

**New Jersey Administrative Code**  
**Department of Health and Senior Services**  
**Title 8, Chapter 57, Communicable Disease**

**SUBCHAPTER 5: MANAGEMENT OF TUBERCULOSIS**

**8:57-5.1: Purpose and Scope**

The principle purpose of this subchapter is to protect the public from the spread of tuberculosis (TB) disease by maximizing the use of currently available and highly effective treatments and interventions.

This subchapter applies specifically to persons who:

1. Have suspected or confirmed TB disease, as diagnosed by a health care provider, especially those with infectious or potentially infectious TB disease,
2. Those identified by public health professionals as contacts to persons with suspected or confirmed infectious or potentially infectious TB disease **AND**
3. Class B1 or B2 referrals from the Centers for Disease Control and Prevention's Division of Global Migration and Quarantine (CDC-DGMQ) reported to reside in New Jersey.

The persons primarily responsible for implementing this subchapter are:

- Health officers,
- Public health nurse case managers,
- Health care providers,
- Hospital administrators **AND**
- Correctional facility administrators.

Health officers in areas where a person with suspected or confirmed infectious or potentially infectious TB disease resides, frequents, or receives care, **may** take any action authorized under this subchapter when necessary to protect the health of the person with disease and/or the public.

### **8:57-5.2: Incorporated Documents**

To further the purposes of this subchapter, the Department incorporates as amended and supplemented, the *Morbidity and Mortality Weekly Report (MMWR)*, *Treatment of Tuberculosis*, published by the Centers for Disease Control and Prevention on June 20, 2003, Volume 52, Number RR-11. This document is available by written request to the TB Program at:

**New Jersey Department of Health and Senior Services  
TB Program  
PO Box 369  
Trenton, NJ 08625-0369**

**OR** online at the Centers for Disease Control and Prevention's web page at:  
**<http://www.cdc.gov/mmwr/PDF/rr/rr5211.pdf>**

The following forms are also referenced in this subchapter:

1. **TB-70:** Tuberculosis Case, Suspect, and Status Report (Appendix A). This form is used for reporting suspected and/or confirmed TB disease and to update the status of these patients over time.
2. **TB-41:** Record of Contact Interview (Appendix B). This form is used to report the identification, findings of the medical evaluation and final disposition of contacts exposed to persons with suspected or confirmed infectious or potentially infectious TB disease.

Each of the forms listed above are available by written request to the TB Program at the address above.

The TB-41 form is also available online at the Department's "forms" web page at  
**<http://web.doh.state.nj.us/forms/>**

### **8:57-5.3: Definitions**

This subchapter will use the following words and terms, listed below in bold type and alphabetical order, with the following meanings, unless the context clearly indicates otherwise:

**Acid-fast bacilli (AFB):** Organisms that remain stained after being washed in acid solution, may be detected using a microscope, then are reported as a positive AFB on smear.

TB disease is a possibility when AFB is present on a stained smear. AFB on smear also indicates the likelihood of infectiousness if from a pulmonary source such as, but not limited to:

- Sputum,
- Bronchioalveolar lavage,
- Gastric aspirate,
- Lung tissue, **AND**
- Other tissue of the respiratory tract such as the larynx or epiglottis.

**Administrator:** Any person having control or supervision over a hospital or correctional facility.

**Class B1 and B2 referrals:** Refugees, parolees, asylees or recent legal immigrants to the United States whom were screened overseas, classified as having a significant TB condition and referred to the Department by the CDC's Division of Global Migration and Quarantine. Classifications are valid up to 12 months prior to immigration and require evaluation of their current TB status within 30 days of arrival to prevent potential transmission. The classifications of significance are:

- **B1:** TB, clinically active, not currently infectious
- **B2:** TB, not clinically active

**Contact:** Refers to a person, identified by the health department, who has had an exposure to a patient with suspected or confirmed infectious or potentially infectious TB disease. This exposure is sufficient in both duration and proximity to make him or her at increased risk for recent acquisition of LTBI.

**Directly Observed Therapy (DOT):** The direct observation of the ingestion of prescribed medications by a person trained in the performance of these duties. DOT is the only method available to fully ensure a patient's adherence to the prescribed treatment.

**Extensively Drug Resistant Tuberculosis (XDR-TB):** A form of TB that is resistant to at least isoniazid, rifampin, any fluoroquinolone, and either amikacin, kanamycin or capreomycin.

**Field Services:** The provision of DOT, as ordered by a health care provider. Field services may also include other services in which the provider is trained and equipped to perform, such as interviews, transportation and delinquent investigations.

**Health Care Provider:** A person who is directly involved in the clinical diagnosis of and the prescribing of medication for individuals with suspected or confirmed TB disease or LTBI. Health care providers include physicians, advanced practice nurses, certified nurse midwives and physician assistants.

**Health Officer Order:** An order issued by a health officer to a person with suspected or confirmed infectious or potentially infectious TB disease, a contact to a person with suspected or confirmed infectious or potentially infectious TB disease or a Class B1 or B2 referral under specific circumstances as described in N.J.A.C. 8:57-5.10 through 5.12.

**Hospital:** The meaning set forth in the Department's Hospital Licensing Standards for general hospital and special hospital at N.J.A.C. 8:43G-1.3(b), which treat patients with TB disease.

**Immediate or Imminent Public Health Risk:** A patient with suspected or confirmed infectious or potentially infectious TB disease who does any of the following:

1. Threatens to leave an acute care facility against medical advice.
2. Leaves an acute care facility against medical advice.
3. States he or she will not adhere to infection control measures.
4. Does not adhere to infection control measures.
5. Refuses to take anti-tuberculosis medications as prescribed.
6. Threatens to travel on a public conveyance.

**Index Case:** A patient with suspected, confirmed infectious or potentially infectious TB disease. The index case may also be a child less than five years of age whose diagnosis results in a source case investigation.

**Infection Control Measures:** Restrictions imposed by a health care provider, nurse case manager or health officer to protect the public from transmission of TB by a patient with suspected or confirmed infectious or potentially infectious TB disease. The measures taken with each patient will vary on a case-by-case basis.

**Interferon Gamma Release Assay:** Refers to the QuantiFERON-Gold or T-Spot.TB blood assay.

**Latent TB Infection (LTBI):** The presence of *Mycobacterium tuberculosis* bacteria in the body as evidenced by a significant reaction to a Mantoux tuberculin skin test or positive interferon gamma release assay. A person with LTBI and no evidence of active TB disease is not ill nor is he or she infectious.

**Least Restrictive Environment or Manner:** The intervention that would limit the patient's activities the least while still providing protection for the public against the likelihood of TB transmission.

**Multiple Drug Resistant Tuberculosis (MDR-TB):** A form of TB disease that is resistant to at least isoniazid (INH) and rifampin (RIF).

**Nucleic Acid Amplification Test (NAAT):** A polymerase chain reaction (PCR) or *Mycobacterium tuberculosis* direct test (MTD test).

**Public Health Nurse Case Manager:** Refers to the nurse providing public health nurse case management services which include, but are not limited to:

1. Providing patient education regarding the transmission of TB, prevention, treatment and the importance of keeping appointments for clinical assessment.
2. Facilitating the continuity of care for a patient with suspected or confirmed TB until treatment is completed by monitoring adherence to therapy, scheduling diagnostic evaluations and intervening to address non-adherence.
3. Assessing adherence with community infection control precautions and intervening as necessary to address adherence issues.
4. Coordinating TB care with any co-existing medical conditions among multiple medical providers as necessary.
5. Identifying psycho-social barriers to adherence and treatment completion, including, housing, food, transportation, communication, child care, parenting, incarceration, substance abuse and mental illness and intervention.
6. Coordinating contact and source case investigation and care. This includes identification, evaluation and appropriate treatment of all identified contacts.
7. Coordinating investigations for all Class B1 and B2 referrals including, location, evaluation and initiation of appropriate treatment.
8. Coordinating all field services, including provision of DOT as prescribed by a health care provider.

9. Building and maintaining effective working relationships with infection control professionals at hospitals and private health care providers who identify and report tuberculosis in the designated coverage area.

**Public Health Warning Notice:** Refers to a notice issued by a public health nurse case manager to a patient with suspected or confirmed infectious or potentially infectious TB disease. The notice may also be directed to a contact or a Class B1 or B2 referral as specified in N.J.A.C. 8:57-5.10.

**Risk of Flight:** Refers to any of the following circumstances pertaining to a patient with suspected or confirmed infectious or potentially infectious TB disease **and** posing an immediate or imminent public health risk:

1. Threatens to leave an acute care facility against medical advice.
2. Has left an acute care facility against medical advice in the past.
3. Threatens not to appear in court.
4. Has failed to appear in court in the past.
5. Is homeless or residency is unstable.
6. Has been lost to medical supervision in the past.
7. Threatens to travel on a public conveyance.

**Suspected or Confirmed Infectious or Potentially Infectious TB Disease:** Means one or more of the following is true:

1. Smear positive for AFB from a respiratory specimen\* **AND/OR**
2. Nucleic acid amplification test positive for *M.tb* from a respiratory specimen\* **AND/OR**
3. A culture positive for *M.tb* or *M.tb* complex from a respiratory specimen\* **AND/OR**

\* **Respiratory specimens** include specimens from sputum, bronchioalveolar lavage, gastric aspirate, lung tissue or other tissue of the respiratory tract such as the larynx or epiglottis.

4. Chest radiograph (x-ray), computed tomography (CT) scan or clinical evidence indicative of pulmonary TB sufficient to prescribe treatment with anti-tuberculosis medications **AND/OR**

5. Chest x-ray or respiratory symptoms improve while taking anti-tuberculosis medication **AND/OR**
6. Respiratory symptoms indicative of pulmonary tuberculosis until a diagnostic evaluation can be completed to rule out TB as a cause of the symptoms.

**Suspected or Confirmed TB Disease:** Means one or more of the following is true:

1. Meets the definition of suspected or confirmed infectious or potentially infectious TB disease above, **AND/OR**
2. Positive AFB smear and/or nucleic acid amplification test for *M.tb* and/or a positive culture for *M.tb* or *M.tb* complex from a location outside the respiratory tract, **AND/OR**
3. Extra-pulmonary (outside the lungs) evidence indicative of TB sufficient to prescribe anti-TB treatment, **AND/OR**
4. Extra-pulmonary symptoms improve while taking anti-TB treatment, **AND/OR**
5. Symptoms indicative of extra-pulmonary TB until a diagnostic evaluation can be completed to rule out TB as the cause of the symptoms.

**Vulnerable Population:** Refers to persons who are vulnerable to rapid progression to TB disease once LTBI occurs. This includes persons with a single or combination of the following conditions or treatments:

1. HIV infection or AIDS,
2. Corticosteroid therapy,
3. Tumor necrosis factor (TNF) alpha blocker therapy,
4. Cancer chemotherapy,
5. End-stage renal disease,
6. Cancer of the head or neck, **AND/OR**
7. Children less than five (5) years of age.

#### **8:57-5.4: Reporting Requirements**

**Health care providers and hospital or correctional facility administrators** providing care for any person with a diagnosis of suspected or confirmed TB disease, at any anatomical site, shall report to the Department's TB Program or designee using the **TB-70** within the timeframes and under the circumstances specified below:

1. Within 24 hours of diagnosis of suspected or confirmed TB disease. TB suspects must be reported within 24 hours of initiation of treatment.
2. By the tenth day of the following month whenever any of the following events occur for a patient with suspected or confirmed TB disease:
  - Change in clinical status
  - Change in treatment regimen
  - Treatment ceases for any reason
  - New laboratory findings
  - New radiographic findings
  - Change in medical supervision
  - Change in patient location or contact information
3. At least every three months after the confirmation of TB disease if none of the events listed above have taken place.

Health care providers and administrators must report the information on the **TB-70** form to the Department's TB Program Surveillance Unit either by telephone at **(609) 588-7522**, or by mail to:

**New Jersey Department of Health and Senior Services  
TB Program  
PO Box 369  
Trenton, NJ, 08625-0369**

Health care providers and administrators may also submit the TB-70 form to an appropriate designee of the Department. Call the TB Program to determine the appropriate local designee (public health nurse case manager in the health jurisdiction in which they practice or in which their facility operates) if not known.

4. Upon request by the public health nurse case manager, report the evaluation results and final disposition for any contact to a TB index case under their medical supervision.
5. Immediately report to the Department's TB Program or appropriate public health nurse case manager whenever any patient with suspected or confirmed infectious or potentially infectious TB disease misses two consecutive appointments for medical assessment.

The report of two consecutive missed appointments shall include:

- The name of the patient,
  - Patient's date of birth,
  - Patient's residence address,
  - Date of patient's last medical assessment,
  - Dates of patient's missed appointments **AND**
  - Whether or not the provider wishes to retain medical supervision of the patient or transfer supervision to the public health clinic.
6. Within 24 hours, report any inpatient with suspected or confirmed infectious or potentially infectious TB disease posing an immediate or imminent public health risk as defined in 8:57-5.3 above to the Department's TB Program.
  7. On the last business day that is at least 48 hours prior to the proposed discharge date report the proposed discharge date of a patient with suspected or confirmed infectious or potentially infectious TB disease regardless of time on treatment or smear status to the Department's TB Program or appropriate public health nurse case manager.

The report of impending patient discharge shall include the patient's name, address, contact phone number, and proposed date of discharge.

The hospital shall delay discharge if the administrator cannot achieve this timeline.

8. At least two working days in advance of the release (if the release date is known in advance) **OR** within one working day after the release (if the release is unanticipated), the administrator of a correctional facility shall report the release of an inmate with suspected or confirmed infectious or potentially infectious TB disease to the Department's TB Program or appropriate public health nurse case manager.

The report of impending release shall include the inmate's name, address, contact phone number and date of release.

Reporting requirements for **public health nurse case managers** include:

1. Satisfaction of the reporting requirements 1-3 above for patients with suspected or confirmed TB disease who reside in the health jurisdiction(s) for which they have primary responsibility whenever the public health clinic is medically managing the patient.
2. Report the identification, evaluation results and final disposition of contacts associated with any index case residing in the health jurisdiction for which they have primary responsibility. This reporting requirement is applicable whenever an index case with suspected or confirmed TB has **any** of the following characteristics:

- Nucleic amplification test positive for *M.tb* from a sputum specimen or sputum culture identified as *M.tb* or *M.tb* complex,
- Cavitory lesions on chest x-ray or computed tomography (CT) scan,
- Non-cavitory chest x-rays with respiratory symptoms.
- Children less than 5 years of age with pulmonary or extra-pulmonary TB.

This reporting regulation is satisfied by completion and submission of a **TB-41** form to the Department's TB Program.

If contacts exist outside the health jurisdiction of residence for the index case, public health nurse case managers in the health jurisdictions where these contacts live shall:

1. Assist the public health nurse case manager responsible for the index case in the identification, evaluation and final disposition of contacts associated with the index case.
2. Submit the results of these activities to the public health nurse case manager primarily responsible for the index case for coordination and submission to the Department's TB Program.

If the index case has contacts outside New Jersey, the Department's TB Program shall assist in securing information regarding the identification, evaluation and final disposition of contacts and provide this information to the public health nurse case manager primarily responsible for the index case.

An administrator, nurse case manager or health care provider may delegate the reporting requirements in N.J.A.C. 8:57-5.4 to a subordinate, **BUT** a delegation **does not** transfer responsibility for adherence to the reporting requirements.

Failure to comply with the reporting requirements established at N.J.A.C. 8:57-5.4 shall subject required reporters to the penalties set forth at N.J.A.C. 8:57-5.18.

No person(s) reporting patient information in order to comply with this subchapter shall be subject to civil, administrative, disciplinary or criminal liability.

### **8:57-5.5: Hospital Discharge**

Health care providers, who are managing a patient with suspected or confirmed infectious or potentially infectious TB disease may discharge the patient from a hospital as long as the following criteria are met:

1. The patient has an established and stable residence that is validated by the public health department **AND**
2. This residence is **not** shared by any individual who is a member of a vulnerable population (see Definitions 8:57-5.3) unless it is known that this individual has LTBI **OR**
3. TB has been ruled out as the cause of the patient's disease.

If the patient:

- Is a resident of a congregate living facility,
- Is homeless,
- Reports a private residence that the public health department has not verified as being valid and stable **OR**
- Has a private residence where uninfected members of a vulnerable population reside

Then the patient must meet at least one of the following criteria for a discharge to be appropriate:

1. Have three consecutive sputum smears negative for AFB collected at least eight hours apart.
2. Have a nucleic amplification test that is negative for *M.tuberculosis*.
3. Have at least one sputum culture negative for *M.tuberculosis* after the appropriate anti-TB treatment has been initiated.
4. Had no sputum smears positive for AFB, been on the appropriate anti-TB medications for a period of at least two weeks AND no current respiratory symptoms.
5. Is granted an exception by the Department's TB Program based upon clinical evidence and patient interview if none of the conditions 1-4 above have been met.

The Department's Division of Health Facilities Evaluation and Licensing may investigate any hospital's discharge of a patient who does not meet the criteria for appropriateness as defined in 8:57-5.5. Any hospital that fails to discharge a patient in accordance with the regulation may be subject to penalties for licensure violations.

### **8:57-5.6: Health Officer Responsibilities**

1. Each health officer **shall** have a health care provider(s) (as defined in N.J.A.C. 8:57-5.3) available for medical evaluation and management services.

The health care provider(s) may be provided through existing local health department staff, by contractual agreement or through a Memorandum of Agreement with a public health TB clinic. This health care provider(s) will service each patient with suspected or confirmed TB disease and LTBI within his or her jurisdiction(s).

Any health care provider providing medical services and treatment to residents of New Jersey with suspected or confirmed TB disease or LTBI shall provide all services in accordance with the *MMWR Treatment of Tuberculosis* referenced in N.J.A.C. 8:57-5.2.

Health care providers may also use the Department's *Standards of Care for Tuberculosis and Disease and Latent TB Infection* (TB Standards of Care) as a guide for the appropriate medical management of patients with TB disease or LTBI. The TB Standards of Care are available by written request to the:

**New Jersey Department of Health and Senior Services  
TB Program  
PO Box 369  
Trenton, NJ, 08625-0369**

**OR** Online at: <http://www.state.nj.us/health/cd/tbhome.htm>  
Click on Standards of Care

2. Each health officer shall make public health nurse case management services (as defined in N.J.A.C. 8:57-5.3) available for the following types of patients:
  - Suspected or confirmed TB disease,
  - Identified contacts **AND**
  - Class B1 and B2 referrals within his or her jurisdiction.

These services may be provided through existing staff, by contractual agreement or through a Memorandum of Agreement with an established public health TB clinic.

3. Each Health Officer shall make field services (as defined in N.J.A.C. 8:57-5.3) available for each patient with
  - Suspected or confirmed TB disease,
  - Identified contacts **AND**
  - Class B1 and B2 referrals within his or her jurisdiction.

These services may be provided through existing staff, by contractual agreement or through a Memorandum of Agreement with an established public health TB clinic.

To overcome communication barriers, verbal translation services shall be made accessible through the Department's TB Program to the:

- Public health TB clinics,
- Public health nurse case managers **AND**
- Field staff who serve patients with TB disease or LTBI.

### **8:57-5.7: Notification of Precautions to Protect the Public Health**

1. Public health nurse case managers or their designees shall notify any patient verbally and in writing of the infection control precautions required to protect the public health. Patients shall be notified **within three working days** of the receipt of an initial TB-70 form. Patients to be notified are those with the following characteristics:
  - A. Sputum smear positive for AFB **OR**
  - B. Cavitory lesions on chest x-ray or CT scan **with** respiratory symptoms, with no sputum collected **or** all sputum smears reported negative for AFB.
2. If the patient described above is hospitalized outside the health jurisdiction of his or her residence, then the public health nurse case manager or their designee in the health jurisdiction **where the patient is hospitalized** shall deliver the “Notification” set forth in section (1) above. Notifications of infection control precautions shall be delivered **within three working days**, regardless of the patient’s health jurisdiction of residence.
3. The “Notification” shall list all infection control precautions applicable to the patient **AND** request that the patient observe these precautions until told that they are no longer necessary to protect the public health.
4. Infection control precautions will **no longer be required** when the patient described in 1.A. above has:
  - Three sputum smears reported negative for AFB collected at least eight hours apart, **OR**
  - A nucleic amplification test negative for *M.tuberculosis*, **OR**
  - At least one sputum culture reported negative for *M.tuberculosis*, **OR**
  - TB is ruled out as a cause of disease by a health care provider.
- a. Infection control precautions will **no longer be required** when the patient described in 1.B. above has:
  - Taken at least two weeks of appropriate treatment **AND** no respiratory symptoms are observed **OR** when
  - TB has been ruled out as a cause of disease by a health care provider.
5. The public health nurse case manager in the patient’s health jurisdiction of residence shall inform the patient **within one business day** of the patient meeting the criteria in either (4) or (5) above (whichever is applicable), that infection control precautions are no longer necessary.

6. If a patient violates or refuses to comply with appropriate infection control precautions, the health officer in the patient's health jurisdiction of residence shall **either**:
  - Serve the patient with a health officer's order for isolation as established at N.J.A.C. 8: 57-5.11 **OR**
  - Serve the patient with a health officer's order for temporary commitment as established in N.J.A.C. 8: 57-5.12

Whichever measure is necessary to adequately protect the public health.

7. The health officer or their designee in **any** health jurisdiction shall serve a health officer's order as described in (7) above, if the patient refusing to comply with or violating the infection control precautions is currently located in his or her health jurisdiction.
8. The health officer order must be served to the patient **within one business day** of being informed by the public health nurse case manager of the patient's refusal to comply or violation of infection control precautions.

## **8:57-5.8: Diagnostic Evaluations**

### **Applicability & Timeliness**

1. The public health nurse case manager shall monitor and facilitate timely diagnostic evaluations for the following groups of patients within the health jurisdiction(s) for which they have responsibility, regardless the health care provider providing medical management:
  - Suspected or confirmed infectious or potentially infectious TB disease,
  - Identified contacts **AND**
  - Class B1 and B2 referrals.
2. If a health care provider believes that a patient has suspected or confirmed infectious or potentially infectious TB disease based on direct observation, clinical and/or laboratory findings, he or she shall schedule an appointment for a diagnostic evaluation in his or her office or by referral **within five business days**.
3. If a patient is to be managed by a public health TB clinic, the public health nurse case manager shall schedule a diagnostic evaluation **within ten working days**. The timeline for this evaluation begins on the date a patient is discharged from a hospital or correctional facility with suspected or confirmed infectious or potentially infectious TB disease.
4. The public health nurse case manager shall schedule diagnostic evaluations in the public health clinic for any contact or Class B1 or B2 referral **within 20 working days** of:
  - Identification (if a contact) **OR**
  - Notification by the Department's TB Program, if a Class B1 or B2 referral.

### **Content**

1. Diagnostic evaluations for persons with suspected or confirmed infectious or potentially infectious TB shall consist of at least a physical examination including:
  - Chest x- ray,
  - Sputum collection or induction,
  - Laboratory testing, **AND**
  - Visual acuity testing, if ethambutol is prescribed for treatment.

The health care provider may utilize the Department's **TB Standards of Care** as a guideline for appropriate practices.

2. A diagnostic evaluation of a contact or Class B1 or B2 referral shall consist of at least:
  - Mantoux (PPD) tuberculin skin test or an interferon gamma release assay to detect LTBI **AND**
  - Chest X-Ray if the skin test is considered significant or the interferon gamma release assay is positive for LTBI.

3. If active TB disease is suspected, based on the results of the diagnostic evaluation of a contact or Class B1 or B2 referral, the health care provider shall complete the requirements listed at (1) under Content above.

The health care provider may also utilize the Department's **TB Standards of Care** as a guide for appropriate practices.

### **8:57-5.9: Directly Observed Therapy (DOT)**

1. In order to monitor the adherence of a patient to his or her prescribed treatment for TB disease, a health care provider may prescribe DOT.

Health care providers may utilize the Department's **TB Standards of Care** as a guideline for appropriate utilization of DOT.

2. The local health officer, in the patient's health jurisdiction of residence **shall ensure** that DOT is provided as ordered by the health care provider. This will be accomplished by providing field services, as required by N.J.A.C. 8:57-5.6.
3. The provision of DOT on daily, twice weekly or three times weekly basis shall continue until discontinued by the health care provider.
4. The time and place for providing DOT shall be negotiated by the designated public health nurse case manager or designee responsible for the health jurisdiction of the patient's residence.
  - The patient may request a reasonable change in time or place to an established DOT schedule from the public health nurse case manager or designee.
  - The public health nurse case manager or designee shall take into consideration the patient's needs and the availability of resources to provide field services in determining whether to make an accommodation.
5. The public health nurse case manager shall intervene if a patient is not at least 80 percent adherent to a prescribed DOT regimen over any one month period throughout the duration of treatment. The prescribed process for intervention is described in N.J.A.C. 8: 57-5.10.
6. Only the patient's health care provider (as defined in N.J.A.C. 8:57-5.3) shall have the authority to order or discontinue DOT. If a health care provider discontinues an order for DOT:
  - Any health officer's order requiring DOT shall be immediately rescinded.
  - If a court order for DOT is in force, the health officer who petitioned the court shall request that the court order be rescinded.

**8:57-5.10: Management of Non-Adherent Patients Requiring a Diagnostic Evaluation or Directly Observed Therapy (DOT)**

The public health warning notices and health officer orders (diagnostic evaluation and adherence with DOT) in this regulation are **NOT mutually exclusive**. They may be imposed concurrently if such action will best protect the public health.

**Criteria for Intervention for the Purpose of Diagnostic Evaluation**

1. The sequence of interventions to promote adherence with the need for a diagnostic evaluation allowed under this regulation may be applied to:
  - Patients with suspected or confirmed infectious or potentially infectious TB disease,
  - Identified contacts for whom a diagnostic evaluation is needed to determine their current TB status, **AND**
  - Class B1 and B2 referrals for which a diagnostic evaluation is needed to determine their current TB status.

**STEP 1: Public Health Warning Notice for Diagnostic Evaluation**

2. The first available intervention is the **public health warning notice**.
3. A public health warning notice is **issued by the public health nurse case manager** with responsibility for the health jurisdiction of residence of the person for whom a diagnostic evaluation is needed.

When issuing a public health warning notice to a patient, a public health nurse case manager shall seek a diagnostic evaluation to protect the public health.

4. A public health warning notice shall be issued **within two (2) business days** of when any person meeting the criteria for such a notice (see 1. above) **either**:
  - Misses two (2) consecutive scheduled appointments **OR**
  - Refuses a diagnostic evaluation.
5. The Public Health Warning Notice **shall**:
  - State the nature of the non-adherence (see 4. above),
  - Require the patient to contact the health care provider or clinic indicated in the notice **within three business days of receipt of the notice** to schedule an appointment for diagnostic evaluation,

- State the consequences of **not** satisfying the conditions of the notice, including the potential risks to the public health and the issuance of a health officer order, **AND**
  - Be copied and filed in the patient's medical record by the public health nurse case manager or designee.
6. If a public health warning notice is issued, the public health nurse case manager or designee shall serve the notice by certified mail, return receipt requested **OR** hand delivery.
- Successful hand delivery shall include a face-to-face encounter with the patient.
  - Hand delivery by the public health nurse case manager or designee is **preferred** because receipt of the notice is witnessed and the conditions of the notice can be discussed with the patient.
  - If the notice is hand delivered, the results of the face-to-face encounter shall be documented clearly in the patient's medical record and include the date and time of the encounter **AND** the patient's response to the conditions of the notice.
7. The public health nurse case manager shall notify the appropriate health officer **within two business days** to request a health officer order if the conditions of the public health warning notice are **not** met (see STEP 2 below for the appropriate health officer to notify).

### **STEP 2: Health Officer Order for Diagnostic Evaluation**

The appropriate health officer to issue a health officer order for diagnostic evaluation is usually the health officer in the patient's health jurisdiction of residence, **BUT** if the person is institutionalized or hospitalized, it is appropriate for the health officer **in the health jurisdiction where the institution or hospital is located** to issue the order.

When issuing a health officer's order, the health officer shall **require** a diagnostic evaluation to assess the patient's current TB status to protect the public health.

8. The health officer shall issue a health officer's order for diagnostic evaluation **within three business days** of the request for such an order by the public health nurse case manager.
9. The health officer's order **shall:**
- State the nature of the non-adherence, including the applicable option under 1. above **AND** failure to comply with the conditions of the public health warning notice,

- State the public health consequences of continued non-adherence,
  - Require that the patient contact the health care provider or clinic indicated in the order **within three business days of receipt** of the order to schedule an appointment for diagnostic evaluation, **AND**
  - State the consequences of **not** satisfying the conditions of the order, including possible court action.
10. If a health officer order is issued, the health officer or designee shall serve the notice by certified mail, return receipt requested **OR** hand delivery.
- Successful hand delivery shall include a face-to-face encounter with the patient.
  - Hand delivery by the health officer or designee is **preferred** because receipt of the notice is witnessed and the conditions of the notice can be discussed with the patient.
  - A health officer order for diagnostic evaluation authorizes local law enforcement officers to assist the health officer or designee in hand delivery of the order upon request of the health officer, in accordance with N.J.S.A. 26:1A-9.
  - If the order is hand delivered, the results of the face-to-face encounter shall be documented clearly in the patient's medical record and include the date and time of the encounter **AND** the patient's response to the conditions of the order.

A health officer's order for diagnostic evaluation of a Class B1 or B2 referral or contact to a patient with suspected or confirmed infectious or potentially infectious TB disease ***shall remain in force*** until the evaluation is completed and infectious or potentially infectious TB disease is ruled out by a health care provider.

A health officer's order for diagnostic evaluation of a patient determined to have infectious or potentially infectious TB disease ***shall remain in force*** until treatment is completed as determined by a health care provider.

11. If the conditions of a health officer order for diagnostic evaluation are not met **within three business days**, then the health officer that issued the order **may** petition the Superior Court for commitment of the patient who is violating the order (see N.J.A.C. 8:57-5.14).
12. The health officer is **required** to consult with the Department's TB Program, State Epidemiologist and/or designee before petitioning the Superior Court.

Representatives of the Department's TB Program and/or its Medical Advisory Board **will** accompany local health authorities and their legal representatives to court and testify upon request.

When initiating a commitment hearing on a patient, a health officer's primary objective is to **request** the court to order a diagnostic evaluation(s) to assess the patient's current TB status to adequately protect the public health.

If at any time during the intervention process described above, the patient becomes adherent, the process shall be immediately halted.

If the patient with suspected or confirmed infectious or potentially infectious TB disease becomes non-adherent **again** before completing treatment, the intervention process shall resume at whatever step was next appropriate when the patient became adherent.

### **Criteria for Intervention for the Purpose of Promoting Adherence with DOT**

1. The sequence of interventions to promote adherence to a prescribed treatment regimen of DOT allowed under this regulation may be applied to any patient with suspected or confirmed infectious or potentially infectious TB disease.

### **STEP 1: Public Health Warning Notice for Adherence with DOT**

2. The first available intervention is the **public health warning notice**.
3. A public health warning notice is **issued by the public health nurse case manager** with responsibility for the health jurisdiction of residence of the non-adherent patient.

When issuing a public health warning notice to a patient, a public health nurse case manager shall seek adherence to a prescribed DOT treatment regimen to protect the public health.

4. A public health warning notice shall be issued **within two (2) business days** of when any person meeting the criteria for such a notice (see 1. above) falls below a medication adherence rate of 80 percent of prescribed doses on a treatment regimen of DOT over any one month period.
5. The Public Health Warning Notice **shall**:
  - State the nature of the non-adherence (failure to take at least 80 percent of prescribed doses by DOT over a one month period),
  - Require the patient to contact the health care provider or clinic indicated in the notice **within three business days of receipt of the notice** to rectify the issue of non-adherence with the prescribed treatment regimen of DOT,
  - State the consequences of **not** satisfying the conditions of the notice, including the potential risks to the public health and the issuance of a health officer order, **AND**
  - Be copied and filed in the patient's medical record by the public health nurse case manager or designee.
6. If a public health warning notice is issued, the public health nurse case manager or designee shall serve the notice by certified mail, return receipt requested **OR** hand delivery.
  - Successful hand delivery shall include a face-to-face encounter with the patient.

- Hand delivery by the public health nurse case manager or designee is **preferred** because receipt of the notice is witnessed and the conditions of the notice can be discussed with the patient.
  - If the notice is hand delivered, the results of the face-to-face encounter shall be documented clearly in the patient's medical record and include the date and time of the encounter **AND** the patient's response to the conditions of the notice.
7. The public health nurse case manager shall notify the appropriate health officer within two business days to request a health officer order, if the conditions of the public health warning notice are **not** met (see STEP 2 below for the appropriate health officer to notify).

### **STEP 2: Health Officer Order for Adherence with DOT**

The appropriate health officer to issue a health officer order for adherence with a prescribed treatment regimen of DOT is usually the health officer in the patient's health jurisdiction of residence, **BUT** if the person is institutionalized or hospitalized it is appropriate for the health officer **in the health jurisdiction where the institution or hospital is located** to issue the order.

When issuing a health officer's order, the health officer shall *require* adherence with a prescribed treatment regimen of DOT to protect the public health.

8. The health officer shall issue a health officer's order for adherence with a prescribed treatment regimen of DOT **within three business days** of the request for such an order by the public health nurse case manager.
9. The health officer's order **shall**:
- State the nature of the non-adherence, including failure to take at least 80 percent of prescribed doses by DOT over a one month period **AND** failure to comply with the conditions of the public health warning notice,
  - State the public health consequences of continued non-adherence,
  - Require that the patient contact the health care provider or clinic indicated in the order **within three business days of receipt** of the order to rectify the issue of non-adherence with the prescribed treatment regimen of DOT **AND**
  - State the consequences of **not** satisfying the conditions of the order, including possible court action.
10. If a health officer order is issued, the health officer or designee shall serve the notice by certified mail, return receipt requested **OR** hand delivery.

- Successful hand delivery shall include a face-to-face encounter with the patient.
- Hand delivery by the health officer or designee is **preferred** because receipt of the notice is witnessed and the conditions of the notice can be discussed with the patient.
- A health officer order for diagnostic evaluation authorizes local law enforcement officers to assist the health officer or designee in hand delivery of the order upon request of the health officer in accordance with N.J.S.A. 26:1A-9.
- If the order is hand delivered, the results of the face-to-face encounter shall be documented clearly in the patient's medical record and include the date and time of the encounter AND the patient's response to the conditions of the order.

A health officer's order for adherence with a prescribed treatment regimen of DOT for a patient determined to have infectious or potentially infectious TB disease **shall remain in force until either:**

- Treatment is completed as determined by a health care provider **OR**
- A DOT treatment regimen is no longer prescribed by a health care provider.

11. If the conditions of a health officer order for adherence with a prescribed treatment regimen of DOT are not met **within three business days**, the health officer that issued the order **may** petition the Superior Court for commitment of the patient who is violating the order (see N.J.A.C. 8:57-5.14).

12. The health officer is **required** to consult with the Department's TB Program, State Epidemiologist and/or designee before petitioning the Superior Court.

Representatives of the Department's TB Program and/or its Medical Advisory Board **will** accompany local health authorities and their legal representatives to court and testify upon request.

When initiating a commitment hearing on a patient, a health officer's primary objective is to **request** the court to order adherence with a prescribed treatment regimen of DOT to adequately protect the public health.

If at any time during the intervention process described above the patient becomes adherent, the process shall be immediately halted.

If the patient with suspected or confirmed infectious or potentially infectious TB disease becomes non-adherent **again** before completing treatment, the intervention process shall **resume** at whatever step was next appropriate when the patient became adherent.

### **8:57-5.11: Management of Non-Adherent Patients Through a Health Officer Order for Isolation**

N.J.S.A 26:4-2 allows a health officer to **prohibit** a patient who poses an immediate or imminent risk to the public health (see N.J.A.C. 8:57-5.3 for definition) from attending his or her job, school or other premises the health officer deems necessary to protect the public health.

If the order for isolation:

- Places a hardship on the patient or patient's family **AND/OR**
- Presents a risk for loss of current residence,

They **may** be temporarily eligible for the TB Program's incentive and/or housing program to assist with necessary financial obligations during the duration of the order.

Under **no** circumstances may a health officer order prohibit a patient from attending their place of work, school, or other premises for more than 60 days without a court order authorizing such exclusion (see N.J.A.C. 8: 57-5.14 for the hearing process).

1. The health officer shall consult with the Department's TB Program, State Epidemiologist or designee **before** prohibiting a patient from returning to work, school or other such premises.
2. The health officer in the patient's health jurisdiction of residence shall issue a health officer order for isolation **within two working days** of when the patient meets the definition of an immediate or imminent risk to the public health, **UNLESS:**
  - Such action is not approved by the Department's TB Program, State Epidemiologist or designee upon consultation, **OR**
  - The patient is a risk for flight (see 8:57-5.3 for definition and 8:57-5.12 for appropriate action) **OR**
  - The patient is institutionalized or hospitalized. Then the health officer **in the health jurisdiction where the institution or hospital is located** shall issue the order.
3. The health officer's order **shall:**
  - State the reason for the order, including all criteria that make the patient an immediate or imminent risk to the public health,
  - Reiterate the infection control measures necessary to protect the public health (may vary on a case-by-case basis),

- State the conditions that must be met for the order to be lifted (may vary on a case-by-case basis), **AND**
  - State the consequences of violating the order, including court ordered commitment.
4. If a health officer order for isolation is issued, then the health officer or designee **shall hand deliver the order.**
- Successful hand delivery requires a face-to-face encounter with the patient.
  - The results of the face-to-face encounter shall be documented clearly in the patient's medical record, including the date and time of the encounter and the patient's response to the conditions of the notice or order.
  - A health officer may request local law enforcement to assist with hand delivery of the order, in accordance with N.J.S.A. 26:1A-9.
5. If a patient who is prohibited from attending their job, school or other premises requests a review of the health officer order for isolation, the health officer that issued the order shall file an application for a court order authorizing the exclusion. This shall be done **within five business days** from the date of the patient's request and in accordance to N.J.S.A. 26: 4-2.
- If a review of the order is requested by a patient, their exclusion from work, school, and other premises shall not continue for **more than ten business days** without a court order.

If the patient:

- Has suspected or confirmed infectious or potentially infectious TB disease, **THAT**
- Is suspected or confirmed to be either MDR or XDR-TB, **AND**
- Is non-adherent **OR** threatens non-adherence with infection control measures,

**THEN** the appropriate intervention is to serve a health officer order for temporary commitment (see N.J.A.C 8: 57-5.12) due to the severity of the consequences of potential transmission.

6. If the patient **violates** the conditions of the health officer order for isolation, the health officer that issued the order **may** petition the Superior Court for commitment of the patient for protection of the public health (see N.J.A.C. 8: 57-5.14 for the process).

The health officer shall consult with the Department's TB Program, State Epidemiologist or designee before petitioning the Superior Court for a commitment order.

7. If court commitment is sought, the Commissioner, State Epidemiologist or designee shall designate the **least restrictive environment** acceptable for the patient to serve the term of the commitment order in collaboration with the Department's TB Program and the requesting health officer. This environment may be:

- An acute care facility **OR**
- A private residence, if the patient has a stable residence.

If the location of commitment is a private residence **and** the Superior Court orders electronic monitoring, an electronic device may be used to monitor adherence to the court order for commitment.

If at any time during the course of treatment, the **same** patient again poses:

- An immediate or imminent public health risk **AND**
- Violates the conditions set forth in a health officer's order for isolation,

**THEN** the appropriate health officer (see STEP 2 above) **may** immediately petition the Superior Court for a commitment order.

**8:57-5.12: Management of Non-Adherent Patients Through a Health Officer Order for Temporary Commitment**

1. If it is determined that a patient:

- Is an immediate or imminent risk to the public health, **AND**
- Poses a risk for flight (see definition N.J.A.C. 8:57-5.3), **OR**
- Has or is suspected to have MDR-TB or XDR-TB, **AND**
- Is non-adherent or threatens non-adherence with infection control precautions,

The health officer shall **immediately** order the temporary commitment of the patient pending an accelerated commitment hearing before the Superior Court.

The determination that a patient meets the criteria for temporary commitment may be made by the Commissioner, State Epidemiologist or designee, but is primarily the responsibility of the health officer in the patient's health jurisdiction of residence.

If the person is institutionalized or hospitalized, the health officer in the health jurisdiction where the institution or hospital is located shall determine the patient's eligibility and issue the temporary commitment order.

The Commissioner or designee shall determine the site where the temporary detention will be served.

2. A health officer order for temporary commitment shall state:

- The reason for the order, including the criteria used to determine the necessity for the order (see 1 above),
- The site of commitment as determined by the Commissioner or designee,
- The conditions of commitment (infection control precautions, etc.) **AND**
- That a Superior Court hearing will occur within the next 30 days or the order will be rescinded.

**Under no circumstances shall a health officer order a temporary commitment to remain in force for more than 30 days without a court order.**

3. The health officer's order for temporary commitment shall be **hand delivered** to the patient by the health officer or designee.

- A health officer may request local law enforcement to assist with hand delivery of the order in accordance with N.J.S.A. 26:1A-9.
4. N.J.S.A. 26:1A-9 also authorizes local law enforcement officers to:
    - Take the patient into custody under an order for temporary commitment,
    - Escort the patient to the designated temporary commitment location,
    - Monitor to ensure the patient remains at the designated temporary commitment location until the hearing date, **AND**
    - Ensure the patient is available for the hearing.
  5. If the assistance of local law enforcement is requested by the health officer issuing the order for temporary commitment in locating and/or taking the patient to the designated location, the health officer must provide the following information to law enforcement officials:
    - A copy of the order for temporary commitment,
    - The site where temporary commitment will be served,
    - The patient's name, address or last known location, a picture (if available), skin color, hair color, height, weight, age and any tattoos or scars that could assist in identification, **AND**
    - The date of the expedited commitment hearing (as soon as it is known).
  6. The health officer, who issued the order for temporary commitment, shall seek the assistance of local legal counsel to prepare the petition for commitment by the Superior Court.
  7. The health officer issuing the order for temporary commitment or designee shall notify the patient of the date and time of the Superior Court hearing **at least two days in advance** of the hearing.

### **8: 57-5.13 Grounds for Commitment**

1. In accordance with N.J.S.A 30:9-57, the Commissioner or the local health officer in consultation with the TB Program and/or State Epidemiologist may petition the Superior Court for an Order of Commitment **whenever a patient violates:**
  - A health officer order for diagnostic evaluation or DOT, issued under N.J.A.C. 8:57-5.10, **OR**
  - A health officer order for isolation, issued under N.J.A.C. 8:57-5.11, **OR**
  - A health officer order for temporary commitment issued under N.J.A.C. 8:57-5.12 (see 2. below).
2. **In addition**, any local health officer issuing an order for temporary commitment under N.J.A.C. 8:57-5.12 shall petition the Superior Court for an expedited hearing to consider court-ordered commitment.

Any patient for whom commitment is being sought shall be advised of the reason for the proposed commitment and granted an opportunity for a hearing per N.J.A.C 8:57-5.14 and 5.15.

### **8:57-5.14 Hearing Process**

1. In accordance with N.J.S.A 30:9-57, the issuance of a health officer order requires informing the patient of their right to a hearing in the Superior Court.
2. If a hearing is requested **or** required then at least two days prior to the hearing, the health officer or designee shall serve the patient with:
  - A copy of the applicable rules (regulations),
  - Notification of the reason(s) for the proposed commitment **and**
  - The time and place of the hearing.
3. If the Superior Court finds the patient committable, then the patient shall be committed to a hospital or private residence, as designated by the Commissioner, State Epidemiologist or their designee.

Under no circumstances shall any patient be committed for more than 90 days at a time by the court.

Should the patient continue to pose an immediate or imminent risk to the public health, a subsequent court order is required to continue the commitment beyond the 90 day limit. This court order shall be sought before the initial court order expires.

If the patient's risk to the public subsides during the initial 90 day commitment period, the court shall be informed and requested to rescind the court-ordered commitment.

Any violation of the court ordered commitment by the patient shall be reported to the Superior Court for action that the court deems appropriate.

### **8:57-5.15 Due Process**

The patient shall have the following due process right at any hearing conducted according to these regulations:

1. Written notice detailing the grounds and underlying facts of the matter (individualized for each patient's unique situation),
2. The right to counsel present at the hearing and, if indigent, the right to appointed counsel, **AND**
3. The right to be present at the hearing to cross examine and to present witnesses. This right may be exercised through the use of telecommunications technology.

**8:57-5.16 Annual Report**

The manager of the TB Program shall submit to the Commissioner an annual report describing trends in prevalence and incidence rates of TB and MDR-TB in New Jersey.

The report shall include descriptive statistics showing the frequency and trends of those reportable events set forth in N.J.A.C. 8:57-5.4.

The first report shall be issued 12 months after the effective date of these rules.

Subsequent reports shall be due annually thereafter.

The reports shall be made available to the public through the TB Program's website at **<http://nj.gov/health/cd/tbhome.htm>**.

### **8:57-5.17 Confidentiality of Information**

Patient medical information concerning any reportable events shall not be disclosed except under the following circumstances:

1. For research purposes provided the study is reviewed and approved by the applicable Institutional Review Board and is done in a manner that does not identify any person by name or other identifying data element,
2. With the written consent of the patient identified, **AND/OR**
3. When the Commissioner or designee determines that disclosure is necessary to enforce public health laws or to protect the life or health of the named patient in accordance with applicable state and federal laws.

The reports and forms submitted to the Department contain demographic and medical information related to the Department's investigations and epidemiological studies of TB. These reports shall **not** be considered "government records" which are subject to public access or inspection.

These records instead fall within the meaning of N.J.S.A. 47: 1A-1 et seq. and shall be deemed as:

1. "Information relating to medical...history, diagnosis, treatment, or evaluation", within the meaning of Executive Order 26, §4(b)1 (McGreevey, August 13, 2002),
2. "Records concerning morbidity, mortality, and reportable diseases of named persons required to be made, maintained or kept by any state or local government agency" within the meaning of Executive Order 9, §2(c) (Hughes, September 30, 1963), **AND/OR**
3. Information "for use in the field of forensic pathology or for use in medical or scientific education or research" according to N.J.S.A. 47:1A-1.1.

### **8:57-5.18 Penalties for Violation of Rules**

Any of the following who fail to comply with the requirements of 8:57-5, **shall** be subject to a fine as set forth within N.J.S.A. 26:4-129 and 4-130 or N.J.S.A. 26: 1A-10:

1. Health care providers,
2. Administrators of health care facilities,
3. Health officers, **AND/OR**
4. Public health nurse case managers.

The Department of Health and Senior Services **may** issue a written notification of this failure to any of the parties above and warning to comply with these regulations **prior** to initiation of any other enforcement action.

In the case of a violation by a health care provider, the Department **may** report the failure to comply with the provisions of this subchapter to the New Jersey Board of Medical Examiners. This may initiate disciplinary actions as set forth within N.J.A.C. 13:35-6.24.

In the case of a violation by a health care facility, The Department **may** report failure to comply with the provisions of this subchapter to the Department's Division of Health Care Quality and Oversight. This Division may initiate enforcement actions as set forth within N.J.A.C. 8:43E-3.

In the case of a violation by a health officer, the Department **may** report failure to comply with the provisions of this subchapter to the Department's Public Health Licensing and Examination Board. This board may initiate disciplinary actions set forth within N.J.A.C. 8:7-1.7 and N.J.S.A. 26:1A-10.

In the case of a violation by a public health nurse case manager, the Department **may** report failure to comply with the provisions of this subchapter to the Board of Nursing. This board may initiate disciplinary actions as set forth within the N.J.S.A. 45: 1-21.