



**State of Hawaii TB Document L:
Notifiable Disease Report for Tuberculosis: Definitions and Instructions**
Hawaii State Department of Health, Tuberculosis Control Program

This document provides reporting requirements for suspected or confirmed tuberculosis (TB) as well as definitions and instructions for completing the Notifiable Disease Report (NDR) for Tuberculosis (TB).

NDR QUESTION LIST

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Reporting Requirements for Suspected or Confirmed Tuberculosis

Health care providers, laboratories, and infection control practitioners are required by section 325-71, Hawaii Revised Statutes to report any patient suspected of or confirmed with active TB disease to the Hawaii State Department of Health, TB Control Program. The reports must be submitted to the TB Control Program by facsimile or mail within 72 hours of a diagnosis of confirmed or suspected TB.

It is **mandatory** to report patients who have any of the following criteria:

- Any laboratory specimen with smear positive results for acid fast bacilli (AFB) with suspicion of active TB disease.
- Any laboratory specimen with a positive result from a rapid diagnostic test, such as nucleic acid amplification (NAA) test [e.g., Gen-Probe's Amplified MTD[®] (Mycobacterium Tuberculosis Direct)].
- Any laboratory specimen with a positive culture for *M. tuberculosis* complex.
- Any other clinical specimen or pathology or autopsy findings consistent with active TB disease. For example, this may include, but is not limited to, caseating granulomas in a biopsy of the lung, lymph node, or other anatomic area.
- Treatment with two or more anti-TB medications (e.g., isoniazid, rifampin, pyrazinamide, ethambutol) for suspected or confirmed active TB disease.
- Clinical suspicion of pulmonary or extrapulmonary TB such that the health care provider has initiated or intends to initiate airborne isolation, or treatment for TB.
- *FOR HAWAII DEPARTMENT OF HEALTH TB CLINICS ONLY:* TB classification of 3, 4 or 5.

For infection control purposes, practitioners are required to report whenever TB is suspected, even if bacteriologic evidence of disease is lacking, or is preliminary, or treatment has not yet been initiated. When a patient has an AFB-positive smear or has been started on clinical treatment for TB, reporting should not be delayed pending laboratory identification of *M. tuberculosis* with rapid diagnostic tests (e.g., NAA tests) or culture results.

Definitions and Instructions for Completing the NDR for TB

1. Name

Indicate the last name, first name, and middle initial for the TB patient. Also, indicate any aliases or maiden names.

2. Address

Indicate the street number, street names, city, state, and zip code of the TB patient's residence at the time of diagnosis. To the extent possible, the address should represent the home address (whether permanent or temporary) of the TB patient.

Follow these guidelines for special circumstances:

- a. Patients who are residents of correctional facilities (e.g., local, state, federal, military) – the address of the correctional facility should be entered in this field.
- b. Patients who are residents of long term care facilities – the address of the long-term care facility should be entered in this field.
- c. Homeless persons or others without any fixed residence – the address at which they are living at the time of diagnosis (e.g., the locality of the shelter in which the patient was living) should be entered in this field.

3. Homeless Within Past Year

- Check “**No**” if the patient was not homeless during the 12 months prior to the time when the TB diagnostic evaluation was performed.
- Check “**Yes**” if the patient was homeless at any time during the 12 months prior to the time when the TB diagnostic evaluation was performed.
- Check “**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.

A homeless person may be defined as:

1. An individual who lacks a fixed, regular, and adequate nighttime residence and who has a primary nighttime residence that is:
 - a. 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
 - b. A public or private place not designated for, or ordinarily used as, a regular sleeping accommodation for human beings; or
 - c. An institution that provides a temporary residence for individuals intended to be institutionalized
2. An individual who has no home (e.g., is not paying rent, does not own a home, and is not steadily living with relatives or friends).
3. An individual who lacks customary and regular access to a conventional dwelling or residence. Included as homeless are persons who live on streets or in non-residential buildings.

4. 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.

5. Being homeless does not refer to a person who is imprisoned or in a correctional facility.

4. Home Phone, Cellular, and Work

Indicate the home, cellular, and work phone numbers that can be used to contact the TB patient.

5. Next of Kin, Relationship, and Phone

Indicate the next of kin of the TB patient, the relationship to the TB patient, and the phone number that can be used to contact this person.

6. Date of Birth

Indicate the month, day, and year of birth for the TB patient. For example: 04/26/1968. A complete date of birth is required. Partial dates are acceptable **ONLY** for patients where date of birth is truly unknown. For example, certain societies or cultures throughout the world do not document the day, month, or sometimes, even the year of birth. In such cases, enter "99" for either the day and/or month, and enter the year of birth. If the month, day, and year of birth are all unknown, enter "99/99/9999" on the form.

7. Sex at Birth

Check the appropriate box for the biological sex of the TB patient at birth: "**Male**" or "**Female**".

8. U.S. Citizen

Check the appropriate box for the U.S. citizenship of the TB patient: "**No**", "**Yes**", or "**Unknown**". Persons born abroad to a U.S. citizen parent are considered U.S. citizens. NOTE: People born in the Commonwealth of the Northern Mariana Islands, Guam, Puerto Rico, and U.S. Virgin Islands are U.S. citizens. Those born in the Federated States of Micronesia, Republic of Marshall Islands, and Palau are not considered U.S. citizens.

9. Place of Birth

Enter the country in which the patient was born. If the patient was born in one of the 50 United States, include the specific state.

10. Foreign Born

"**Date Arrived in U.S.**" – For patients who were NOT born in one of the 50 United States, indicate the month, day, and year that the TB patient arrived in the U.S., for example: 04/26/1968. A complete date of arrival in the U.S. is required. Partial dates are acceptable **ONLY** for patients where date arrived in U.S. are truly unknown. In such cases, enter "99" for either the day and/or month, and enter the year of arrival. If the month, day, and year of arrival are not all known, enter "99/99/9999" on the form.

11. Primary Occupation Within the Past Year

Within the past 12 months from the diagnostic TB evaluation, select the primary occupation of the patient (*select one*). If more than one occupation is applicable to the patient, choose the occupation which the patient performed for the longest period of time within the past 12 months (i.e. the patient's

primary occupation). For example, if the patient was a health care worker and a student (e.g. taking night classes), then the patient's primary occupation would be classified as "**Health Care Worker**".

- Check "**Unemployed**" if the patient was not employed during the past 12 months prior to the diagnostic TB evaluation. This should not include persons who are not seeking employment such as infants, children, students, homemakers, retirees, and persons receiving permanent disability benefits or persons who were institutionalized. Such individuals should be included in the appropriate occupation option such as "Retired" or "Not Seeking Employment". "**Unemployed**" should be checked if the person was unemployed for the majority of the prior 12 month period; shorter time frames, such as 1 week of unemployment in the past 12 months should not be marked as "**Unemployed**".
- Check "**Retired**" if the patient was retired within the 12 months before the TB diagnostic evaluation was performed.
- Check "**Health Care Worker**" if the patient was a paid or unpaid person working in healthcare settings with potential for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, part-time staff, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, outreach workers, dietary, housekeeping, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).
- Check "**Migrant/Seasonal Worker**" if the patient was required to be absent from a permanent place of residence for the purpose of seeking employment or who may vary their employment for the purpose of remaining employed while maintaining a permanent place of residence [e.g., migratory agricultural worker, seasonal agricultural worker, migrant factory worker, migrant construction worker, migrant service industry worker, migrant sporting worker (e.g., horse racing, dog racing)].
- Check "**Unknown**" if the employment status during the 12 months prior to the diagnostic TB evaluation of the patient was unknown.
- Check "**Correctional Facility Employee**" if the patient works in a correctional facility. The facility may be a federal or state prison, local jail, juvenile correctional facility, Immigration and Customs Enforcement (ICE) Detention Center, or other correctional facility (see Question 35).
- Check "**Not Seeking Employment**" if the patient was not employed for reasons other than unemployment within the 12 months before the TB diagnostic evaluation, such as infants, children, students, homemakers (e.g., housewife, househusband), persons receiving permanent disability benefits, or persons who were institutionalized.
- Check "**Other**" if the patient was a person who has been regularly employed for pay or income at any occupation that is not included in the above choices within the 12 months before the TB diagnostic evaluation and specify the primary occupation within the past year.

12. Race/Ethnicity

The answer to this question should be based on the individual's self-identity or self-reporting (if possible). Indicate the race/ethnicity that the patient considers themselves to be and check all that apply.

Check "**Other**" if the race/ethnicity of the TB patient is not included in the above choices and specify the race/ethnicity.

Note: If the patient is Micronesian (i.e., from the Federated States of Micronesia), check one of the following if known: Chuukese, Kosraean, Pohnpeian, or Yapese. If this information is not known, check "**Micronesian**".

13. Reason Evaluated for TB

Indicate the single primary or initial reason why the TB patient was evaluated for TB disease (*select one choice only*). The definition of "single primary or initial" for the purpose of this question is the situation or reason that led to the initial suspicion that the patient may have TB disease. If a TB patient was referred, but the reason is unknown, an attempt should be made to identify that initial reason.

- Check "**TB Contact Investigation**" if the patient was diagnosed with TB disease as a result of a contact investigation or source case finding.
- Check "**Immigration Medical Exam**" if the patient underwent a medical examination as part of the immigration application process and was found to have TB disease. A medical examination is mandatory for specific persons seeking admission to the U.S. (e.g., immigrants, refugees, asylees). These medical examinations may occur overseas or in the U.S. depending on the situation. This includes patients found to have TB disease as a result of being evaluated for a Class A or B (i.e., Class A, Class B1, Class B2, or Class B3) TB condition. In addition, some persons applying for non-immigrant visas or special status (e.g., parolees) for temporary admission to the U.S. may be required to have a medical examination.
- Check "**TB Symptoms**" if the patient was evaluated for TB disease due to signs and symptoms consistent with TB (e.g., prolonged or persistent cough, fever, lymphadenopathy, night sweats, weight loss). For example, if a TB patient seeks medical care due to TB symptoms, then "**TB Symptoms**" should be the primary reason the TB patient was evaluated for TB disease. If however, a TB patient was initially encountered via a contact investigation, and during the contact investigation the TB patient was also noted to have TB symptoms, "**TB Contact Investigation**" should be chosen as the primary reason the TB patient was evaluated for TB disease.
- Check "**Health Care Worker Screening**" if the patient was evaluated for TB disease due to a positive tuberculin skin test 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 for exposure to *M. tuberculosis*. These may include but are not limited to physicians, nurses, aides, dental workers, technicians, staff in laboratories and morgues, emergency medical personnel, students, part-time staff, temporary and contract staff, and persons not involved directly in patient care but potentially at risk for occupational exposure (e.g., volunteers, outreach workers, dietary, housekeeping, maintenance, clerical, and janitorial staff). Also included are persons who deliver health care in the community (e.g., public health nurse, visiting nurse, outreach worker).

- Check “**Lab Result (Incidental Finding)**” if an incidental specimen is positive for acid fast bacilli (AFB) or an incidental culture is positive for *M. 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, autopsy, organ donation, hospitalization, or evaluation for other disease).
- Check “**Abnormal Chest Radiograph (Incidental Finding)**” if the patient had an incidental chest radiograph consistent with TB disease. The reason for taking the chest radiograph should be independent of the other choices listed in the question and should not have been done to rule out TB disease. For example, if a chest radiograph was taken as part of preoperative testing, where there was no suspicion of TB disease, then select “**Abnormal Chest Radiograph (Incidental Finding)**”.
- Check “**DOH Mandated TB Screening**” if the patient was diagnosed with TB disease due to a positive tuberculin skin test administered because the patient was fulfilling the requirements of the mandated TB screening per the Hawaii Administrative Rules (HAR) for TB.

Enter one of the following categories of “**DOH Mandated TB Screening**” that led to the TB diagnosis:

- Primary and Secondary Schools: Personnel
- Primary and Secondary Schools: Student
- Post-Secondary Schools: Personnel
- Post-Secondary Schools: Student
- Child Care Facilities: Personnel
- Child Care Facilities: Children
- Persons living or working in health care facilities or residential care settings licensed or otherwise regulated by the department
- Foodhandler

Note: The following mandated screening categories are listed as separate options: Health Care Worker, Contact/Source Investigation, and Immigrant.

- Check “**Other**” if the reason why the TB patient was evaluated for TB disease is not included in the above choices and specify the reason the patient was evaluated for TB.

14. Date of Diagnosis

Indicate the month, day, and year of the diagnosis of TB.

- Check “**Suspect**” if laboratory or clinical confirmation of TB is not available.
- Check “**Confirmed**” if there is laboratory or clinical confirmation of TB.

15. Status at TB Diagnosis

- Check “**Alive**” if the patient was alive at the time of TB diagnosis. Patients whose TB was suspected and who were started on at least two anti-tuberculosis 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.

- Check **“Dead”** if the patient was deceased at the time the evaluation for possible TB disease was initiated. This applies to patients who were only on one anti-tuberculosis drug prior to the day of death because TB disease was not suspected, and who were then diagnosed with TB disease after death. For example, if a person was taking isoniazid as preventive therapy for latent TB infection dies, and was found after death to have had TB disease, this person should be classified as **“Dead”** at TB diagnosis.

If **“Dead”** (e.g., those patients that were classified as “dead” at the time of TB diagnosis), enter the date (month, day, year) that the patient died. For example: 01/17/2005. If the day is unknown, enter ‘99’ on the form (e.g., 01/99/2005).

16. Previous TB Disease

- Check **“No”** if the patient has not had a previous diagnosis of TB disease.
- Check **“Yes”** if the patient has had a previous diagnosis of TB disease. A previous diagnosis of suspected TB or 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/she had verified TB disease in the past, had completed therapy, or was lost to supervision for more than 12 consecutive months, and now has verified TB disease again. Often, TB disease is confused with latent TB infection (LTBI) and LTBI should not be considered 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), then 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”**, provide the year in which the patient's previous episode of TB disease was diagnosed. For example, if the patient was diagnosed with TB disease in 1985, was reported to have completed therapy, or was lost to supervision in 1986, and is found to have verified disease again in 2005, enter "1985" in the boxes provided. If the patient had more than one previous episode of TB disease, enter the year of the most recent previous episode.

17. Site(s) of TB Disease

NOTE: If there is evidence that more than one organ or disease site involved, then check all appropriate sites of disease in Question 18 **“Site of Disease”**. If the initial chest radiograph is reported “miliary TB” or as showing a “miliary” or “bilateral micronodular” pattern, indicate this finding on Question 22, **“Date of 1st Chest Radiograph”** and/or Question 24, **“Date of 1st Chest CT Scan or Other Chest Imaging”**.

- Check the boxes corresponding to the site(s) of TB disease (select all that apply). **“Lymphatic: Intrathoracic”** includes hilar, bronchial, mediastinal, peritracheal, and other lymph nodes within the thorax.
- If the site of TB disease is **“Other”**, specify the other organ or disease site.

18. Bacteriology

- Date Collected: Indicate the month, day, and year the specimen was collected.
- Specimen Type & Site:
 1. Enter the type of specimen used to make TB diagnosis. Examples of specimens include: sputum, tracheal aspirate, bronchial washing or lavage, urine, bone marrow, lymph node, cerebral spinal fluid, lung, or pleura which are collected from various procedures (e.g., bronchoscopy, biopsy, gastric aspiration, pleural fluid aspiration).
 2. Enter the site if the specimen type is tissue or body fluid. This field does not need to be completed if the specimen type is sputum.
- Smear Result:
 - Check “**NEG**” if the smear result was negative for AFB.
 - Check “**POS**” if the smear result was positive for AFB and indicate the smear count (e.g., 1+, 2+, 3+, or 4+).
 - Check “**PENDING**” if the smear result has not been finalized.
- Nucleic Acid Amplification (NAA):
 - Check “**NEG**” if the NAA test does not detect *M. tuberculosis*.
 - Check “**POS**” if the NAA test detects *M. tuberculosis*.
 - Check “**PEND**” if the NAA test has not been finalized.
 - Check “**INDET**” if the NAA test results were indeterminate and could not be determined to be positive or negative.
- Culture:
 - Check “**PEND**” if the culture result has not been finalized.
 - Check “**NEG**” if the culture result was negative for *M. tuberculosis* complex.
 - Check “**MTB COMPLEX**” if the culture result was positive for *M. tuberculosis* complex.
 - Check “**NOT TB**” if the culture growth was not *M. tuberculosis*. Specify the identification of the organism that grew, if available.
- Drug Susceptibility Results:
 - Check “**PEND**” if drug susceptibility testing results have not been finalized.
 - Check “**PAN SUSCEPTIBLE**” only if the isolate is completely susceptible to all of the first-line anti-tuberculosis medications tested.
 - Check “**RESISTANT TO**” if there was any degree of resistance, even partial resistance or resistance at a low concentration of the drug or other than completely susceptible result. Enter the drugs that the isolate is resistant to.

19. Tuberculin Skin Test (TST) at Diagnosis

NOTE: If skin testing was not performed during the current diagnostic evaluation because the patient has a history of a past **positive** tuberculin skin test, **AND** the previous positive test is documented in the medical record, the previous positive test result may be reported in this field. Patient self-report of a previous positive TST is not acceptable. A history of a previous **negative** tuberculin skin test, whether documented or not, and a patient self-report of a negative previous or current skin test are also not acceptable.

- Check “**Not Done**” if the TST was not performed or if a patient states he/she had a positive TST in the past and it cannot be documented, and now the patient refuses to have a new TST placed.
- Check “**Positive**” if the TST met criteria for a positive tuberculin skin test as defined by current guidelines.
- Check “**Negative**” if the TST did not meet current criteria for a positive test and was negative as defined by current guidelines.
- **IMPORTANT:**
For “**Positive**” or “**Negative**” tuberculin skin tests (TST), indicate:
 1. The “**Date TST Placed**”. The complete date (month, day, year) should be entered. However, if the “day” or “month” portion of the date is unknown, “99” may be entered in the “day” or “month” field.
 2. The “**Induration in Millimeters (mm)**”. If the available skin test result indicates only that the result was "positive" or "negative," but does not give the millimeters of induration, indicate whether the test is recorded as “positive” or “negative” and code the millimeters of induration as "99.”

20. Interferon Gamma Release Assay (IGRA)

Interferon gamma release assays (IGRA) are blood tests for detecting *Mycobacterium tuberculosis* infection. For this variable, indicate the result of an IGRA test performed during the diagnostic TB disease evaluation.

- Check “**Not done**” if an interferon gamma release assay for *M. tuberculosis* was not performed.
- Check “**Negative**” if all IGRA test results were interpreted as *M. tuberculosis* infection is unlikely.
- Check “**Positive**” if any IGRA test result was interpreted as *M. tuberculosis* infection is likely.
- Check “**Indeterminate**” if the IGRA test results could not be determined to be positive or negative.
- Write in “**Borderline**” if result was interpreted as borderline.
- If any interferon gamma release assay for *M. tuberculosis* was conducted, indicate:
 1. The date the blood sample was collected (“**Date Collected**”). The complete date (month, day, year) should be entered. However, if the “day” portion of the date is unknown, “99” may be entered in the “day” field. 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.
 2. Specify the type of blood test performed (“**Type of IGRA (specify):** _____”). If more than one test was conducted, list the test type corresponding to the blood sample result entered.

21. Date of 1st Chest Radiograph

Indicate the date that the 1st chest radiograph was taken during the diagnostic evaluation for tuberculosis and whether the chest radiograph was “**Abnormal**”, “**Normal**”, or “**Not Done**”.

- Check “**Abnormal**” if the 1st chest radiograph showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB and:
 1. Indicate if the 1st chest radiograph obtained showed evidence of one or more cavities by checking “**No**”, “**Yes**”, or “**Unknown**”.
 2. Indicate if the 1st chest radiograph obtained showed evidence of “miliary” disease (e.g., “miliary” TB or “miliary or “bilateral micronodular” pattern) by checking “**No**”, “**Yes**”, or “**Unknown**”.
- Check “**Normal**” if the 1st chest radiograph showed no abnormalities consistent with TB and was normal.
- Check “**Not done**” if the 1st chest radiograph is known not to have been done.

22. Date of 2nd Chest Radiograph

Indicate the date that the 2nd chest radiograph was taken during the diagnostic evaluation for tuberculosis and whether the chest radiograph was “**Stable**”, “**Worsening**”, or “**Improving**”.

- Check “**Stable**” if the 2nd chest radiograph showed no change in any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB.
- Check “**Worsening**” if the 2nd chest radiograph showed worsening abnormalities consistent with TB.
- Check “**Improving**” if the 2nd chest radiograph shows improvement of abnormalities consistent with TB.

23. Date of 1st Chest CT Scan or Other Chest Imaging

Indicate the date that the 1st chest CT scan or other chest imaging study was taken during the diagnostic evaluation for tuberculosis and whether the chest CT scan or other chest imaging was “**Abnormal**”, “**Normal**”, or “**Not Done**”.

- Check “**Abnormal**” if the 1st chest CT scan or other chest imaging study showed any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB and:
 1. Indicate if the 1st chest CT scan or other chest imaging study obtained showed evidence of one or more cavities by checking “**No**”, “**Yes**”, or “**Unknown**”.
 2. Indicate if the 1st chest CT scan or other chest imaging study obtained showed evidence of “miliary” disease (e.g., “miliary” TB or “miliary or “bilateral micronodular” pattern) by checking “**No**”, “**Yes**”, or “**Unknown**”.
- Check “**Normal**” if the 1st chest CT scan or other chest imaging study showed no abnormalities consistent with TB and was normal.
- Check “**Not Done**” if the 1st chest CT scan or other chest imaging study is known not to have been done.

24. Date of 2nd Chest CT Scan or Other Chest Imaging

Indicate the date that the 2nd chest CT scan or other chest imaging study was taken during the diagnostic evaluation for tuberculosis and whether the chest CT scan or other chest imaging was “**Stable**”, “**Worsening**”, or “**Improving**”.

- Check “**Stable**” if the 2nd chest CT scan or other chest imaging study showed no change in any abnormalities (e.g., hilar adenopathy, infiltrate(s), cavity, scarring) associated with TB.
- Check “**Worsening**” if the 2nd chest CT scan or other chest imaging study showed worsening abnormalities consistent with TB.
- Check “**Improving**” if the 2nd chest CT scan or other chest imaging study shows improvement of abnormalities consistent with TB.

25. Date Therapy Started

Enter the date (month, day, year) the patient began multidrug therapy for TB disease or suspected TB disease.

This may be one of several dates:

- a. Date patient first ingested medication, if documented from a medical record, such as hospital or clinic or directly observed therapy (DOT) record; or
- b. Date medication was first dispensed to the patient, as documented by medical or pharmacy record; or
- c. Date medication was first prescribed to the patient by health care provider, as documented by medical record or by prescription given to patient.

Date of ingestion is the preferred date for this field. If date of ingestion is not known, enter date of dispensation. If neither of those dates is known, enter date of prescription. Patient history without medical documentation is not acceptable.

If an exact date cannot be determined based on the above guidelines, a partial date may be entered in this field. If the month and year are known, but the exact day therapy was started is not known, "99" may be entered for the 2-digit "day" of the date. For example, if after following the above guidelines, an exact Date Therapy Started cannot be determined for a patient known to have started therapy in August of 2007, enter "08/99/2007" on the form. If the month, day, and year therapy started are all unknown, enter "99/99/9999" on the form.

Check “**Therapy Not Started**” if the patient did not begin multidrug therapy for TB disease.

26. Patient on Directly Observed Therapy

Directly observed therapy (DOT) or supervised therapy involves the direct visual observation by a health care provider (e.g., public health nurse, outreach worker, nurse, nurse’s aide) or other reliable person (e.g., designated family member or homeless shelter worker) of a patient's ingestion of medication. Delivering medication to a patient without visual confirmation of ingestion does not constitute DOT. Confirmation that the medication has been swallowed may sometimes be necessary. Using such techniques as having the patient swallow a glass of water or talk following ingestion, inspecting the oral cavity with the tongue raised by the patient, or using a tongue blade to inspect between the cheek and the gums are helpful in determining if the medication has been swallowed.

DOT regimens may be administered daily, three times a week, twice weekly, or weekly. DOT is not limited by the location in which it is given. DOT can be administered in the health department, correctional facility, long-term care facility, in the patient's home, or in the field, as long as the person administering the DOT is qualified.

- Check “**No**” if no doses of medication were given under direct supervision and visual observation of ingestion by a health care provider or other reliable person.
- Check “**Yes**” if the medications were given under direct supervision and visual observation of ingestion by a health care provider or other reliable person.
- Check “**Unknown**” if it is not known whether any doses of medication were given under supervision.

27. Patient's Weight at Diagnosis

Indicate the weight of the patient at diagnosis in kilograms.

28. Initial Drug Regimen and Frequency

Indicate the dosage in milligrams for each drug and the frequency that was prescribed for treatment of active TB disease. For combination drugs (e.g., Rifamate, Rifater), indicate the dosage in milligrams for each individual drug.

29. HIV Status at Time of Diagnosis

CDC recommends that **ALL** TB cases receive HIV counseling, testing, and referral at the time of TB diagnostic evaluation or TB diagnosis.

- HIV status is “**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 less than 12 months before the TB diagnostic evaluation or TB diagnosis 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.
- HIV status is “**Positive**” if one of the following is applicable:
 1. The patient is tested for HIV and the laboratory result is interpreted as positive; or
 2. The patient has a documented medical history of a previous positive HIV test, or a documented previous diagnosis of HIV infection or AIDS.
- HIV status is “**Refused**” if the patient was offered the test at the time of the TB diagnostic evaluation or TB diagnosis, but declined to be tested.

- HIV status is “**Indeterminate**” if the patient has had a documented indeterminate HIV test result at the time of TB diagnostic evaluation or TB diagnosis. Undocumented patient history is not acceptable.
- HIV status is “**Not Offered**” if the patient was not offered the test at the time of the TB diagnostic evaluation or TB diagnosis.
- HIV status is “**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.
- HIV status is “**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) but it is unknown whether the HIV counseling and testing was done.

30. HIV Antibody Test Date

Indicate the month, day, and year that the HIV antibody test was performed.

31. Excess Alcohol Use Within Past Year

- Check “**No**” if the patient has not used alcohol to excess within the past 12 months.
- Check “**Yes**” if the patient has used alcohol to excess within the past 12 months.
- Check “**Unknown**” if it is not known if the patient used alcohol to excess within the past 12 months.

This information is intended to assess the ability of the patient to adhere to anti-tuberculosis drug therapy and to screen for hepatitis risks. Excessive use of 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 of the patient at multiple visits. If, during the course of TB treatment, information is obtained concerning this variable, please inform the Hawaii TB Control Program.

There is no standard definition for excess alcohol use. Excess alcohol use can be assessed using different methods. Reliable indicators of excess alcohol use include participation in Alcoholics Anonymous or alcohol treatment programs (e.g., outpatient, residential or inpatient, halfway house, prison or jail treatment, or other self-help). There are also numerous screening instruments that can be helpful in identifying persons who may use alcohol to excess (e.g., CAGE, AUDIT, MAST). Other indicators include hospitalizations for alcohol-related medical conditions [e.g., delirium tremors (DT's), pancreatitis, cirrhosis].

The National Household Survey on Drug Abuse assesses alcohol use by asking quantity and frequency of use within the past month. It does not assess if a person has or had a longer history of alcohol use. “Binge alcohol use was defined as drinking five or more drinks on the same occasion (at the same time or within a couple of hours of each other) on at least 1 day in the past 30 days. A drink was defined as a can or bottle of beer, a glass of wine or a wine cooler, a shot of liquor, or a mixed drink containing alcohol. Heavy alcohol use was defined as drinking five or more drinks on the same occasion on each of 5 or more days in the past 30 days.”

32. Injecting Drug Use Within Past Year

- Check “**No**” if the patient has not injected drugs within the past 12 months.
- Check “**Yes**” if it is known that the patient injected drugs within the past 12 months.
- Check “**Unknown**” if it is not known if the patient injected drugs within the past 12 months.

The purpose for collecting this information is to assess the patient's ability to adhere to anti-tuberculosis drug therapy and to screen for hepatitis risks. The intent of this question is not to require a detailed systematic interview of each patient, but to identify those patients whose drug use might interfere with their ability to complete anti-tuberculosis drug therapy. Use of medically unsupervised injecting drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last inject drugs). If, during the course of TB treatment, information is obtained concerning this variable, please inform the Hawaii TB Control Program.

Medical documentation or other indices of a history of enrollment in a drug treatment program (e.g., methadone detoxification, methadone maintenance, outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, narcotics anonymous, cocaine anonymous, or other self-help), medical or laboratory documentation of injecting drug use (e.g., urine testing, if done), 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 of the patient at multiple visits.

Injecting 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 (e.g., skin popping), or intramuscular. Drugs injected may include heroin or other opiates (e.g., Demerol, Dilaudid, Morphine, opium), cocaine, heroin and cocaine (e.g., speedball), methamphetamines, amphetamines or other stimulants (e.g., Ritalin), phencyclidine (e.g., PCP, Angel Dust), lysergic acid diethylamide (e.g., LSD) or other hallucinogens, barbiturates, steroids or other hormones, Fentanyl, MDMA (e.g., Ecstasy), other drugs or unknown drugs.

33. Non-Injecting Drug Use Within Past Year

- Check “**No**” if the patient did not use non-injecting drugs within the past 12 months.
- Check “**Yes**” if it is known that the patient used non-injecting drugs within the past 12 months.
- Check “**Unknown**” if it is not known whether the patient used non-injecting drugs within the past 12 months.

The purpose for collecting this information is to assess the patient's ability to adhere to anti-tuberculosis drug therapy. The intent of this question is not to require a detailed systematic interview of each patient but to identify those patients whose drug use might interfere with their ability to complete anti-tuberculosis drug therapy. Use of non-injecting drugs or illicit drugs within the past year should be sought as an indicator of recent activity (e.g., when did the patient last use non-injecting drugs). If, during the course of TB treatment, information is obtained concerning this variable, please inform the Hawaii TB Control Program.

A history of enrollment in a drug treatment program (e.g., outpatient drug free, residential or inpatient, halfway house, prison or jail treatment, cocaine anonymous, or other self-help), as well as medical or laboratory documentation of 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 of the patient at multiple visits.

NOTE: Alcohol is *not* included as a drug in this question (see “Excess Alcohol Use within Past Year” - Question 32).

Non-injecting drug use involves the use of licensed or prescription drugs or illegal drugs that were not injected and were not prescribed for the patient by a health care provider. The drugs may be ingested, inhaled, sniffed, or smoked. Non-injected drugs may include: heroin or other opiates (e.g., Demerol, Percocet, Codeine, Dilaudid, MS Contin, non-prescription methadone), cocaine (e.g., snorting), crack (e.g., smoking cocaine), ingested amphetamines (e.g., speed, uppers, bennies), Xanax, Ativan, Valium or other benzodiazepams, phencyclidine (e.g., PCP), ketamine, LSD, or other hallucinogens, barbiturates, marijuana (e.g., pot, weed, grass, reefers), hashish, THC, inhalants (e.g., nitrous oxide [whippets], poppers, rush, huff, gasoline, spray paint, butane), steroids, other drugs, or unknown drugs.

34. Resident of Correctional Facility at Time of Diagnosis

NOTE: Any questions regarding classification of a specific correctional facility as federal, state, local, juvenile, or other should be referred to the Department of Corrections within the state.

- Check “**No**” if the patient was not an inmate when the TB diagnostic evaluation was performed.
- Check “**Yes**” if the patient was an inmate of a correctional facility at the time when the TB diagnostic evaluation was performed. If “**Yes**”, indicate the type of facility (*select one*). If the TB patient was a resident 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**” is a confinement facility administered by a federal agency. For the purpose of this question, privately operated federal correctional facilities are included in “federal prison.”
 - A “**State Prison**” is a confinement facility administered by a state agency. For the purpose of this question, privately operated state correctional facilities are included in “state prison.”
 - A “**Local Jail**” is 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.”

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- A “**Juvenile Correctional Facility**” is 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.
 - “**Unknown**” if the patient was an inmate when the TB diagnostic evaluation was performed, but the type of correctional facility is not known.
 - “**Other Correctional Facility**” includes ICE Detention Centers, 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 type.
- Check “**Unknown**” if it is not known if the patient was an inmate when the TB diagnostic evaluation was performed.

35. Resident of Long-Term Care Facility at Time of Diagnosis

NOTE: The state licensing agency for long-term care facilities can assist in determining under which of these categories a facility is classified.

- Check “**No**” if the patient was not a resident of a long-term care facility when the TB diagnostic evaluation was performed.
- Check “**Yes**” if the patient was a resident of a long-term care facility at the time the TB diagnostic evaluation was performed. If “**Yes**”, indicate the type of facility (*select one*). If the TB patient was a resident of more than one facility when the diagnostic evaluation was performed, select the facility where the majority of the TB diagnostic evaluation was performed.
 - A “**Nursing Home**” is defined as a freestanding facility having 3 or more beds that provides nursing care services (e.g., nursing or medical care and/or supervision over medications that may be self-administered). Facilities may be certified by Medicare or Medicaid, or not certified but licensed by the State as a nursing home (e.g., skilled nursing facility, intermediate care facility, nursing care unit of a retirement center).
 - A “**Hospital-based Facility**” is defined as a nursing home 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.
 - An “**Alcohol or Drug Treatment Facility**” includes only long-term rehabilitation/residential facilities designated for treatment of 30 days or longer. *Excluded* are all ambulatory or outpatient facilities, detoxification units, and facilities designated for less than 30 days of treatment. The state alcohol and drug treatment agency can assist in

determining if a facility is considered residential. The National Survey of Substance Abuse Treatment Services (N-SSATS) and the Substance Abuse and Mental Health Services Administration (SAMHSA) are useful references.

- A “**Mental Health Residential Facility**” is defined as a mental health residential facility 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, Department of Veterans Affairs (VA) medical centers, residential treatment centers (RTC’s) for emotionally disturbed children, and multi-service mental health organizations with residential treatment programs. *Excluded* are other federal psychiatric facilities, such as those of the Department of Defense, Bureau of Prisons, Public Health Service, and Indian Health Service. *Also excluded* are Indian reservation facilities that are not federal.
 - A “**Residential Facility**” having 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).
 - “**Other Long-term Care Facility**” includes facilities not mentioned above that are designated for treatment of 30 days or longer and is not “Unknown.” Please specify type.
 - “**Unknown**” if the patient was a resident of a long-term care facility, but the type of facility is unknown.
- Check “**Unknown**” if it is not known if the patient was a resident of a long-term care facility when the TB diagnostic evaluation was performed.

36. Additional TB Risk Factors

Indicate any 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. Please note that other specific TB risk factors (e.g., occupation, HIV) are collected elsewhere.

- Check “**Diabetes Mellitus**” if the TB patient has diabetes mellitus (Type I or Type II) at the time of TB diagnosis.
- Check “**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.

- Check “**Incomplete LTBI Treatment**” if 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.
- Check “**None**” if no TB risk factors could be identified.
- Check “**Contact of Infectious TB Patient**” if the TB patient was a contact of an 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 TB patient.
- Check “**Contact of MDR TB Patient**” if the TB patient was a contact of a multidrug resistant (MDR) TB patient, regardless of whether the MDR-TB case was infectious or not. Multi-drug resistant TB is defined as resistance to at least isoniazid and rifampin. 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.
- Check “**Missed Contact**”, if after having been diagnosed with TB disease, this TB patient 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, because 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 a preventable case of TB.
- Check “**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]. Additional space (“*Specify _____*”) is provided to write comments regarding “Other” reasons.
- Check “**Post-Organ transplantation**” if the TB patient has a history of solid organ transplantation (e.g., renal, cardiac).
- Check “**Immunosuppression**” 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, do not check “immunosuppression” unless the patient has another immunosuppressive condition. Check either “Diabetes Mellitus” and/or “End-Stage Renal Disease” for this question.

If the patient is infected with HIV, do not check “immunosuppression” for this question, unless the patient has another immunosuppressive condition. Instead, complete:

- “HIV Status at Time of Diagnosis” – Question 30
- “HIV Antibody Test Date” – Question 31

- Check “**Tumor Necrosis Factor-Alpha (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. Examples of three currently FDA approved TNF- α antagonists are infliximab (Remicade[®]), etanercept (Enbrel[®]), and adalimumab (Humira[®]).

37. Reporting Section

- “**Date Reported**” – Indicate the month, day, and year that the NDR form was submitted to the Hawaii TB Control Program.

- “**Reported By**” – Indicate the name of the person who is reporting the TB patient.

- “**Name of Institution**” – Indicate the name of the institution that the person reporting the TB patient represents.

- “**Address**” – Indicate the street number, street name, city, state, and zip code of the institution reporting the TB patient.

- “**Work Phone, Cell Phone, Pager, Fax, and Email Address**” – Indicate the preferred methods of corresponding with the person who reported the TB patient.

38. Hospital Admission Date

Indicate the month, day, and year that the TB patient was admitted into the hospital, if applicable.

39. Hospital Discharge Date

Indicate the month, day, and year that the TB patient was discharged from the hospital, if applicable.

40. Name and Phone Number of Primary Care Physician

Indicate the name of the Primary Care Physician of the TB patient and the preferred phone number of that physician.

41. Will the Patient Be Referred to the Hawaii Department of Health for TB Care? (This question is only applicable to non-DOH providers)

- Check “**Yes – For TB treatment and DOT**” if discharge plans indicate that the TB patient will receive complete follow-up care for TB treatment and DOT at a Hawaii DOH TB Clinic. Please call DOH to initiate referral.

- Check “**Yes – For DOT only**” if discharge plans indicate that the TB patient will receive TB care from a private physician but will have DOT through the Hawaii Department of Health. Please call DOH to initiate referral.

- Check “No” if discharge plans indicate that the TB patient will receive all TB care from a private physician. Indicate the name of physician who will treat the patient for TB and the preferred phone number of that physician.

42. Additional Notes/Remarks - Space for additional notes or remarks.

43. DOH USE ONLY

- CC#/MR# – Indicate the DOH TB Clinic number or DOH medical record of the TB patient.
- TB Class – Indicate the TB classification of the TB patient.
- TBCMD – Indicate the name of the TB Clinic Medical Doctor who is treating the TB patient.
- Nurse Case Manager – Indicate the name of the Nurse Case Manager for the TB patient.