despite induction – Select “Clinically Improved: No follow-up sputum despite induction” if repeat sputum collection was attempted, including induced sputum collection, but patient was not able to produce sputum due to clinical improvement.

No follow-up sputum collection – Select “No follow-up sputum collection” if induction was not attempted (e.g., if the health care provider did not order a repeat specimen, or if there were no facilities or equipment for induction).

No initial sputum result or none collected – Select “No initial sputum result or none collected” if a sputum sample was not collected or a positive culture result was not obtained at the time of diagnosis.

Died – Select “Died” if the patient died before having an opportunity to submit sputum to document whether the sputum culture had converted.

Patient Lost – Select “Patient Lost” if the patient was lost to follow-up before having an opportunity to submit sputum to document whether the sputum culture had converted.

Patient Refused – Select “Patient Refused” if the patient refused to provide a sputum specimen for a repeat culture.

Other – Select “Other” if there was another reason not included in the above choices, such as treatment failure or the patient moved outside the U.S. If “Other” is selected, please indicate the reason there was no sputum culture conversion documented in the text field.

Unknown – Select “Unknown” if the reason for not obtaining a repeat sputum culture to document sputum culture conversion is unknown.

3. US-Mexico Binational Status – This field indicates whether the TB patient held US-Mexico Binational status. For the purposes of this question, a TB patient with US-Mexico Binational status is one for which optimal case management requires communication or collaboration with TB control programs or health-care providers on the opposite side of the border. For example, a TB control program in the United States would transfer clinical or laboratory data, refer a patient for treatment completion, or share information for contact investigation with a Mexican TB control program OR the case-patient is a contact of a Binational TB case-patient or is the TB source case-patient for contacts on the opposite side of the U.S.-Mexico border.

If a Binational TB case, reason why – If the TB patient is a Binational case, please indicate the reason.

Diagnostic/Clinical/Treatment Information Exchange – Select “Diagnostic/Clinical/Treatment Information Exchange” if the TB patient’s case management involved exchange of information regarding the diagnosis, clinical management and/or

treatment between entities in the US and in Mexico.

Contacts – Select “Contacts” if the TB patient is a contact of a Binational TB case-patient or is the TB source case-patient for contacts on the opposite side of the U.S.-Mexico border.

Laboratory/Radiologic Testing – Select “Laboratory/Radiologic Testing” if the TB patient’s care involved either laboratory or radiologic testing, performed in Mexico, which was used in the TB patient’s diagnosis.

4. Did the patient move during TB therapy – This field indicates whether the patient moved anytime during TB therapy. Communication between TB control programs to ensure continuity of care and submission of follow-up reports regarding a patient who is moving from one area to another should be conducted in the most efficient manner possible and the responsibility for submitting follow-up reporting generally remains with the reporting area that initially reported the case to MDCH and counted it.

No – Select “No” if a patient did not move during TB therapy or moved within the same local health department jurisdiction.

Yes – Select “Yes” if the patient moved to an area where a new local health jurisdiction had to provide and/or coordinate TB care. In addition to determining whether a patient moved or not, it is of interest as to where the TB patient moved.

Unknown – Select “Unknown” if it is not known whether the TB patient moved during treatment.

If Yes, moved to where – In addition to determining whether a patient moved or not, it is of interest as to where the TB patient moved. For those who moved any time during their TB disease episode, identify to where the TB patient moved: (select all that apply).

In-state, out of jurisdiction – Select “In-state, out of jurisdiction”, if the patient moved within the current state, but moved out of the local health jurisdiction, such as to a different county or health district.

Out of state – Select “Out of state”, if the patient moved to another state during their TB treatment. If the patient moved to one of the U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands), select “Out of state”.

Out of the U.S. – Select “Out of the U.S.” if the patient moved outside the U.S. to another country. If the patient moved to one of the U.S. Territories, U.S. Island Areas, and U.S. Outlying Areas (e.g., American Samoa, Federated States of Micronesia, Guam, Republic of the Marshall Islands, Commonwealth of the Northern Mariana Islands, Republic of Palau, Puerto Rico, U.S. Virgin Islands): for the purpose of this question, select “Out of state”.

If transnational referral was made to another TB program or physician outside the U.S., please indicate in the comments section. Transnational referral includes participation in programs such as TBNNet or CureTB, communication with Immigrations and Customs Enforcement to ensure case management after deportation, or individual efforts by local TB programs to complete a case management transfer and obtain information from TB programs and physicians outside the U.S. for case completion.

If moved in state, out of jurisdiction, enter county #1 – If “In-state, out of jurisdiction” was marked above, please select the jurisdiction to which the patient moved from the dropdown menu. There are two spaces to indicate jurisdictions to which the patient moved. If the patient moved more than twice, enter the two first moves.

If moved in state, out of jurisdiction, enter county #2 – If “In-state, out of jurisdiction” was marked; please select the jurisdiction to which the patient moved from the dropdown menu. There are two spaces to indicate jurisdictions to which the patient moved. If the patient moved more than twice, enter the two first moves.

If moved out of state, enter state #1 – If “Out of state” was marked above, please select the state to which the patient moved from the dropdown menu. There are two spaces to indicate states to which the patient moved. If the patient moved more than twice, enter the two first moves.

If moved out of state, enter state #2 – If “Out of state” was marked above, please select the state to which the patient moved from the dropdown menu. There are two spaces to indicate states to which the patient moved. If the patient moved more than twice, enter the two first moves.

If moved out of the US, enter country #1 – If “Out of the U.S.” was marked above, please select the country to which the patient moved from the dropdown menu. There are two spaces to indicate countries to which the patient moved. If the patient moved more than twice, enter the two first moves.

If moved out of the US, enter country #2 – If “Out of the U.S.” was marked above, please select the country to which the patient moved from the dropdown menu. There are two spaces to indicate countries to which the patient moved. If the

patient moved more than twice, enter the two first moves.

5. **Date Therapy Stopped** – Enter the date (month, day, year) that the patient stopped taking therapy for TB disease or suspected TB disease. This may be (in order of preference) the date the patient last ingested medication, the date medication dispensed to patient would have run out if the patient had taken all the medication, or the date medication prescribed to patient would have run out if the patient had taken all the medication from the date of the prescription. The time period represented by the interval between “Date Therapy Started” (From the RVCT section of the MDSS TB form) and “Date Therapy Stopped” is meant to encompass the entire period (including interruptions in therapy) that the patient was receiving medication to treat TB disease or suspected TB. Treatment with anti-tuberculosis medications for disease caused by a mycobacterium other than *M. tuberculosis* complex should not be included.
6. **Reason Therapy Stopped or Never Started** – Provide the primary reason that therapy was ended and not resumed. This item should be completed when the case is closed to supervision.

Completed Therapy – Select “Completed Therapy if the patient successfully completed the prescribed course of therapy.

Lost – Select “Lost” if the patient cannot be located prior to the completion of treatment.

Uncooperative or Refused – Select “Uncooperative or Refused” if the patient is uncooperative or refuses to complete treatment. If the patient later restarts, the Completion form should be updated as appropriate.

Adverse Treatment Effect – Select “Adverse Treatment Effect” if therapy was permanently stopped due to an adverse treatment event due to antituberculosis medications (e.g., life threatening drug reaction).

Not TB – Select “Not TB” if the completed diagnostic evaluation determined that the diagnosis of active TB was not substantiated.

Died – Select “Died” if the patient died before therapy was completed. If “Died” is selected please attempt to obtain documentation of death (e.g., death certificate) as this will help ascertain whether the patient’s cause of death was related to TB.

Other – Select “Other” if therapy is discontinued for a reason not listed above. Please specify the reason treatment was stopped in the space provided.

Unknown – Select “Unknown” if the reason that therapy stopped is not known.

If Died, enter cause of death – If the patient was alive at diagnosis but died before TB therapy was completed, indicate the cause of death. Information under “If Died” may be filled out for cases whose reason for stopping therapy was death, who stopped therapy due to adverse treatment event then died, or patients who were lost but later determined to have died from another source such as death indices. Ideally, written documentation of the cause of death (e.g., death certificate, autopsy report, medical records) is recommended; however, a reliable verbal source (e.g., a health care provider) will be accepted.

Related to TB disease – Select “Related to TB disease” if the patient’s cause of death was related or due to TB disease. If TB is listed on the death certificate as the immediate cause, an underlying cause, or other significant condition contributing to death, select “Related to TB disease”.

Related to TB therapy – Select “Related to TB therapy” if TB therapy (e.g., adverse treatment event) was related to the cause of death.

Unrelated to TB disease – Select “Unrelated to TB disease” if TB disease or therapy did not have anything to do with the cause of death or if TB was not listed as the immediate cause, an underlying cause, or other significant condition contributing to death.

Unknown – Select “Unknown”, if the patient’s cause of death is unknown.

7. Reason Therapy Extending >12 months – This variable will help assess the reason(s) attributed to why antituberculosis therapy extended for more than 12 months. “Date Therapy Started” (RVCT Section) and “Date Therapy Stopped” (Follow-up 2 Section) should be used to calculate the length of antituberculosis therapy and determine if it was more than 12 months. Sources for the reasons why therapy was extended include patient medical records, patient interview, and health care provider interview. Please select all that apply. For MDR TB, please select the “Rifampin resistance (only)” option as well as the “Other Drug Resistance (non-Rifampin)” option.

Rifampin resistance (only) – Select “Rifampin resistance (only)” if the patient had TB that was resistant to at only Rifampin which would require a treatment protocol lasting more than 12 months as per recommended TB treatment guidelines. For MDR TB, please select this option as well as the “Other Drug Resistance (non-Rifampin)” option.

Other Drug Resistance (non-Rifampin) – Select “Other Drug Resistance (non-

Rifampin)” if the patient had TB that was resistant to anti-tuberculosis drugs other than Rifampin which would require a treatment protocol lasting more than 12 months as per recommended TB treatment guidelines. Please specify the type of drug resistance in the space provided.

Adverse drug reaction – Select “Adverse drug reaction”, if the patient had a significant adverse drug reaction or adverse treatment event due to antituberculosis medications that prolonged therapy (e.g., life threatening reactions, reactions requiring permanent change in antituberculosis medications).

Non-adherence – Select “Non- adherence”, if there were barriers to adherence to anti-tuberculosis therapy for the patient (e.g., patient did not adhere to therapy causing treatment interruption) or if the patient was non-compliant resulting in extension of therapy beyond 12 months.

Failure – Select “Failure”, if the patient has a positive sputum culture at or beyond month 4 of treatment. All treatment failure isolates should be compared to the initial isolate using DNA fingerprinting.

Clinically indicated - other reasons – Select “Clinically indicated – other reasons”, if the patient had clinically indicated reasons other than those listed above for extending therapy more than 12 months (e.g., central nervous system (CNS) TB, including tuberculosis meningitis, severe liver disease).

Other – Select “Other” if the reason for stopping therapy does not include any of the choices listed above (e.g., health care provider choice) and is not “Unknown.” Additional space is provided at the bottom of the form to write comments regarding “Other” reasons. Please specify the reason treatment was extended >12 months in the space provided.

Unknown – Select “Unknown” if the reason for therapy being extended is not known.

8. Type of Health Care Provider – This field indicates the type of health care provider the TB patient had during their TB treatment.

Local/State Health Department (HD) – Select “Local/State Health Department (HD)” if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is the local or state health department (e.g., TB program, health clinic).

Public non-Local/State HD – Select “Public non-Local/State HD” if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a Public non-

Local/State HD.

IHS, Tribal HD, or Tribal Corporation – Select “IHS, Tribal HD or Tribal Corporation” if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is the Indian Health Service (IHS) or an American Indian or Alaska Native Tribal Health Department or Tribal Healthcare Corporation.

Private – Select “Private” if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a private provider [e.g., private physician or health care provider, private Health Maintenance Organization (HMO), or private managed care provider]. This category also includes the private provider that has the primary responsibility for clinical outpatient decision making for a TB patient, even though the TB control program or local/state health department may be periodically contacting the private provider for the purpose of completing the RVCT and to ensure proper TB case management.

Institutional – Select “Institutional” if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is an institution such as, a correctional facility or a long-term care facility (e.g., nursing home, assisted living facility).

No Outpatient Care – Select “No Outpatient Care” if the patient did not receive any outpatient TB care. Such situations could include TB diagnosed at autopsy, patients who died prior to receiving outpatient TB care, and patients that received all of their TB care as an inpatient in a hospital or similar acute care facility.

Other – Select “Other” if the primary responsibility for clinical outpatient decision making (*excluding* diagnostic work-up, contact investigations, anti-TB medications, and DOT) is a provider that is not included in any of the other categories and is not “Unknown” (e.g., city/county/state owned hospitals that are not part of the health department providing outpatient care, private hospital providing outpatient care, Veterans Administration, federal program, military facility, or community-based organization (CBO)).

Unknown – Select “Unknown” if the type of health care provider is unknown. If “Unknown” is checked, no other choice for type of health care provider should be checked.

9. Directly Observed Therapy – This field indicates whether the TB patient received

Directly Observed Therapy (DOT) defined as supervised therapy in which a health care provider (e.g. nurse, outreach worker, etc.) has direct visual observation of a patient's ingestion of medication. This is the recognized standard of care for TB in the United States. Performing pill counts or dropping the filled prescription off to the patient without observing the patient ingest the medication is not acceptable and does **not** constitute DOT.

Number of DOT weeks – Please indicate the total number of calendar weeks (Sunday through Saturday) that the patient received the following minimum amounts of medication under supervision at either type of site. If the patient was both DOT and Self-administered, *only* count those weeks that were supervised, thus the number of weeks recorded here will be less than the total weeks of therapy given. For patients on a daily DOT regimen, count the week only if *five or more* of the week's doses were supervised. For patients on a twice-weekly DOT regimen, count the week only if *both* the week's doses were supervised. For patients on a thrice-weekly DOT regimen, count a week only if *all three* of the week's doses were supervised.

Number of self-administered weeks – Please indicate the total number of calendar weeks (Sunday through Saturday) that the patient did not receive DOT and took his or her medication without supervision.

Number of unknown weeks – Please indicate the total number of calendar weeks (Sunday through Saturday) that it is not known how the patient's TB medication was administered.

10. Was Follow-up Drug Susceptibility Testing Done – This variable will help assess the frequency of acquired drug resistance. Provide information on drug susceptibility testing performed on any TB isolate more than 30 days after the initial susceptibility testing.

No – Select “No” if no follow-up drug susceptibility testing was done.

Yes – Select “Yes” if the patient had Follow-up drug susceptibility testing performed after the initial testing

Unknown – Select “Unknown” if it is unknown whether the patient had Follow-up drug susceptibility testing performed after the initial testing.

If Yes, Enter Date Final Isolate Collected for Which Drug Susceptibility Was Done –

If Yes, enter specimen type – Please indicate the type of specimen on which the

follow-up drug susceptibility testing was performed.

Sputum – Select “Sputum” if follow-up drug susceptibility testing was performed on a sputum sample.

Other – Select “Other” if follow-up drug susceptibility testing was performed on a sample other than sputum.

If not Sputum, enter Anatomic Code – If the specimen for follow-up drug susceptibility was something other than sputum, please select the anatomic code from the drop down menu.

11. Isolate submitted for genotyping – **(State Use Only)**. This Field indicates whether a specimen was submitted for genotyping.

Genotype Accession Number for current episode – **(State Use Only)**. This field indicates the number that is used to identify a patient’s genotype result and is used as an identifier at MDCH and CDC.

12. Final Susceptibility Results – This table is used to record results for the final isolate for which drug susceptibility testing is performed. For each drug listed, please indicate the result of susceptibility testing by selecting “Resistant”, “Susceptible”, “Not Done”, or “Unknown” as appropriate. “Not Done” indicates that susceptibility testing was not done for that specific drug. If there is another drug for which susceptibility is performed that is not listed, please indicate which drug was tested in the comments field at the end of the MDSS TB form and select the result of the testing from the dropdown menu next to “Other” in the table.

IV. Contact Information – This section is used to collect information on the contacts of active TB patients that are identified in contact investigations.

1. Name of Contact – Please indicate the last and first name of the contact in this field.
2. Birthdate – Please indicate the date of birth for the contact in this field (mm/dd/yyyy).
3. Contact Level – Please indicate the level of interaction that each contact had with the patient by selecting from the dropdown menu. This should correspond to the concentric circle approach to contact investigation. The contact level choices are Close (1st Circle), Casual (2nd Circle), and Remote (3rd Circle).
4. Prior Positive PPD – This field indicates whether the contact had a prior positive tuberculin skin test. Please select the appropriate response (Yes, No, Unknown) from the dropdown menu.

5. Initial PPD Date – This field indicates the date the initial TST was placed (mm/dd/yyyy).
6. Initial PPD Result – This field indicates the result of the initial TST. Please indicate the measurement of induration in millimeters (mm).
7. Final PPD Date – This field indicates the date the final TST was placed (mm/dd/yyyy). This test is usually placed 8-10 weeks after the contact's initial exposure to TB.
8. Final PPD Result – This field indicates the result of the final TST. Please indicate the measurement of induration in millimeters (mm).
9. X-Ray Date – This field indicates the date of X-Ray for the contact to the TB patient. This X-Ray should be done if a contact has a positive PPD or other risk factors.
10. X-Ray Result – This field indicates the result of an X-Ray if it was taken. Please type the result of the X-Ray in the space provided.

V. Other Information:

1. Local 1 – This field should be used as needed for local health department notes.
2. Local 2 – This field should be used as needed for local health department notes.
3. Name of Person Interviewed – If a proxy is interviewed for the patient please indicate the name of the person interviewed. A proxy is someone who is close enough to the patient to provide reliable information regarding the patient's life and/or medical history (e.g., spouse, parent, son or daughter, close friend) if for some reason the patient cannot provide the needed information.

Relationship to Patient – If a proxy is interviewed, please indicate the proxy's relationship to the patient.

Date of interview – If a proxy is interviewed, please indicate the date the interview was performed.

4. Submitted by – Please indicate the name of the local health department or other clinic staff member submitting the MDSS TB form.
5. Date – Please indicate the date the MDSS TB form is submitted. This date should be the date that the investigation status is marked "Active".

6. Health Department – Please indicate the local health department that is submitting the MDSS TB form.
7. Phone Number – Please indicate the phone number for the person submitting the MDSS TB form.

Ext – Please indicate the extension number for the telephone number of the person submitting the MDSS TB form.
8. Comments or Additional Information – This section is for any comments or additional information that is pertinent about the TB patient or investigation. If a field elsewhere on the MDSS TB form asks for additional information to be written in the “comments section” this is the field where it should be written.

Appendix A

Tuberculosis Case Definition for Public Health Surveillance¹

Tuberculosis (Revised 9/96)

Clinical description

A chronic bacterial infection caused by *Mycobacterium tuberculosis*, characterized pathologically by the formation of granulomas. The most common site of infection is the lung, but other organs may be involved.

Clinical case definition

A case that meets all of the following criteria:

- A positive tuberculin skin test result; and
- Other signs and symptoms compatible with tuberculosis, such as an abnormal, unstable (i.e., worsening or improving) chest radiograph, or clinical evidence of current disease; and
- Treatment with two or more antituberculosis medications; and
- A completed diagnostic evaluation.

Laboratory criteria for diagnosis

- Isolation of *M. tuberculosis* from a clinical specimen,^{*} or
- Demonstration of *M. tuberculosis* from a clinical specimen by nucleic acid amplification test,[†] or
- Demonstration of acid-fast bacilli in a clinical specimen when a culture has not been or cannot be obtained

Case classification

Confirmed: a case that meets the clinical case definition or is laboratory confirmed

Comment

Only one case should be counted in a person within any consecutive 12-month period. However, a case in a patient who had previously had verified disease should be reported again if more than 12 months have elapsed since the patient was discharged from treatment. A case should also be reported again if the patient was lost to supervision for >12 months and disease can be verified again. Mycobacterial diseases other than those caused by *M. tuberculosis* complex should not be counted in tuberculosis morbidity statistics unless there is concurrent tuberculosis.

¹ CDC. *Case definitions for infectious conditions under public health surveillance*. *MMWR* 1997;46(No. RR-10):40-41.

^{*}Use of rapid identification techniques for *M. tuberculosis* (e.g., DNA probes and mycolic acid high-pressure liquid chromatography performed on a culture from a clinical specimen) are acceptable under this criterion.

[†]Nucleic acid amplification (NAA) tests must be accompanied by culture for mycobacteria species. However, for surveillance purposes, CDC will accept results obtained from NAA tests approved by the Food and Drug Administration (FDA) and used according to the approved product labeling on the package insert.